FINAL SUBMISSIONS ON BEHALF OF LEIGH DAY CORE PARTICIPANTS

CONTENTS

GLOSSARY OF TERMS

Term	Abbreviation/ acronym	Further information (where relevant)
Advisory Committee on Transfusion Transmitted Diseases	ACTTD	
Advisory Committee on the Virological Safety of Blood	ACVSB	
Arms Length Body	ALB	
Advanced Liver Disease	ALD	
Hepatitis B Core Antibody	Anti-HBc	
Better Blood Transfusion	BBT	
Blood-Borne Viruses	BBVs	
British Medical Journal	BMJ	
Blood Products Laboratory	BPL	
Central Blood Laboratories Authority	CBLA	
Chief Medical Officer	CMO	
Department of Health tasked Central Management Services	CMS	
Core Participants	CPs	This includes clients who have not been given CP status. Also note that when referring to CP, this encapsulates both the experience of infected and affected people (by virtue of their relation to the infected person).
Committee on Safety of Medicines	CSM	
Committee on Safety of Medicine's Biological	CSM(B)	
Counsel to the Inquiry	CTI	
Directly-Acting Antiviral	DAA	
Deputy Chief Medical Officer	DCMO	
Direct Detection Assay	DDA	
Department of Health and Social Security	DHSS	

Department of Health and Social Care	DHSC	
Department of Work and Pensions	DWP	
European Convention on Human Rights	ECHR	
England Infected Blood Support Scheme	EIBSS	
Food and Drug Administration	FDA	
Fresh Frozen Plasma	FFP	
General Medical Council	GMC	
Genito-Urinary Medicine	GUM	
Hepatitis B	HBV	
Hepatitis B Surface Antigen	HBsAG	
Hepatocellular Carcinoma	HCC	
Hepatitis C	HCV	
Human Immunodeficiency Viruses	HIV	
Human T-Lymphotrophic Virus Type 3	HTLV-III	
Infected and affected persons	IAP	
Improving Access to Psychological Therapies	IAPT	
Integrated Care Board	ICB	
Independent Medicines and Medical Devices Safety Review	IMMDSR	
Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee	JPAC	
Liver Function Tests	LFT	
Multi-Disciplinary Team	MDT	
Medicines and Healthcare products Regulatory Agency	MHRA	
Men who have sex with men	MSM	

Minoritised ethnic groups		These submissions use the term minoritised ethic groups to refer to all ethnic groups except white British. This is in line with current Law Society guidance which states *'Minoritised ethnic' (or the similar term 'racially minoritised') has been recommended more recently as it recognises that individuals have been minoritised through social processes of power and domination rather than just existing in distinct statistical minorities. It also better reflects the fact that ethnic groups that are minorities in the UK are majorities in the global population.* https://www.lawsociety.org.uk/topics/ethnic-minority-lawyers/a-guide-to-race-and-ethnicity-terminology-and-language We invite the Chair to use this term in his final report and to note that care should be taken when using umbrella terms for groups of people. While this language is still evolving, the Chair may consider using alternative terms such as 'the global majority' or 'communities experiencing racial inequality'.
National Blood Authority	NBA	
National Blood Transfusion Committee	NBTC	
National Blood Transfusion Service	NBTS	
NHS Blood and Transplant	NHSBT	
National Institute for Health Care Excellence	NICE	
Obsessive Compulsive Disorder	OCD	
Operational Delivery Networks	ODN	
Patient Advice and Liaison Service	PALS	
Polymerase Chain Reaction	PCR	

Protein Fractionation Centre	PFC	
Protein Misfolding Cyclic Amplification	PMCA	
Post-Traumatic-Stress-Disorder	PTSD	
Regional Health Authority	RHA	
Regional Transfusion Centres	RTC	
Regional Transfusion Directors	RTD	
(The) Relevant Period		The 1960s, 70s, 80s and early 90s
Serious Adverse Blood Reactions and Events	SABRE	
Serious Hazards of Transfusion	SHOT	
Scottish Intercollegiate Guidelines Network	SIGN	
Scottish National Blood Transfusion Service	SNBTS	
Sustained Virological Response	SVR	
The Transfusion Requirements in Critical Care	TRICC	
Transfusion Transmitted Infections	TTIs	Infections resulting from the introduction of a pathogen into a person through blood transfusion.
United Kingdom Haemophilia Centre Doctors' Organisation	UKHCDO	
United Kingdom Health Security Agency	UKHSA	
Variant Creutzfeldt-Jakob disease	vCJD	
World Health Organisation	WHO	

INTRODUCTION AND EXECUTIVE SUMMARY

"I would like the Inquiry to find out why and how this scandal happened. I would like the Inquiry to understand how it has totally destroyed lives. I want answers to why I had to sit and watch the person I loved die."[1]

"Nothing like this should ever happen again."[2]

1. Infected Blood has shattered the lives of tens of thousands of people across the UK. The transmission of the infection was for many only the start of the pain and suffering they would endure over the years to come. This was a tragedy on an unprecedented scale, and one which was avoidable.

2. This Inquiry provides a long-awaited opportunity to examine what happened and why, the extent to which this disaster could have been prevented or its impact mitigated, and crucially what lessons can be learnt to ensure that the same mistakes are not repeated. Much of the evidence heard has echoed concerns expressed in many other inquiries and reviews into the operation of the healthcare system.

3. The terms of reference of this Inquiry and the issues it has set out to consider reach far beyond the NHS: to the mechanics of government, the relationships between ministers, civil servants and medical advisory committees; the developing knowledge of new viruses and of advances in healthcare; the dissemination (or lack thereof) of this knowledge to those in the Department of Health, clinicians and the general public; the relationship between doctors and their patients; the involvement of pharmaceutical companies in clinical decision making; questions of the rights of the individual to give informed consent and to be provided with candid information about their diagnosis and treatment options; and, crucially, the reluctance, and in many cases outright refusal, of those in government to recognise wrongdoing and to provide redress for the harm caused.

[1] W2019 §51.
[2] GRO-D

4. The evidence before this Inquiry has demonstrated significant failures in leadership, ethics and culture sustained over decades and with serious and catastrophic consequences. These failures, some of which continue to the present day, span from the top of government to regional health boards, hospital wards and GP surgeries across the country.

5. Unlike other inquiries before it, this Inquiry is in an almost unique position to consider these systems together and to make recommendations that, if implemented, will improve not only the lives of infected and affected persons ("**IAP**") but of the entire population who as individuals are impacted by government decision making.

6. Throughout these submissions (and collated in Annex 1) we have proposed recommendations which we consider address both historic wrongdoing and ongoing issues in the systems on which we rely.

7. On behalf of all the Leigh Day Core Participants ("**our CPs**"), we wish to thank the entire Inquiry team and Sir Brian Langstaff, its chair, for their warmth, humanity, courtesy and respect. Our CPs feel finally that they have been listened to and valued, after years of being ignored and overlooked.

8. These submissions highlight three key issues:

   a. The disempowerment of patients through a paternalistic culture that failed to protect their health or promote their choices;

   b. The defensiveness of the government and clinicians in refusing to admit their wrongdoing and the extent of the tragedy; and

   c. The dismissiveness of institutions created to support survivors, which in many cases simply compounded their trauma.

Disempowerment

9. As set out in the chapters on blood services, medical practitioners, haemophilia and other NHS bodies, there was a collective failure on multiple levels to minimise the use

of blood and blood products despite the known risk of transfusion transmitted infections ("**TTIs**"), particularly Hepatitis B ("**HBV**"), Hepatitis C ("**HCV**") and Human Immunodeficiency Viruses ("**HIV**").

10. A paternalistic culture and the focus upon clinical freedom led to patient safety being deprioritised. Warnings from prominent sources were ignored. There were no systems in place to ensure that doctors were provided with up-to-date guidelines, followed good practice, or were subject to appropriate oversight.

11. This extended to a lack of information given to patients about the risk of transmission of viruses by blood and blood products, and an assumption by clinicians that the benefits of treatment outweighed this risk. The significant majority, if not all, of our CPs reported that they had not provided informed consent for the treatment that led to their infection. This was a failure to recognise patient autonomy and was symptomatic of the deference to clinicians by all of society during the Relevant Period (1960s, 70s, 80s and early 90s) ("**the Relevant Period**").

12. Any systems in place to monitor, report, investigate or analyse adverse outcomes of blood transfusions were ineffective and often not used, or used incorrectly, by clinicians. There was no proper haemovigilance system that spanned the entire history of a blood component. This meant that those infected were often unable to recognise that their ill health was linked to a blood transfusion or to the use of blood products. Similarly, the healthcare system was, for the majority of cases, unable to recognise and trace infections. As a result, the system underestimated post transfusion infections, and therefore did not provide support for those infected or take action to address possible clinical malpractice to prevent further infections.

13. There was no "whole systems" approach to blood and blood products. There were a number of different organisations at the local, regional, national and UK level which failed to collaborate to ensure information and guidance was disseminated and oversight provided. For example, the National Blood Transfusion Service ("**NBTS**") did not think it was its place to give advice about the use of blood, but neither did the Chief Medical Officer ("**CMO**") or other public health bodies. Within hospitals, whilst those involved with the blood bank and its administration knew about tracing

donations, this does not seem to have percolated to the actions of individual clinicians, and there were too few transfusion committees to provide direction for every practitioner in a hospital. Many hospitals did not have such a committee at all.

14. Whilst there was a handbook of transfusion medicine and a panoply of advice, it would appear that each speciality in each hospital could take a different approach to the circumstances in which a transfusion should be given, and in haemophilia centres to the selection of blood products to be used. Indeed, individual clinicians had their own idiosyncratic practices, which they passed down to junior colleagues. The NBTS did not often speak to clinicians who were transfusing blood, and the clinicians did not speak to the haematologists working alongside them to ask for advice or guidance, nor did they seem to consider that such a discussion would have been useful. The association of Haemophilia Clinicians, the United Kingdom Haemophilia Centre Doctors' Organisation ("**UKHCDO**"), had no formal status but was allowed to set the agenda for haemophilia treatment despite providing positively misleading, and in some cases lethal, advice.

15. Similar fragmentation was seen in the system of Regional Transfusion Centres ("**RTCs**"). The absence of executive oversight by NHS bodies and the Department of Health meant that there was no centralised control over how blood was collected and supplied to the NHS for transfusion and fractionation. A focus on getting "enough" blood acted as a disincentive to introduce stringent measures, such as donor exclusion and testing to ensure collection of the safest possible blood. The lack of a four nations blood service until 1994 meant that overprovision in one nation did not lead to greater supply to another.

16. There was a lack of leadership from central government bodies and from the Department of Health in respect of the safety of the system for collecting, fractionating and supplying blood and blood products for clinical use in the NHS. They failed in their role as "systems stewards" with ostensible and ultimate authority for ensuring patient safety.

Defensiveness

17. The approach by all within the relevant government and healthcare systems was to defend their actions to the hilt. At best there was a failure to recognise their mistakes, and at worst active steps were taken to cover these up. The reputation of the systems, and of the individuals working within them, was more important than examining what went wrong. The Department of Health and its constituent ministers and civil servants should have shown leadership on this issue. They did not.

18. Effective leadership means taking responsibility; in this case, there was an abdication of responsibility by all those involved in central government, advisory committees, NHS bodies, and by clinicians. None were willing to accept their part in this tragedy. This compounded the trauma and distress of IAPs, prolonging their physical, psychological and emotional suffering as well as, for many, their financial hardship.

19. By acting defensively, clinicians and others within the healthcare system ignored concerns raised by patients. Those in central government ignored questions put by campaigners. There was a view that these individuals were "difficult" or "neurotic" and did not understand what was best for them.

20. Allied to this was a lack of candour, by which we mean openness and transparency, and a willingness to tell the whole truth, no matter how unpalatable. This again was present at every level. This lack of candour prevented lessons being learned; delayed access to treatment; and led to inadequate redress with schemes that were hastily set up and failed to address the financial, social, or psychological needs of those they purported to support.

Dismissiveness

21. When our CPs sought treatment and support they were often dismissed and in many cases were not provided with adequate care. This was the experience of the infected and affected across the four nations, indicating that the failure to listen to and act on

complaints of symptoms and pleas for support, were rooted in a system which prioritised itself over the needs of those whom it serves.

22. This Inquiry has revealed appalling stigma, prejudice, cruelty and disrespect targeted at individuals infected with HBV, HCV and HIV, as well as their families. That these viruses can be transmitted by intravenous drug use or sex, and that cirrhosis of the liver can be caused by drug or alcohol addiction led to those infected having to endure an attitude not experienced by those with other chronic conditions. It led to the ostracising of families from their communities, and the breakdown of close relationships.

23. There is significant and compelling evidence of a lack of compassion and bigotry from clinicians and health professionals. The insult of being subjected to this from the very system that caused the infection in the first place is difficult to comprehend, but is one which many of our CPs have described articulately and in detail. The failure then by central government to acknowledge and raise awareness of these viruses being transmitted through NHS treatment deepened the indignity felt by many.

24. The evidence has highlighted systemic inequalities in healthcare, in particular as relates to women and minoritised ethnic communities. Many women were infected through blood transfusions during obstetric and gynaecological procedures but faced misogynistic attitudes and were disregarded when they presented with symptoms. Similarly, many people from minoritised ethnic communities faced double discrimination due to their ethnicity and infected status. Wider discriminatory attitudes in society and bias in the medical profession caused and still causes further, often severe, harm to these communities.

25. IAPs were denied redress through the piecemeal and inadequate financial support schemes which were belatedly and begrudgingly set up. These schemes operated in such a way that even when limited *ex gratia* support was eventually provided, further distressed was caused. Many found the application process humiliating and described that they felt they were "*forced to beg for scraps off the table*".

26. In order to match and acknowledge the scale of the moral harm which infected and affected individuals have suffered, we call on the Inquiry to be bold in its recommendations and on the government to be generous and proactive in its response. Significant investment is needed due to successive UK governments ignoring this tragedy for decades. Now only substantial, prompt, and comprehensive compensation will be sufficient.

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16 December 2022

CHAPTER 1: IMPACT ON INFECTED AND AFFECTED PEOPLE

"I hope that the Inquiry will [be] an opportunity for people's voices to be heard."[3]

Introduction

1. This chapter seeks to identify the impact of being given contaminated blood on our CPs. It seeks to convey some of the repeated themes, messages and experiences expressed in our CPs' witness statements. Wherever possible, direct quotes or wording has been taken from those witness statements in an attempt to ensure that our CPs' voices are heard and represented.

Infection and diagnosis

Transmission of infection

2. Annexes 5 and 6 contain graphical representations of the statistics regarding how our CPs were infected, including: whether they were infected by blood product or blood transfusion; the type of blood product or reason for transfusion; the type of infection; the date the person was infected; and the number of years between infection and diagnosis. The majority of our CPs were infected via blood transfusion. For those infected by both blood products and transfusions, the number of infections peaked in the early 1980s.

Consent[4]

3. The overwhelming majority of our CPs were given no information regarding the risk of contaminated blood before or after receiving the blood product or transfusion which infected them or their loved one.[5] Therefore, even if our CPs nominally

[3] GRO-D

[4] Please note that the clinical and ethical dimension of practitioners' failures to obtain consent is explored fully in the chapter on the Role of Medical Practitioners

[5] W3103 §7, W2690 [ANON] §8, W1820 [ANON] 2, W2009 §5, W2631 [ANON] §9, W1876 §9, W2012§5, W1888 §4, W1890 §5, W1891 §7, W1892 [ANON] §3, W2820 [ANON] §8, W1894 §8, W1895 §5, W1899 [ANON] §7,

consented to the blood transfusion or blood product, they were unable to give informed consent having not been made fully aware of the risks. Even those CPs who were given a form or document to read prior to an operation or treatment – which *may* have contained information regarding any risk – recall that they were not given sufficient time to read the document, nor did they have the contents of the document explained to them; they just felt pressured into signing it.[6] Crucially, a number of our CPs state that if they had been fully informed about the risks of contaminated blood, they would not have consented to having the blood transfusion or product.[7]

4. It is appreciated that it was more difficult to obtain consent prior to administering the blood product or transfusion in some cases because, for example, the person was a baby or child at the time and their parents were not available,[8] or because the person was unconscious and required emergency treatment.[9] However, a number of our CPs recall how even after they woke up from an operation during which they were given a transfusion, they were not given any information about potential risk of having been exposed to infection.[10] Some of our CPs raised concerns about the risk of infected

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GRO-D, W1896 §4, W0031 [ANON] §2.9, W1900 [ANON] §8, W1902 [ANON] §10, GRO-D, W1905 §6, W1907 [ANON] §5, W1908 [ANON] §2, W1910 §4, 9, W1913 §6,W2019 §17, W2638 §6, W1919 [ANON] §3, 9, W2641 §6, W1921 [ANON] §3,8, W1922 [ANON] §12, W1923 §4, W1925 [ANON] §3, W1929 §6, W1932 §6, W1934 §9, W1935 §4, W1938 §7, GRO-D, W1945 §8, W1947 [ANON] §6 W1949 §8, W3713 §7, W1954 §6, GRO-D W1960 §17, W5209 §5, W1963 §6, W2036 §11, W2701 §4, W2644 §4, W1970 §8, W2645 §4, W1972 §5, W1974 [ANON] §4, 5, W1982 §5, W2041 §16, W1987 [ANON] §4, W1988 §4, W2059 [ANON] §9, W1990 §4, W2043 §3, W2702 §5, W1991 §10, W1992, W1995 §8, W1996 [ANON] §7, W1997 §5, W2062 §7,W2000 §5, W2001 §3, 5, W2002 [ANON] §5, W0394 §7, W1967 [ANON] §5 W1999 §5, W2013 §13, W2634 §4, GRO-D 10, W1814 §6, W1817 §11, W819 [ANON] §7, W1821 §12, W1823 §7, 11, W3323 [ANON] §10, W2870 §10, W1825 §5, W3914 §26, W1842 §5, W2057 §18, W1848 §6, W1883 §9, W1850 §23, W0709 §10, W1867 §10, W1867 §5 W1877 §7, W1882 §7, GRO-D, W1917 §5, W3697 §9, GRO-D, W2028 §8, W1926 §19, W1928 §7, GRO-D W1950 §10, W2033 §7, W1962 §6, W2643 [ANON] §11, W1968 [ANON] §6, W1975 §5, W1977 §6, W1981 §4, W2703 §13, W2026 [ANON] §5, W2031 §7, W1875 §5, W3710 §17, W3326 §9, W1886 [ANON] §4, W1910 §5, W1832 §5, GRO-D W3712 §7, GRO-D §18, W2710 §7, W1980 §5, W2694 §5, GRO-D, GRO-D

[6] W1818 §12, 23, W2005 §7, W2631 [ANON] §9

[7] W2644 §5, W1879 §30, W1910 §5, W1913 §6

[8] W1818 §12, W1902 [ANON] §10, W1908 [ANON] §2, W5209 §5, W1963 §6, W2644 §5, GRO-D

[9] W1826 [ANON] §8, W1838 §28, W3693 §8, 22, W2692 §3, W3916 §4, 22, W1820 [ANON] §2, W1871 [ANON] §4, W1888 §6, W1889 [ANON] §7, W1905 §6, W1907 [ANON] §5, W1925 [ANON] §3, W1932 §6, W1935 §4, W1947 [ANON] §6, W3713 §7, W2701 §4, W2645 §3, W1972 §5, W1974 [ANON] §4, W1997 §4, W2634 §4, W1825 §5, W1848 §6, W1867 §10, W1961 §4, W1832 §5 GRO-D W2694 §5, GRO-D GRO-D

[10] W1818 §12, 24, W1822 [ANON] §5, W1826 [ANON] §8, 18, W1829 §21, W1834 §5, W0622 §14, W1855 §9, W2853 [ANON] §4, W1857 [ANON] §7, W2629 [ANON], W1860 §7, W1859, W1862 §12, W0671 [ANON] §10, W1820 [ANON] 2, W0065 §6, W1871 [ANON] §5, W1888 §6, W1889 [ANON] §7, 36, W1895 §5, W2891 §2, W1905 §6, W1907 [ANON] §5, W1919 [ANON] §3, W1935 §4, 5, W1947 [ANON] §3, W3713 §7, W1832 §5, GRO-D, W2694 §5, GRO-D

blood by directly asking medical staff if the blood used was safe and were assured that it was and there were no risks involved.[11] One CP was even told that the blood they received was 100% safe, there was *"no chance"* it could be contaminated, and that the doctor was so sure of this that he would have *"given it to his 7 year old daughter."*[12]

5. Other CPs explain that even though they had concerns about the safety of the blood given to them, they trusted the doctors and were led by them.[13] As one CP put it, *"in those days the doctors were gods and you just did what they said."*[14] One CP recalls that she was harshly told by the ward sister that she had to have a transfusion because the doctor had said so.[15] Other CPs commented that they felt that they had *"no choice"* but to accept the blood transfusion or blood product;[16] this is particularly so given the blood product or transfusion was sometimes given in an emergency (and at times life-threatening) situation, when the person was in extreme pain, and in some cases, were told they would die if they did not have it.[17] Indeed, it was often in those extremely distressing and panicked moments, that people were asked to give their consent. As one CP commented, *"when you are in the full throes of labour, in serious pain, I don't think you really care at that time what they give to you."*[18]

6. One CP recalls an incident where she refused to consent to a blood transfusion for her daughter which would speed up her recovery, but which was not strictly necessary. However, when she returned to the hospital the following day the doctors had given her daughter the blood transfusion anyway. The doctors did not give an explanation when asked why they had given the blood transfusion against the mother's wishes and without warning, when her daughter's condition was much improved, and her life

[11] W1987 [ANON] §3, W2702 §5, W3325 §4, W1850 §21
[12] W1885 §6
[13] W1850 §21, W1879 §30
[14] W1850 §21
[15] W1921 [ANON] §3
[16] W3325 §4, 23, W1921 [ANON] §3
[17] W2062 §7, GRO-D , W2631 [ANON] §5, W1900 [ANON] §8, W1923 §4
[18] W3103 §31

was not in danger. The mother recalls that the doctors simply laughed at her, could not understand her concern, and did not seem bothered that she was upset.[19]

7. Another CP describes her particularly distressing experience of being pressured into having a blood transfusion despite her serious, and valid, concerns:

> *"I told the doctors I didn't want blood because some blood was infected: we knew that much then. They dismissed my concerns and said it was nothing to worry about. I insisted I wouldn't have the transfusion and held off. They began really nagging me and were losing patience. My father was of the same blood group and said he would donate, but they said I would need a couple of units and that they wouldn't be able to take more than a pint from my father. They said I needed blood from a proper blood bank, which was Seacroft in Leeds. Eventually a consultant came and shouted at me, in front of everyone on the ward, and called me a 'bed blocker'. He said he needed me off the maternity ward because I had had my baby, but said that because I needed a blood transfusion, they could not move me because I was too ill. He said that 'without this blood transfusion you could die'. The consultant told me that there was no risk from blood supplies in relation to HIV. He told me I was at more risk of dying and leaving my baby with no mother. He said my fears were groundless. I was in floods of tears. I felt humiliated. I remember ringing my dad from a payphone on the ward. In the end I caved in. A junior doctor came to me and said that they knew enough to know that if blood is heat treated it kills HIV. He said he would be honest with me and said that not all supplies are heat treated, some are of older stock. He said that if he could guarantee that the blood would be heat treated would that put my mind at rest? I said I supposed so, I thought that was as good as I would get."*[20]

8. In terms of the impact, being given blood products or a blood transfusion without having given informed consent is described by our CPs as making them feel incredibly angry[21] and as if their rights have been violated.[22]

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[19] W1823 §7-8
[20] W1934 §5-6
[21] W1818 §12, 23, W2005 §7, W2631 [ANON] §9
[22] W1893 §9

Communication of diagnosis[23]

9. A number of our CPs describe being diagnosed with HCV, HBV and HIV as like being given a death sentence;[24] some CPs feared they would die immediately.[25] Our CPs were taken aback, shocked, horrified, frightened, confused, anxious, distraught, in tears, extremely upset, angry, and devasted when diagnosed,[26] particularly those individuals who thought they would die[27] or who were told they would not have long to live[28] (in some cases only a couple of months).[29] Indeed, one CP recalls the doctor who diagnosed them saying that the disease could kill them so they should enjoy the time they had left and go to Disneyland.[30] Another CP, who at the time was a single mother with two young children, describes having been diagnosed with HBV and told there was no cure and that it would eventually kill her.[31] Understandably, this caused immense fear and distress at the thought of dying and leaving her two children with no one to care for them.[32] Another CP recalls being asked when diagnosed whether they wished to die at home or in hospital.[33]

10. Receiving such news is traumatic. One CP describes it as like being hit by a truck, stripping you of an ability to see a future;[34] another describes it as being like a physical jolt and displacement from reality, as if someone had picked up the rest of the universe and moved it several yards away.[35] For many, the overwhelming emotion was complete shock:

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[23] Please note that the clinical and ethical dimension of communication of diagnosis is explored fully in the chapter on the Role of Medical Practitioners.
[24] W3713 §12, W1822 [ANON] §8, W2006 [ANON] §12 – 13, GRO-D
[25] W2028 §15
[26] W2004 [ANON] §17, 18, W1842 §18, W1928 §11, W2033 §9, 12, W1814 §8, 11, W1991 §14,W1860 §7, W2853 [ANON] §8, W2629 [ANON] §13, W2854 [ANON] §7, W1860 §11, W0065 §10, W3325 §15, W0031 [ANON] §2.41-2.43, W1832 §9
[27] W2634 §13, 15
[28] W1928 §11
[29] W2033 §9, 12
[30] W1885 §12
[31] W1906 §14
[32] W1906 §14
[33] W2638 §17
[34] W1908 [ANON] §6-9, GRO-D
[35] W2041 §19

"I didn't know what HCV was at the time, but I nearly fell off the chair with shock and told the doctor he had the wrong results in front of him. I have never put myself at risk for anything, so I was flabbergasted by it all. The doctor told me that I needed to be counselled about my HCV, and sent me to a room to speak to a nurse. […] The nurse that I saw did not provide me with any information about the prognosis of HCV or how to cope with it. Instead, she asked me if I was promiscuous, if I took drugs, and if I was an alcoholic. I was offended by this because the doctor knew that my infection was due to blood transfusions but I was still being made to listen to a lecture from a nurse that was clearly intended for people who had contracted it through lifestyle choices. I thought, I have done none of these things! Then I think the nurse said something about me being lucky that I didn't have HIV. I walked round for days in a daze not knowing what to do or what to say. [...] I feel there could have been better communication between the doctor and nurse so that I was given relevant information about the virus, how I had contracted it and what I should do next. I remember thinking at the time, "what the hell is happening" and feeling very scared."[36]

11. Although in a minority, some of our CPs commented that as well as feeling shocked and frightened when they were diagnosed, they also felt relieved as they finally had an explanation for the previously unexplained symptoms which they had been experiencing for years;[37] this was particularly validating for CPs who had faced doctors refusing to accept that there was anything wrong with them for years.[38]

12. A number of our CPs describe being mortified and horrified at having been very casually diagnosed with a life-threatening illness without any forewarning or display of empathy.[39] GRO-D GRO-D GRO-D [40] This is particularly the case for those

[36] W1998 §11-12, 19
[37] W1950 §13, 16, W1934 §35, W2043 §39, W0065 §24, W1900 [ANON] §21
[38] W1934 §35
[39] W1997 §13, W1822 [ANON] §8, W GRO-D V1838 §11, W1829 §13 W1834 §12, W1871 [ANON] §14, W1905 §20, 21, W1925 [ANON] §10, W3712 §9
[40] GRO-D

individuals diagnosed over the phone[41] or by letter,[42] who were consequently often alone and without anyone with them for support when they received the news.[43] Receiving the diagnosis without warning and not in person is described by many of our CPs as disgusting, devastating, "*wrong*", very frightening, extremely distressing, very upsetting and unnecessarily stressful, such that it had an ongoing impact on their mental health.[44] Our CPs commented that they are appalled that it was thought to be appropriate to communicate the diagnosis in this way and that they should have been told in person, by someone they knew and not a stranger, and provided with support and information.[45] Indeed, one CP commented that the way in which they were told about the infection was so inhumane and mentally damaging that they nearly took their own life.[46]

13. A number of CPs also commented how they discovered their diagnosis entirely by accident, casually dropped into a conversation during a routine appointment,[47] or following routine blood tests,[48] a blood donation[49] or during tests/treatment for an unrelated condition.[50] One CP discovered they had HCV when overhearing a nurse talking while she was recovering on a ward,[51] and another described being diagnosed in a busy corridor of a hospital with lots of people around.[52]

14. A number of our CPs describe that the delivery of the diagnosis was in a very blunt, brutal, unsympathetic, nonchalant and matter-of-fact manner,[53] demonstrating a

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[41] W3103 §33, W2702 §11, W1891 §10, W1932 §11, W1935 §10, W1945 §10, W1954 §8, GRO-D, W1990 §7, W2702 §8, W2000 §14, W1968 [ANON] §10, W0031 [ANON] §2.41-2.43, W1934 §16

[42] W2641 §9, 18, W1974 [ANON] §7, W2692 §5, W3916 §10, W1826 [ANON] §9, 15, W1818 §18, W3693 §15, 20, W0065 §7, W1895 §9, W2637 §8, W1908 [ANON] §5, W1923 §6, W1974 [ANON] §6, W2041 §18, W2043 §4, W2001 §7, W1848 §8, W2819 §7, W2028 §12, W1966 §6,W2001 §7, W2041 §19, W0065 §8, 16, W1895 §9, 10, W3712 §9

[43] W2702 §11, W3916 §10, 19, W2001 §7, W1860 §7, W2853 [ANON] §8, W2629 [ANON] §13, W2854 [ANON] §7, W1892 [ANON] §9

[44] W1974 [ANON] §7, W1908 [ANON] §14, W1966 §6, W1826 [ANON] §9, 15, W1818 §18, W3693 §15, 20, W1995 §10, W2001 §7, W1895 §11, W1842 §18

[45] W3693 §20, W2000 §14, W1935 §10, 16, 17, W1895 §11, W0031 [ANON] §2.41-2.43

[46] W1921 [ANON] §19, 24

[47] W1951 §4-5, 10, W1975 §12, W1926 §21, GRO-D, W2039 §14

[48] W1975 §12, W0709 §14, W1880 [ANON] §11, W1890 §7, GRO-D

[49] W2638 §10, 11, W1826 [ANON] §9, 15, W1820 [ANON] §4, GRO-D, W1908 [ANON] §5, W1974 [ANON] §6

[50] W1962 §26, W3692 §25, W1895 §9, 10, GRO-D, W0031 [ANON] §2.41-2.43

[51] W2039 §14

[52] W2012 §11, 18

[53] W1951 §4-5, 10, W1975 §12, W1926 §21, GRO-D, W1814 §8, 11, W1970 §13, W1888 §18, GRO-D

complete lack of forethought or consideration of the need to communicate such a life-changing diagnosis sensitively and with care.[54] For example, one of our CPs describes being informed of her mother's HIV status five days after her funeral.[55] Another CP describes how the diagnosis was made without warning with their 15- and 18-year-old children in the room.[56] Another CP recalls that their father was diagnosed when he was alone, very ill, very confused and in a vulnerable state.[57] Yet another CP describes how their diagnosis was erroneously communicated to their mum instead of them, breaching patient confidentiality.[58]

15. Many individuals when diagnosed were not given sufficient information, advice or support to enable them to understand what the infection meant, how it had happened, how severe it was or what to expect going forward.[59] One CP commented that the doctor seemed more concerned with preventing spread of infection to the public than helping them understand the diagnosis.[60] Failing to provide such information made people feel as if they were being kept in the dark, and threw them into a state of uncertainty, panic, alarm, and anxiety.[61] In particular, some CPs describe their anger and disappointment at not being told how serious the diagnosis was, how it would cost their loved one their life and leave them devastated.[62] A number of our CPs also commented that the shock of receiving the diagnosis prevented them or their loved one from feeling able to push for further information and ask questions.[63] One CP recalls that the impact of not being told what HCV meant for their life when diagnosed has been that they have forever since experienced health-related anxiety, such that they constantly think they have Covid or a brain tumour.[64]

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[54] W1814 §8, 11, W1826 [ANON] §9, 15, W1818 §18, W3693 §15, 20, W1995 §10, GRO-D
[55] W3323 [ANON] §12
[56] W1950 §13, 16
[57] W2011 [ANON] §6, 11
[58] W1822 [ANON] §8
[59] W3323 [ANON] §12, GRO-D 23, W1906 §14, W1951 §4-5, 10, W1975 §12, W2039 §14, W1926 §21, W1814 §8, 11, W1970 §13, W3693 §20, W1945 §13, W1860 §11, W1880 [ANON] §11, W1895 §9, 10
[60] W1905 §20, 21
[61] W1814 §8, 11, W2634 §13, 15, W3693 §20, W1967 [ANON] §11
[62] W1950 §13, 16, W1926 §21, W1814 §8, 11
[63] W1882 §13 W2634 §13, 15, W1905 §20, 21
[64] W2634 §13, 15

16. Upon being diagnosed, a number of CPs describe how their doctor refused to accept that their infection was caused by blood product or transfusion and instead desperately tried to find another explanation; doctors would frequently ask invasive questions about the person's private life and make assumptions about their sexual promiscuity, sexual orientation, drinking habits and drug use, often in front of loved ones or other doctors.[65] Our CPs describe how they found this shocking, offensive, humiliating, embarrassing, deeply insulting, and extremely distressing, leaving them feeling dirty, degraded, disrespected and discriminated against.[66] Often our CPs were asked these distressing questions when they were feeling very ill, were in intense pain and when they had just been diagnosed with a life-threatening illness.[67]

Late diagnosis[68]

17. A theme running throughout our CPs' evidence is the impact of having lived for many years with the infection prior to being diagnosed. For many, this was a period of well over 10 years, in some cases, over 40 years. A snapshot of the delay in diagnosis is set out below and graphs of the delays are included at Annexes 5 and 6:

Infected 1981, diagnosed 1992, 11 years.[69]

Infected 1985, diagnosed 1996, 11 years.[70]

Infected 1985, diagnosed 1996, 11 years. [71]

Infected 1978, diagnosed 1991, 13 years.[72]

Infected 1979, diagnosed 1994, 15 years.[73]

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[65] GRO-D , 23, W2703 §8, W1814 §8, 11, W1823 §26, W2055 [ANON] §12, W1892 [ANON] §7, W1913 §9, 12, W1832 §13

[66] GRO-D , 23, W2703 §8, W1814 §8, 11, W2055 [ANON] §12, W1892 [ANON] §7, W1913 §9, 12

[67] W2055 [ANON] §12, W1892 [ANON] §7

[68] Please note that the clinical and ethical dimension of late diagnosis is explored fully in the chapter on the Role of Medical Practitioners.

[69] W1935 §10

[70] W1900 [ANON] §12

[71] W1883 §14

[72] W3710 §11

[73] W1890 §7

Infected 1982, diagnosed 1997, 15 years.[74]

Infected 1984, diagnosed 1999, 15 years.[75]

Infected 1985, diagnosed 2000, 15 years.[76]

Infected 1988, diagnosed 2004, 16 years.[77]

Infected 1982, diagnosed 1999, 17 years.[78]

Infected 1984, diagnosed 2001, 17 years.[79]

Infected 1987, diagnosed 2004, 17 years.[80]

Infected 1987, diagnosed 2004, 17 years.[81]

Infected 1989, diagnosed 2006, 17 years.[82]

Infected 1972, diagnosed 1990, 18 years.[83]

GRO-D, 19 years.[84]

Infected 1976, diagnosed 1995, 19 years.[85]

GRO-D

GRO-D, 19 years.[87]

Infected 1980, diagnosed 2000, 20 years.[88]

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[74] W1968 [ANON] §2, 5
[75] W1925 [ANON] §7
[76] W1910 §11
[77] W1963 §8
[78] W1962 §8
[79] W0709 §1
[80] W2033 §1
[81] W1891 §4, 9
[82] W2043 §2, 4
[83] W1868 §3, 10
[84] GRO-D
[85] W2042 §10
[86] GRO-D
[87] GRO-D
[88] W1975 §6

Infected 1991, diagnosed 2011, 20 years.[89]

Infected 1978, diagnosed 1999, 21 years.[90]

Infected 1982, diagnosed 2003, 21 years.[91]

GRO-D [92]

Infected 1983, diagnosed 2005, 22 years.[93]

Infected 1985, diagnosed 2007, 22 years.[94]

Infected 1985, diagnosed 2007, 22 years.[95]

Infected 1990, diagnosed 2012, 22 years.[96]

Infected 1982, diagnosed 2005, 23 years.[97]

Infected 1983, diagnosed 2006, 23 years.[98]

Infected 1988, diagnosed 2001, 23 years.[99]

Infected 1985, diagnosed 2010, 25 years.[100]

GRO-D [101]

Infected 1989, diagnosed 2014, 25 years.[102]

Infected 1978, diagnosed 2004, 26 years.[103]

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[89] W2001 §3
[90] W2026 [ANON] §14
[91] W1867 §9
[92] GRO-D
[93] W1947 [ANON] §3, 14
[94] W2638 §3, 6
[95] W1934 §11
[96] W2019 §10
[97] W2631 [ANON] §12, 14
[98] W1895 §8
[99] W1901 §16
[100] W1878 §12
[101] GRO-D
[102] W1888 §17
[103] W2819 §7

Infected 1979, diagnosed 2005, 26 years.[104]

Infected 1983, diagnosed 2009, 26 years. [105]

Infection 1968, diagnosed 1995, 27 years.[106]

Infected 1982, diagnosed 2009, 27 years.[107]

Infected 1976, diagnosed 2004, 28 years.[108]

Infected 1978, diagnosed 2006, 28 years[109]

Infected 1973, diagnosed 2002, 29 years.[110]

Infected 1974, diagnosed 2003, 29 years.[111]

Infected 1973, diagnosed 2002, 29 years.[112]

Infected 1978, diagnosed 2007, 29 years.[113]

Infected 1977, diagnosed 2007, 30 years.[114]

Infected 1979, diagnosed 2009, 30 years.[115]

Infected 1982, diagnosed 2012, 30 years.[116]

Infected 1984, diagnosed 2014, 30 years.[117]

Infected 1986, diagnosed 2016, 30 years.[118]

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[104] W1950 §12
[105] W1825 §11-12
[106] W1908 [ANON] §5
[107] W2644 §7
[108] W1996 [ANON] §12
[109] W1842
[110] W2000 §6
[111] W2002 [ANON] §6
[112] W3325 §1, 14
[113] W1896 §5
[114] W1907 [ANON] §5
[115] W1972 §7
[116] W1892 [ANON] §9
[117] W2059 [ANON] §2
[118] W1921 [ANON] §3, 16

Infected 1975, diagnosed 2006, 31 years.[119]

Infected 1983, diagnosed 2014, 31 years. [120]

Infected 1970, diagnosed 2002. 32 years.[121]

GRO-D [122]

Infected 1980, diagnosed 2012, 32 years.[123]

Infected 1971, diagnosed 2004, 33 years.[124]

Infected 1981, diagnosed 2014, 33 years.[125]

Infected 1980, diagnosed 2014, 34 years.[126]

Infected 1984, diagnosed 2018, 34 years.[127]

Infected 1986, diagnosed 2020, 34 years.[128]

Infected 1971, diagnosed 2006, 35 years.[129]

Infected 1980, diagnosed 2015, 35 years.[130]

Infected 1975, diagnosed 2011, 36 years.[131]

Infected 1975, diagnosed 2011, 36 years.[132]

Infected 1980, diagnosed 2017, 37 years.[133]

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[119] W2011 [ANON] §6
[120] W1932 §11
[121] W1997 §13
[122] GRO-D
[123] W1871 [ANON] §3, 14
[124] W1926 §21
[125] W1961 §5
[126] W1889 [ANON] §8
[127] W0394 §9
[128] W5209 §8
[129] W1982 §9
[130] W1913 §3, 8
[131] W0031 [ANON] §2.5, 2.40
[132] W1832 §7
[133] W1954 §3, 7

Infected 1976, diagnosed 2014, 38 years.[134]

Infected 1979, diagnosed 2017, 38 years.[135]

Infected 1970, diagnosed 2014, 44 years.[136]

18. All our CPs who experienced late diagnosis feel strongly that they should have been tested and diagnosed earlier. They describe the anger, frustration, dismay, annoyance, disgust and upset they feel,[137] particularly those who lost their loved one and who believe that if there had been investigations carried out earlier, then their loved one may still be alive.[138] The consequential effect of a late diagnosis is that damage remains undetected for years and by the time it is discovered it is often too late for effective treatment.[139] Coupled with the physical impact of the virus sitting undetected in the body for years without treatment, is the psychological impact on people having carried the infection so long without knowing. Witness W2641, who was diagnosed in 2017 with HBV after being infected in 1979[140] describes it as: "*...I wonder how many times I have cut myself and somebody has come to help me? Have I infected that person? ....Have I infected anybody in theatre....*" .

19. In a number of cases, the length of delay could have been avoided. For example, one of our CPs says that their medical notes demonstrate that the need for tests was flagged by medical staff - but not followed up on - years before diagnosis;[141] in other cases, medical notes show patients tested positive months or years before they were told of their diagnosis.[142] One CP describes the impact of finding this out: "*In my view this is absolutely devastating and abhorrent. I cannot fathom the logic in the actions of my then treating consultant, who did not tell me that I had HCV. Instead, I have been denied treatment and faced outrageous slurs on my character, including accusations*

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[134] W1995 §10
[135] W2641 §7
[136] W1905 §7 - 14
[137] W2639 §10, W2033 §9, 12, W2059 [ANON] §18, W1855 §42, W3916 §14, W2629 [ANON] §17
[138] W2033 §9, 12, W1825 §11-12
[139] W1825 §11-12
[140] W2641 oral evidence page 28 September 2022. Page 26, lines 11-23.
[141] W3103 §9 - 10
[142] GRO-D , W1901 §11, 17, W3326 §12, W1889 [ANON] §8, W2642 §11, W1825 §11-12, W2643 [ANON] §8. W1832 §8, GRO-D

that my condition was caused by alcoholism."[143] The knock-on impact is that some lost trust in the medical community when they discovered that the people who were meant to be looking after them had kept the diagnosis from them for years.[144] In one account, a CP said she confronted the doctors and nurses about why, despite having tests and treatments for a myriad of other conditions, her infection was not picked up for 30 years; the response was that she *"did not look like an at risk person."*[145]

20. In other cases, the delay was due to misdiagnosis.[146] This is particularly the case with a number of our CPs who were infected during or just after giving birth to their child. The predominant symptoms of HCV and HBV are extreme fatigue, tiredness and anxiety, all symptoms which are also common for new mothers. There were a number of testimonies of new mothers who, upon complaining of their symptoms to doctors, were told they were experiencing what all new mums experience[147] or who did not think of going to the doctors because they thought the way they were feeling was normal.[148] This is particularly the case for first-time mothers.[149] Medical practitioners and others seem to ascribe all feelings of tiredness or fatigue to such rather than critically examining the situation.

Battling to get a test

21. A number of our CPs describe a failure by doctors to suggest they be tested (even in cases where a family member is diagnosed) and that tests were only conducted after they were requested and insisted on.[150] Some CPs describe GPs actively resisting or refusing to give them a test for years,[151] or saying one was not necessary because there was little chance of them having contracted HCV, HBV or HIV.[152] For example, one CP's doctor said that because they had never been a drug user, had medical

[143] W1889 [ANON] §8
[144] W2643 [ANON] §8
[145] W1921 [ANON] §29
[146] W1867 §27-28, W2043 §21, W0580 [ANON] §6, 9, W1998 §7, W2702 §18
[147] W1998 §7, W2702 §18
[148] W2043 §21
[149] W0580 [ANON] §6, 9
[150] W1901 §22, GRO-D, W2009 §11, W1868 §9, W1879 §54, W2640 §13, GRO-D
[151] W1905 §7 – 14, W2691 §24
[152] GRO-D W1899 [ANON] §9

treatment overseas or any piercings or tattoos there were no risk factors and therefore no reason to be tested.[153]

22. Our CPs were also made to feel guilty for requesting an "*unnecessary*" test because it would waste time and money;[154] indeed one doctor said they would only give someone an antibody test, rather than a PCR test, because it was cheaper.[155] GRO-D GRO-D GRO-D ,[156] and in another case, a CP was told that they had not been tested because it was the responsibility of the individual to ask for a test.[157]

23. One CP recounts experiencing symptoms after clearing the virus but being too frightened to go back to the GP for a test because they were made to feel stupid when they had requested a test the first time; the person goes on to say *"if I had the money I would pay privately for a scan for myself so that I am not made to feel stupid and don't have to wait so long."*[158]

Unnecessary, over-use or inappropriate use of blood[159]

24. A significant number of our CPs were given a couple of units of blood during or immediately following the birth of their child, perhaps because they lost blood during pregnancy or in order to speed up their recovery.[160] In a significant number of those cases, the blood transfusion was unnecessary as it was not given on an emergency basis or because the situation was life-threatening;[161] more often than not, it was to speed up recovery so the hospital bed would be vacated more quickly.[162] Indeed, one

[153] W1934 §15
[154] W2054 §13
[155] W1934 §15
[156] GRO-D
[157] W2009 §11, 17
[158] W1987 [ANON] §35
[159] Please note that the clinical and ethical dimension of unnecessary use of blood is explored fully in the chapter on the Role of Medical Practitioners.
[160] W3103, W1838 §3, 5, W1998 §4, W1998 §4, W0394 §5, W1999 §6, W1819 [ANON] §6, W2819 §4, W1846 §2, 5, W2054 §4, W2043 §2, W2009 §4, 7, W2631 [ANON] §5, W1891 §5, W1892 [ANON] §15, W1896 §3-4, W1900 [ANON] §4, W1913 §3, W1921 [ANON] §3, GRO-D W1824 §6, W2870 §9, W1823 §7-8
[161] W3103, W1838 §3, 5, W1998 §4, W1998 §4, W0394 §5, W1999 §6, W1819 [ANON] §6, W2819 §4, W1846 §2, 5, W2054 §4, W2043 §2, W2009 §4, 7, W2631 [ANON] §5, W1891 §5, W1892 [ANON] §15, W1896 §3-4, W1900 [ANON] §4, W1913 §3, W1921 [ANON] §3, GRO-D W1824 §6, W2870 §9, W1823 §7-8, W1879 §15 - 18
[162] W2009 §4, 7

CP recalls a consultant shouting at her when she resisted a blood transfusion saying that she was a "*bed-blocker*" because a blood transfusion would enable them to get her off the maternity ward.[163]

25. Blood was also given unnecessarily to those with mild haemophilia as a precaution before pre-planned minor surgery or following a nosebleed.[164] Other CPs comment that they were given a few units of blood during an operation but there are no records to show why they were necessary.[165] GRO-D GRO-D GRO-D.[166]

Living with the infection

Physical impact

26. A full list of all symptoms of and secondary conditions associated with HCV, HBV and HIV which our CPs have experienced can be found in Annexes 2, 3 and 4.

27. The most widely suffered and overwhelming symptom of HCV reported by our CPs is extreme, debilitating fatigue.[167] The infection is described as draining,[168] leaving CPs with zero energy,[169] making them feel as though they were carrying 10 people,[170] or as though they had not slept at all,[171] rendering them unable to keep their eyes open,[172] or as if they have utterly flat batteries that never recharge.[173] The fatigue is not something you can "*push through*" with willpower; it is completely

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[163] W1934 §1-5
[164] W1111 §3-4, 22, W1938 §9
[165] W2629 [ANON] §3, W1895 §3
[166] GRO-D
[167] W1934 §12, W2039 §30, W2055 [ANON] §21, W2690 [ANON] §25, GRO-D, W3710 §31, W1882 §18, W1882 §18, W1826 [ANON] §20, W1975 §16-17, W1999 §26, W1998 §24, W1857 [ANON] §20, 27, W1820 [ANON] §15, W1871 [ANON] §10, W1899 [ANON] §28, W1905 §58, W1910 §26, W1921 [ANON] §12, GRO-D GRO-D W2707 [ANON] §23, W1867 §41, W1950 §22, W2033 §19-20, W1877 §17, W2698 [ANON] §13
[168] W2055 [ANON] §21
[169] W1826 [ANON] §20
[170] W1921 [ANON] §12
[171] W2690 [ANON] §25
[172] W1998 §24
[173] W0622 §20-21, W0065 §22

incapacitating.[174] Some of our CPs described the tiredness as being so severe that they had to take regular naps and could fall asleep anywhere,[175] with one CP describing that she was once found asleep on the Boots prescription counter.[176] As another CP vividly explains:

> *"I could do nothing. My body was really, really heavy. To go to the toilet, I had to roll off the settee, crawl up the stairs and come down on my backside. I was so exhausted I had to switch off the television because it would tire me out. I could not walk; I could not lift my legs."*[177]

28. The extreme tiredness and inability to concentrate has the consequential effect of rendering individuals confined to the house[178] and unable to partake in activities they enjoy which brought them happiness,[179] whether that be holidays[180] or something as simple as doing a crossword.[181] One CP commented that the fatigue was so severe they were unable to finish sentences, which meant conversations were very difficult, affecting their confidence and ability to engage with other people on a basic level.[182] Another CP described the fatigue as the continual and oppressive screaming of every scintilla of your body to "*lie-down*", which holds you back from doing anything meaningful in your life, while simultaneously you desire to do quite the opposite.[183] Further it has the frustrating and debilitating effect of making it impossible to complete even basic tasks or lead a normal life, forcing people to lie down even after non-strenuous activity such as having a shower, brushing their hair or hanging up the washing.[184] The fatigue also had the knock-on effect for some CPs of gaining weight because of the inability to exercise,[185] and finding pre-planned social engagements stressful, due to anxiety about not having the energy that day and having to let loved

[174] W0622 §22
[175] W1899 [ANON] §28
[176] W1999 §26
[177] W1925 [ANON] §35
[178] W0622 §22
[179] W1867 §41r
[180] W2039 §30, W1882 §18
[181] GRO-D
[182] W1974 [ANON] §22
[183] W1899 [ANON] §28
[184] W0622 §20-21, W1832 §21, W1980 §18
[185] W1975 §16-17, W1910 §26, W1832 §21

ones down.[186] Furthermore, fatigue is a symptom which our CPs describe family members and friends can struggle to understand or accept due to a misconception that the person was being lazy or anti-social.[187]

29. Alongside the extreme fatigue, our CPs recall a myriad of other physical symptoms: excessive sweating requiring them to sleep in towels to absorb the sweat;[188] constant tingling in the feet causing numbness;[189] constant, chronic and maddening itching all over the body, coming from under the skin and causing bleeding and scarring;[190] osteoporosis to the extent that a sneeze could cause bones to snap;[191] brain haemorrhage;[192] requiring constant oxygen therapy throughout the day and night;[193] drastic weight loss to the point of malnutrition;[194] severe mobility issues requiring use of a wheelchair;[195] and kidney failure requiring kidney dialysis or a kidney transplant.[196]

30. In particular, our CPs refer to severe, excruciating and debilitating cluster migraines or "*suicide*" headaches, which could cause them to crouch in pain, clutch their head, recoil, and wail.[197] Additionally, many experienced rashes and swelling on the legs causing skin to split and meaning they were unable to fit into their shoes and trousers; this is described as being particularly embarrassing and upsetting, especially for individuals who took pride in their appearance.[198] Our CPs also suffered memory lapses of such severity that they would stop in the middle of sentences unable to recall what they were talking about just seconds before, leaving them feeling embarrassed, frustrated, upset, and a failure.[199]

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[186] W0622 §22
[187] W2002 [ANON] §16, W3710 §31, W0622 §22, W1950 §22
[188] W1967 [ANON] §21
[189] GRO-D W1967 [ANON] §16
[190] W1899 [ANON] §19, W2707 [ANON] §23, W2019 §11 (second statement), W1901 §32, 33, W1111 §23
[191] W1855 §22
[192] W1896 §24
[193] W1962 §38
[194] W2011 [ANON] §20, 21, W2004 [ANON] §29
[195] W1960 §35, W0072 §11, 23, W2012 §35
[196] W1855 §21, W2012 §7, 31
[197] W2707 [ANON] §34, W1995 §25, W1901 §32, 33
[198] W2011 [ANON] §20, 21, W1860 §23, W1928 §28, W1999 §27
[199] W2005 §25, W1990 §32-33

31. Our CPs' witness evidence also records the physical impact of their infection on their family members: one CP had to have an operation on their right arm and both hands because of all the heavy lifting helping their husband in and out of the bath and pushing his wheelchair;[200] one CP's hair fell out and they developed a stressed bladder as a result of working full time and caring for her husband;[201] one CP developed severed headaches and migraines due to stress;[202] multiple CPs suffered heart attacks due to the stress of caring for a sick relative;[203] one CP was diagnosed with a hyperthyroid condition due to constant stress and worry about their mother;[204] one CP developed arthritis in their thoracic and lumbar spine and severe arthritis and disintegration in their cervical spine due to having been a young carer and pushing their mother's wheelchair from an early age.[205]

Psychological/ mental impact

32. A full list of all psychological and mental health symptoms associated with HCV, HBV and HIV can be found in Annexes 2, 3 and 4.

33. The psychological impact is seen as enduring and significant. The fact that the diagnosis is ever-present in people's minds and therefore inescapable[206] is described as mental torture.[207]

34. Other symptoms include: recurrent night terrors;[208] Post Traumatic Stress Disorder ("**PTSD**");[209] GRO-D [210] panic attacks;[211] paranoia[212] manifesting in continuous self-examination for deterioration in condition;[213] panic about health to a

[200] W1858
[201] W1858
[202] W2696 §29
[203] W1867 §73, W1882 §31
[204] W1874 §21, 22
[205] W2643 [ANON] §51-52
[206] W1880 [ANON] §26, W2001 §11
[207] W1818 §27, W1926 §31
[208] W1932 §43
[209] W1921 [ANON] §19, 24, W1935 §33, W2872 §44
[210] GRO-D
[211] W2872 §44
[212] W1991 §20, GRO-D
[213] W1991 §20

disproportionate degree;[214] anxiety attributable to the fear and worry of accidentally passing on the infection,[215] causing individuals to shut themselves away;[216] memory loss[217] requiring people to use post-it notes as prompts for daily tasks[218] or causing people to forget why they walked into a room or what someone had said to them.[219]

35. A number of our CPs commented on the impact of the infection upon their personality in that it caused a personality change.[220] People described that they lost control of emotions easily,[221] became very blunt, harsh, angry, aggressive, and volatile,[222] behaving differently and making decisions that were out of character;[223] indeed, multiple CPs compared themselves to Dr Jekyll and Mr Hyde.[224]

36. One of the most overwhelming mental impacts of the infection is described as being the constant fear that your health could rapidly deteriorate at any moment, and not knowing if you may die, or if you may live to an old age.[225] Our CPs describe death as becoming an unspoken fact, constantly hovering in the background.[226] They describe lying awake at night and planning their own funeral,[227] locking themselves in a room and crying for hours over the thought they may die soon,[228] being acutely aware of their own mortality and the prospect of leaving their children motherless.[229] One CP quotes from their psychologist who notes: "*[X] lives with the fact that Hepatitis C is a life-threatening virus. The uncertainty that that generates also has a direct effect on his level of anxiety and depression .... also, each time [X] is made aware of someone*

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[214] W2001 §11
[215] W2631 [ANON] §21, W3326 §16, W2043 §24, W1838 §22, W1820 [ANON] §11, W2872 §44
[216] W2631 [ANON] §21
[217] W1913 §17, W2638 §17
[218] W1913 §17
[219] W2638 §17
[220] W1966 §14, W1962 §33, W1825 §21-23, W1982 §24, W1919 §27, W2036 §29, W2637 §20, W1938 §49, GRO-D
[221] W1919 §27
[222] W1962 §33, W1966 §14
[223] W1825 §21-23
[224] W2637 §20, W1938 §49
[225] W2819 §26, W2011 [ANON] §27, W1826 [ANON] §20, W3692 §43, W1838 §38, W1889 [ANON] §47, W1891 §15, W1900 [ANON] §21, W1889 [ANON] §47
[226] W3692 §43
[227] W1838 §38
[228] W1891 §15
[229] W1900 [ANON] §21

who, having been well for years, has suddenly become seriously ill from the virus and died even, it is a powerful reminder of the reality of the threat under which he lives. So intense has his anger and frustration been when those reminders occur that at times he has resorted to self-harm as a way of relief."[230]

37. That overwhelming awareness and fear of death led many individuals to develop chronic and severe depression.[231] The effects of this could be so debilitating, stripping individuals of the willpower and strength to go out,[232] causing them to endlessly procrastinate,[233] requiring them to be encouraged even to eat or do anything,[234] preventing them from leaving the house[235] or answering the phone[236] or getting out of bed in the morning,[237] leaving them crying all the time[238] and not wanting to live anymore.[239] Many CPs have spent a number of years taking anti-depressants;[240] in some cases as long as 30 years.[241] As one CP commented, *"I don't live, I exist, and I go on from day to day."*[242]

38. In many cases, those depressive feelings manifested into suicidal thoughts and actions.[243] A number of our CPs describe trying to take their lives on more than one occasion[244] and having to manage suicidal feelings every day,[245] in one case leading to detention in a psychiatric hospital.[246] One CP describes that after receiving the

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[230] W1822 [ANON] §17
[231] W3710 §23, W2031 §8-9, W1882 §20, W1814 §17, W2043 §43, W2702 §29, W2043 §24, W1963 §22, W1111 §30, W1888 §22, W0031 [ANON] §5.11, W1821 §25, W1935 §33, W2631 [ANON] §21, W2013 §19, W2707 [ANON] §5, W2644 §15, W0671 [ANON] §17 – 19, W2628 §15, GRO-D
[232] W3710 §23
[233] W2031 §8-9
[234] W1882 §20
[235] W2043 §43
[236] W2043 §24
[237] W2013 §19, GRO-D
[238] W2631 [ANON] §21, W2707 [ANON] §5
[239] W2707 [ANON] §5
[240] W1888 §22, W1821 §25
[241] W1111 §30
[242] W0031 [ANON] §5.11
[243] W1921 [ANON] §19, 24, W1997 §43, 45, W2631 [ANON] §21, W1997 §37, W2043 §24, W1988 §27, W1963 §22, W1818 §27, W0072 §34, W1902 [ANON] §25, W1935 §33, W2638 §16, W0671 [ANON] §17 – 19, GRO-D GRO-D
[244] W1997 §43, 45, W1988 §27, W1963 §22, W1818 §27, W0072 §34, W2631 [ANON] §21, W1921 [ANON] §19, 24, W1902 [ANON] §25, GRO-D
[245] W1902 [ANON] §25
[246] W1997 §43, 45

diagnosis they left their doctor's surgery and drove immediately to the viaduct close by and planned to throw themself off it.[247] Another CP describes there being a couple of occasions when they sat on the bridge over a railway line and was ready to jump before someone pulled them back.[248] Another CP describes having taken an overdose because they felt there was nothing left and they could not face the thought of being in misery and pain and disabled for the rest of their life.[249] One CP describes trying to find different ways of killing themselves and only stopping when they checked their insurance documents and realised that the insurer would not pay out to their family if they took their own life.[250]

39. The mental and psychological impact on the family members of those infected has been equally overwhelming and life altering. Our CPs have described loved ones developing severe Obsessive Compulsive Disorder ("**OCD**"),[251] sometimes as a result of learnt behaviour from their childhood when their parents were infected and they had to care for them;[252] one CP has self-harmed due to guilt that her brother passed away;[253] one CP developed an eating disorder[254] as a result of comfort eating to deal with their emotions;[255] some CPs have developed PTSD[256] GRO-D GRO-D .[257] A number of our CPs have also developed anxiety,[258] due to an inability to be more supportive[259] or due to the loss of both parents[260] or due to the concern over becoming infected such that even their home did not feel safe.[261] Anxiety can be so severe that medication is required to manage it.[262]

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[247] W1921 [ANON] §19, 24
[248] W2631 [ANON] §21
[249] W0072 §34
[250] W2638 §16
[251] W1941 §63, W2035 §29, 30, W3326 §24, W2013 §19
[252] W1941 §63, W2035 §29, 30
[253] W3915 §16
[254] W2959 [ANON] §12
[255] W2959 [ANON] §12
[256] GRO-D , W3326 §24
[257] GRO-D
[258] W2958 [ANON] §14, W2696 §13, 28, W2035 §29, 30, W1819 [ANON] §36, W2824 §16
[259] W2958 [ANON] §14
[260] W0709 §49
[261] W2035 §29, 30
[262] W1819 [ANON] §36

40. Finally, a number of affected relatives also describe suffering with depression.[263] This has included feelings that life is not as good as it should have been,[264] or that life is consumed with just trying to survive.[265] In some cases, this was too much and those loved ones attempted to take, and in one case did take,[266] their own lives.[267]

Emotional impact

41. One CP commented that the list of physical and psychological symptoms does not do justice to the pain, fear and confusion of living life with an infection.[268]

42. One of the most prominent emotional side-effects is a constant state of worry and fear. For some this was an intense fear and paranoia that they had unknowingly infected someone else with the disease, particularly family members who cared for them.[269] This worry extended to individuals who had donated blood in the interim years between infection and diagnosis.[270] People were left in a constant state of anxiety,[271] which was heightened for one CP during menstruation.[272] This worry and fear was also felt by family members faced with the conflicting emotions of wanting to care for their loved ones but also being anxious not to contract the infection themselves.[273]

43. For others, the greatest source of worry was a fear that they were going to die, like a death sentence[274] or a ticking time bomb[275] was hanging over them. This caused further anxiety about the impact of their death on their family,[276] particularly for

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[263] W1953 §42, W2828 §22-23, W2959 [ANON] §9 and 11, W2854 [ANON] §15, W2696 §13, 28, W2697 [ANON] §9, W2698 [ANON] §25, W2035 §29, 30, W2872 §31, W2013 §23, 29, W2824 §16, W3326 §25-26, W2004 [ANON] §43

[264] W2959 [ANON] §9 and 11

[265] W2035 §29, 30

[266] W1953 §43

[267] W1821 §45, W3326 §25-26, W1886 [ANON] §37

[268] W1935 §20

[269] GRO-D W1974 [ANON] §34, W2028 §15, W0671 [ANON] §32, W2641 §33, W2693 §22, GRO-D W1972 §21, W1995 §30, GRO-D

[270] W2028 §15 GRO-D

[271]

[272] GRO-D

[273] W3323 [ANON] §31, 33

[274] W3697 §28, W1999 §32-34, W1907 [ANON] §22, GRO-D W2012 §22, W2002 [ANON] §17, W1925 [ANON] §17, W2028 §15, W1857 [ANON] §15, W1972 §21

[275] W1947 [ANON] §68

[276] W1906 §20, W1892 [ANON] §17, W1972 §21

individuals who were single mothers[277] or whose family had limited financial resources.[278] One CP describes how the only thing keeping him going in face of the fear is not wanting to leave the planet without being sure that there will be adequate compensation for his family.[279] One CP described how every day they would wake up with a fear of dying,[280] other CPs describe how they would be frightened to go to sleep as they feared they may not wake up in the morning.[281] The family members of those individuals describe how they would then stay up all night, checking that their loved one was breathing, waiting to hear the "*sweet noise*" of their snoring as confirmation that they were still alive.[282] More generally, the knock-on effect on family members has meant loved ones also carrying an intense fear of death.[283] Even those who have successfully cleared the virus live with the constant fear and worry of the virus returning.[284]

44. Another emotional impact is the sense of guilt. Guilt of potentially and unknowingly having infected someone else,[285] guilt of children whose mothers were infected during or after giving birth to them,[286] guilt at living when an infected family member has died,[287] guilt at having been treated successful when for others treatment has failed.[288] One CP describes a particularly traumatic memory of the moment she realised she was one of the "*lucky ones*":

> "*[I]t was around 1995 when I had been going to the hospital for several years and knew the staff nurse quite well. However, something was weighing heavy on my mind at the time and I asked [the nurse] a question: " I have been coming here on the same day for years now and every time I am here I never see any familiar faces.*

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[277] W1906 §20, W0065 §21
[278] W1892 [ANON] §17, W0065 §21
[279] W1997 §54
[280] W1907 [ANON] §22
[281] GRO-D ; W2019 §28, W1972 §21
[282] W2019 §28, W2006 [ANON] §10
[283] W3697 §39, W1950 §34-36, W2052 §32
[284] W2000 §49, W1999 §32-34, W1994 §35, W2959 [ANON] §19, W3324 [ANON] §19, W2055 [ANON] §27, 33, W1838 §43, W2853 [ANON] §12, W3916 §35, W1878 §23
[285] W2000 §28, W1822 [ANON] §17, W1826 [ANON] §20
[286] W1882 §20, W2000 §28, W1926 §6, GRO-D
[287] W2819 §47-48
[288] W2036 §31-33

Why?", her reply was "you don't know do you? Everyone is dying apart from you". That statement still haunts me to this day, all those people who have attended the clinic for all those years whilst I was there are no longer with us and everyone who has died since. You cannot imagine how that hurts and how hard it is to live with such pain and torture. Yes there has been a lot of physical pain over the years but the mental torture has been the more difficult to contend with and continues to be."[289]

45. Our CPs also describe feeling extremely angry, outraged and furious at having been infected, the impact it has had on them and their loved one's life, the pain it has caused, the lost years, and how, in some cases, it caused them to have their life cut short.[290] GRO-D GRO-D GRO-D.[291] One CP commented that the thing that makes them most angry is the injustice of it,[292] while another stated that they will not give up until every IAP is given an apology.[293]

46. The multiplicity of emotional impact is palpable throughout our CPs' witness evidence:

    a. Our CPs describe experiencing anxiety when waiting to receive the result of their own tests and scans[294] or the result of family members' tests.[295]

    b. Our CPs describe losing faith in the medical system and a fear of any medical treatment.[296]

    c. Our CPs describe being so traumatised by their experience of the infection that they are unable to talk about it and suffer flashbacks and panic attacks.[297]

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[289] W2036 §31-33
[290] W2707 [ANON] §40, W1879 §34, W2644 §15, W2043 §25, W1972 §21, W1892 [ANON] §17, W1826 [ANON] §20, GRO-D, W1838 §39, W1950 §34-36
[291] GRO-D
[292] W1838 §39
[293] W1926 §31
[294] W1972 [ANON] §28
[295] W0394 §16, W1972 §21
[296] W2013 §19, W2643 [ANON] §34-35
[297] W2000 §33, W2635 §13, W1921 [ANON] §46, W1892 [ANON] §17

d. Our CPs describe the intense fear of the unknown and not knowing how or when the infection may impact them.[298]

e. Our CPs describe their worry that the Government may take away their compensation payments, which they would struggle to live without.[299]

f. Our CPs describe being left feeling numb, without emotion and unable to feel anything due to a life spent taking anti-depressants.[300]

g. Our CPs describe having unpredictable emotional breakdowns – at the local shops, or while driving – where they would start uncontrollably crying, feeling completely sad, empty and worthless.[301]

h. Our CPs describe having no enthusiasm or energy for life, experiencing a total crisis of confidence, like they had lost a part of themselves which they are unable to find again.[302] As one CP described it, they are a "*shadow of their former self*".[303]

47. The consequential emotional effect on family members watching their loved ones suffer is described as tough,[304] mental torture,[305] a constant worry,[306] deeply shocking,[307] causing them to completely shut down[308] and be unable to speak.[309] As one CP put it:

> "*The most difficult thing is watching somebody you love falling apart day to day. I can only describe it as like watching an old car with bits progressively breaking and falling off it. […] It is like there is a paleness, or greyness, to every day. But you*

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[298] GRO-D

[299] W1999 §32-34

[300] W2692 §32, 24

[301] W1992, W1943 §18, 21

[302] W1982 §20, W1910 §22, W1885 §25, 43, W1966 §13 W1892 [ANON] §26, W1862 §16, W3693 §56, W1857 [ANON] §17, W2693 §17, W2959 [ANON] §24, W1858, W1882 §30

[303] W3693 §56

[304] W2958 [ANON] §14

[305] W2691 §19

[306] W2696 §20

[307] W2870 §21

[308] W3915 §19-20

[309] W3915 §21, 23

must try to keep your loved one cheerful and keep them going. All you can do if you feel overwhelmed is go out into the nearest field and shout."[310]

Quality of life

48. Our CPs describe how being infected or affected has a significant and devastating impact on their quality of life.[311] They describe having to learn to survive[312] with the constant threat always on their mind,[313] causing every daily task to become like a mountain to overcome;[314] being forced to give up their daily routine,[315] and living life year by year, with one foot in the grave,[316] leaving them feeling that their life has been unlived[317] and being unable to remember what it is like to feel normal.[318] This is particularly so for those who were infected when they were young, who have lived their whole life with the impact of the virus;[319] for those individuals, the infection can render their life feeling very lonely and isolating[320] and can affect their life ambitions, causing them to give up their hopes and dreams.[321] Others describe that the constant hospital appointments are worst, taking over their entire life.[322]

49. As a result of the physical and mental impact of infection, many of our CPs had to give up activities and parts of their lives which gave them the most joy and happiness, such as going on holiday, playing sport and socialising.[323] The infection impacted every aspect of people's lives; some people were forced to have a very strict diet,[324] others

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[310] W1867 §70-72
[311] W1829 §24, W0580 [ANON] §38, W2602 §41, W0031 [ANON] §5.10, W1932 §60
[312] W1838 §40
[313] W3713 §31, W1875 §20, W2028 §17
[314] W1935 §20, W1814 §25, W2602 §41
[315] W2039 §37
[316] W1862 §17
[317] W1935 §51
[318] W0622 §19
[319] W1921 [ANON] §30
[320] GRO-D
[321] W0065 §48
[322] W1850 §35
[323] W2869 §8, W1882 §30, W1901 §47, W0709 §29, W2001 §11, W1987 [ANON] §39, W1820 [ANON] §24, W1972 §28, W2690 [ANON] §27, GRO-D W1855 §68, W3916 §34, W1923 §8, W1876 §25, W1879 §52, W0031 [ANON] §5.8, W1900 [ANON] §36, W1902 [ANON] §26, GRO-D W1905 §67, W1919 [ANON] §30, GRO-D
[324] W2690 [ANON] §28

had to rely on sleeping tablets to get to sleep,[325] others needed to sleep all the time,[326] and some experienced extreme weight gain.[327] Our CPs describe having to "*re-learn*" how to live, how to do even basic tasks such as writing, driving and walking.[328] Our CPs lost their social life[329] and independence,[330] making them feel as if their life ended when they were infected[331] and they simply existed from one day to another.[332] One CP who was successfully treated commented that having returned to full health they fully understood the impact the infection had on their life; not only being able to exercise, eat well, enjoy a glass of wine, but feeling clean and part of the human race again.[333]

50. It is not only those individuals who are infected whose quality of life is impacted; it is also their loved ones. For example, having to attend hospital appointments often far away from home,[334] struggling to find meals to cook for a loved one that they would eat,[335] being unable to ever afford to buy something at full price, or have a haircut, or buy new clothes,[336] having to relocate their home to be closer to the loved one,[337] having to be careful about sharing glasses or utensils,[338] being unable to live their own life due to anxiety and fear over their loved ones' health and wellbeing.[339]

Relationship with and impact on family

51. For a number of our CPs, their infection, and in some cases subsequent death, was described as being catastrophic, devastating and overwhelming for their family

[325] W1857 [ANON] §27
[326] W1820 [ANON] §25, W1902 [ANON] §25
[327] W0031 [ANON] §5.7
[328] W2709 §18, W0709 §29, W2012 §72
[329] GRO-D W0709 §29, W1814 §25, W2602 §41, W1902 [ANON] §2-3, GRO-D
[330] GRO-D W1901 §47, W0709 §29, W1829 §45, W0072 §51, W1902 [ANON] §2-3, W9132 §66, W1932 §60, GRO-D
[331] W1842 §25, W1820 [ANON] §24, W1945 §49, GRO-D
[332] W0031 [ANON] §5.6
[333] W2042 §39
[334] W2691 §10
[335] W2006 [ANON] §19
[336] W1858
[337] W2958 [ANON] §13
[338] W2958 [ANON] §11
[339] W2013 §24

unit.[340] Our CPs describe it being particularly upsetting and devastating to see their loved one suffer and lose their zest for life.[341] Many felt they were unable to be the husband, wife, dad, mum, brother, sister, son, daughter they could have and would like to have been had they not been infected.[342] In particular, the extreme fatigue frequently prevented the nurturing of familial relationships as so much time was spent asleep and in bed.[343] Many experienced intense grief and frustration at having missed important moments in family members' lives such as birthdays, anniversaries, and graduations.[344] The symptoms and effects of the infection also could create distance, disruption and arguments in the family[345] and in some cases changed family relationships irreparably.[346] The constant concern and anxiety of avoiding spreading the infection, particularly to young children, often meant far more physical distance than would be usual.[347] On an emotional level, the infection made it hard for people to be close to family when everything around them felt so impermanent.[348] Further, family members would have to take on caring responsibilities, helping loved ones to undertake personal care or daily living tasks.[349] This did create, in some cases, an unequal dynamic, where the infected person is unable to be there for loved ones when they need support and care because of having to deal with their own illness.[350] In short, the infection shaped and influenced all aspects of family life.[351]

Relationship with and impact on partner

52. Our CPs' relationships with their partners were impacted by the infection in a myriad number of ways. Diagnosis impacted some relationships where the cause of the

[340] W3915 §24, W2052 §15, W1941 §69, GRO-D W2828 §25, W2590 [ANON] §24, W3693 §60, W1953 §37, W3592 §20
[341] W1953 §30, 32, W1858, W1905 §66
[342] W1921 [ANON] §47, W1963 §36, W1834 §38, W1967 [ANON] §23
[343] W1868 §16, W1879 §64, W2960 [ANON] §14
[344] W1838 §49, W0622 §25, W1829 §33
[345] W1941 §69, W1877 §27, W2043 §40, W0072 §54, W1953 §35, W2696 §32, W1928 §51, W1950 §38, W1962 §56
[346] W0622 §19, W2862 §15
[347] W3713 §38, W2707 [ANON] §38, W2059 [ANON] §37, W2019 §40, W2629 [ANON] §14, W1857 [ANON] §35, W2853 [ANON] §14
[348] W1862 §23
[349] W1966 §27
[350] W1932 §71, W2690 [ANON] §36
[351] W2960 [ANON] §21

infection was not initially attributed to blood transfusion, leading some partners to suspect their loved one had been unfaithful.[352] For some CPs, being diagnosed meant they were no longer able, or no longer felt able, to have children,[353] because they did not want to have children if there was a chance they could contract the infection[354] or because they were unable to have safe sex with their partner.[355]

53. A number of our CPs comment that after they were diagnosed their sexual relationship with their partner ended.[356] In some cases, this was because their libido was affected,[357] in other cases it is due to the symptoms of the virus which prevented couples sleeping in the same bed at night[358] or meant our CPs were too fatigued or unwell;[359] in many cases this was due to a concern about passing on the infection to their loved one[360] or because they felt "*dirty*".[361] This was particularly difficult for couples who were recently married when diagnosed.[362] The consequence is that for some couples their relationship changed from one of husband and wife to one of brother and sister[363] or best friends;[364] for other couples this sadly led to the breakdown of their relationship.[365]

54. In some cases, the loss of a sexual relationship between partners was coupled with a change in the dynamic of their relationship from equal partners to carer and patient.[366] Some individuals found this particularly difficult to accept, particularly

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[352] GRO-D, W2590 [ANON] §25
[353] GRO-D, W1951 §48, W1822 [ANON] §24, W1879 §65, W1868 §27, W1974 [ANON] §37
[354] GRO-D, W1879 §65, W1868 §27, W1974 [ANON] §37
[355] W1951 §48
[356] W1947 [ANON] §56, W1967 [ANON] §23, W1977 §25, W2019 §39, W2644 §18, W1997 §40, W2052 §15, W2004 [ANON] §20, W2638 §23, W2631 [ANON] §28, W1970 §31, W2043 §37, GRO-D, W1821 §34, W0394 §21, W2872 §25, W1954 §24, GRO-D, W1934 §26, W1822 [ANON] §24, W3693 §58, W2692 §50, W1890 §15, W1891 §20, W2631 [ANON] §28, W2862 §16, W1950 §30, W1962 §56, W2694 §30
[357] W1947 [ANON] §56, W3693 §58, W2692 §50, W2694 §30
[358] W1997 §40, W0394 §21
[359] W2043 §37, W1891 §20, W2862 §16
[360] W2638 §23, W1970 §31, W2872 §25, GRO-D, W1934 §26, W1822 [ANON] §24, W1891 §20, W2867 §18, 23
[361] W1890 §15
[362] W1954 §24
[363] W2052 §15
[364] W1821 §34
[365] W2631 [ANON] §28
[366] W1967 [ANON] §23, W1894 §32, W2689 §21, GRO-D, GRO-D, W1951 §48, W1967 [ANON] §28, W1998 §41, W1965 §11-13, W1934 §58, 62, W1892 [ANON] §30, W1900 [ANON] §35, W1923 §27, W1997 §56, W1882 §32, W2028 §41, W1981 §9, W2026 [ANON] §35, W1832 §29, W1980 §18

some men who perceived this to be emasculating.[367] The caring responsibilities included attending hospital appointments,[368] providing constant 24 hour a day care, seven days a week,[369] and doing all the childcare and housework, like cooking cleaning and washing.[370] One CP powerfully describes the process of becoming her partner's carer:

> *"Becoming a full-time carer was a slow process. You start off accompanying your husband when he visits medical staff. Then you realise there are times when he simply cannot take in the latest news about his condition so you step in on his behalf. You start to make notes, you come home and type them up and refer back to them at the next visit. Then you are the one who is remembering details neither your husband nor the medical staff can recall. People start to rely on you and relay information to you so you can discuss it with your husband when he is ready. You become the expert on your husband's condition, prompting him to go to the doctor as you sense a change in his condition or making sure he mentions something important when visiting consultants. You become the one breaking bad news to your children, to friends and extended family after your husband has received another setback which he doesn't want to talk about. You are the only witness seeing the impact of another drug trial fail, noticing more symptoms emerge and helplessly observing your husband's continued deterioration. Physical care for [him] began with me driving him to appointments (I am not the most confident driver and this was a constant anxiety for me). As his condition deteriorated I would wash and dress him as well as treat sores and other adverse side effects from heavy (often experimental) drugs he had to take during drug trials. I would even have to lift him at times which often left me sore and injured as my back didn't appreciate the pressure. I was constantly making sure he was warm, fed (even at the times when he had no appetite) and that he had everything to hand."*[371]

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[367] W2689 §21
[368] GRO-D W1998 §41
[369] W1967 [ANON] §28, W1998 §41
[370] W2820 [ANON] §31, W3710 §30
[371] W1965 §11-13

55. Many of our CPs describe that one of the most challenging impacts of the infection upon their relationship with their partner was the way in which it caused people to experience personality changes and mood swings (sometimes associated with treatment for HCV).[372] This would cause those infected to lash out at their partner with force,[373] to become impatient, irritated and argumentative,[374] to be angry, combative and controlling,[375] to display emotions that changed rapidly like a yoyo,[376] such that they became very difficult to live with.[377] The change was so extreme in some cases, that our CPs have commented that their loved one was not the same person they married and loved.[378] In one case, the extent of the mood swings caused a partner to commit suicide before they were diagnosed, and therefore without ever knowing that the reason for the behaviour was the infection.[379] In another case, the stress and impact of the mood swings caused the partner's blood sugar to rise leading to a worsening in their diabetic retinopathy and a significant loss of their eyesight.[380]

GRO-D

GRO-D [381] GRO-D [382]

56. In a large number of cases, the impact of the infection on a person's partner became so intolerable that it led to breakdowns in relationships and marriages.[383] As one CP describes:

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[372] W1867 §75, W2707 [ANON] §38, 39, W2703 §62, W1819 [ANON] §24, W2000 §55, W2036 §29, GRO-D §18, W1970 §31, W1919 [ANON] §33, W1954 §24, GRO-D W2042 §42, W2692 §36, W2062 §39, W2631 [ANON] §28, W1878 §30, W1923 §80, W1932 §61, W1998 §41, W1855 §48, W2631 [ANON] §28, W1858, W2712 [ANON] §16, W1923 §27, W2713 §15, W1817 §25, W1848 §28, W1950 §30, W1821 §45, GRO-D W2694 §34

[373] W1867 §75

[374] W2707 [ANON] §38, 39, W2703 §62, W1919 [ANON] §33, W1858

[375] GRO-D, W2692 §36, W1998 §41, W1858

[376] W1954 §24

[377] W2042 §42, GRO-D GRO-D

[378] W2707 [ANON] §38, 39, W2703 §62, W2062 §39

[379] W1819 [ANON] §24

[380] W2000 §55

[381] GRO-D

[382] GRO-D

[383] W1883 §19, W2638 §23, W2013 §20, W1995 §37, W2036 §29, W1970 §31, W1919 [ANON] §33, W1934 §58, 62, W1899 [ANON] §36, 38, W1913 §25, W1820 [ANON] §27, W0622 §33, W1855 §48, W2590 [ANON] §2, W3692 §43, W0072 §30, W2062 §39, W2631 [ANON] §28, W1888 §35, W5209 §30, W1972 §32, W2001 §12

"One day my husband got up, told me he loved me, kissed me goodbye and went to work. He never came back home after that day. I never saw him again except in court when he sued for divorce. He had been having an affair throughout that year unbeknown to me and that day he left for somebody else. He said the treatment and the drug trial had been too much for him, that he had turned into a carer and not a husband, that he had cleaned up my vomit and nursed me, and that he no longer saw me as a lover and a wife but as a disease. [..] Until that time I had managed to deal with it all, but I found I couldn't deal with the loss of my marriage. I felt as if I had gone through it all for nothing because I lost the person who had meant the most to me in the world apart from my children. The loss was incalculable and that tipped me over the edge. I fell into a complete depression and had a nervous breakdown."[384]

57. For some people, the impact of the infection was such that they chose not to enter into any new relationships or attempt to find a partner.[385] This is for a number of reasons: because they did not want to tell a new partner that they have an infection which will kill them,[386] or because of previous relationship breakdowns which made them frightened of new relationships,[387] or because they did not wish to explain the infection and answer people's questions,[388] or because they were nervous that the person would think less of them, would not accept them or would tell others,[389] or because they had difficulties with personal contact because of the infection.[390]

58. Facing grief and premature death has been the experience of many of our CPs.[391] As one CP recalls:

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[384] W1934 §58, 62

[385] W1987 [ANON] §41, W1972 §32, W1925 [ANON] §24, W1902 [ANON] §38, W1913 §25, GRO-D, W1818 §34, W1862 §24, W1906 §36, W2009 §44, W5209 §30, GRO-D GRO-D

[386] W1987 [ANON] §41, W1913 §25, GRO-D

[387] W1972 §32, W5209 §30

[388] W1925 [ANON] §24, W1943 §34

[389] W1902 [ANON] §38, W1906 §36, W2009 §44

[390] W1862 §24

[391] W1846 §2, W3693 §11, W3697 §32, W3326 §15, W1848 §30, W2689 §24, W2004 [ANON] §28, W2709 §27, W2703 §57, W1981 §18, W2643 [ANON] §44-46, W2643 [ANON] §44-46, W1817 §31, W3914 §32, W3710 §27, W1974 [ANON] §44, E W3920 §8, W3918 §6-7, GRO-D W1966 §43, GRO-D W2039 §39, GRO-D §6, W2707 [ANON] §29, W2011 [ANON] §9, W1850 §46, 47, W2819 §3940, W2057 §15, 19, GRO-D

"It became apparent the following year that [his] condition was deteriorating quickly. We booked our wedding only three days before [he] passed away and bought matching wedding rings two days before. I have a vague memory of the nursing staff at the hospital offering to bring the chaplain to conduct a marriage blessing at [his] bedside during the evening of 29 June 2008. I felt this was unfair as [he] was not able to communicate. A week later I had to go back to the shop to collect my resized ring and the staff said 'hope you have a lovely day'. I feel totally cheated to have lost the man I loved who was only 55 years of age when he died. We should have had years together and he would have loved the fact his son and daughter would have given him another two granddaughters to adore."[392]

Relationship with and impact on parents

59. A number of our CPs describe that when their parents found out about their diagnosis they were devastated,[393] and they worried a lot,[394] particularly in circumstances where they did not fully understand the diagnosis and what it meant.[395] Parents felt guilty, distraught and angry that it stopped their children achieving their potential and ambitions[396] or preventing them from having "*normal*" life experiences.[397] In some cases, children were alienated by their parents, either because they considered that the virus had come from activity which they did not approve of[398] or because they were disgusted by the condition and worried about the family reputation.[399] In other cases, parents blamed themselves for their children's infection,[400] particularly where the infection was passed onto the child in childbirth.[401]

W3326 §20, 21, W2033 §1, W2028 §48-49, W2019 §12, W1917 §21, W2869 §18, W0709 §43, 45, W1965 §15-17, GRO-D ; W1867 §50, W1941 §51, W1883 §22, W1832 §32, GRO-D ; W2710 §23, W1980 §20

[392] W1848 §15

[393] W1821 §48, W1913 §35, W3916 §44, W2698 [ANON] §24, W2019 §44

[394] W1963 §36, W1822 [ANON] §23, W1988 §3, W2702 §32, W2013 §22, W2698 [ANON] §24, W2019 §44

[395] W2702 §32

[396] W2013 §22

[397] W2697 [ANON] §10, 12

[398] W1988 §32

[399] W1951 §34

[400] W1925 [ANON] §32, W2000 §56

[401] W2000 §56

60. Parents also became carers for their adult children,[402] often when parents were becoming elderly and infirm.[403] In some cases, this also meant parents had to continue working longer to support themselves and their adult child[404] and had to give up their own social life.[405] For parents who lost their child due to the infection they describe feeling devastated,[406] *"broken"*[407] and unable to recover from the trauma.[408]

Relationship with and impact on children

61. A number of our CPs describe that their relationship with their children suffered as a result their infection, as they were too tired or ill to spend quality time with them and to participate in the everyday events which make up parenting, such as attending school functions, watching sports matches, or engaging in leisure activities, such as the park, family daytrips or going on holiday.[409] This meant children lost out on the care and attention they deserved, physically and emotionally.[410] As one CP put it, their children lost out on a *"normal"* life;[411] the child did not have the childhood their parents would have liked[412] and the parent missed out on their children growing up.[413] Frequently, children's lives were filled with doctors' appointments, inpatient stays and visits from social workers.[414] In some cases, children were excluded from social activities by other children due to the stigma associated with their parent's infection.[415] Further, children also missed out on activities because the family's general standard of living was affected by the inability of at least one parent to

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[402] W1975 §32, W3916 §44, W1889 [ANON] §72, W1902 [ANON] §46, W2698 [ANON] §4
[403] W3916 §44
[404] W1889 [ANON] §72
[405] W2697 [ANON] §9, W2698 [ANON] §25, 26
[406] GRO-D, W3920 §17, W2004 [ANON] §53, W1823 §45, 46
[407] W2004 [ANON] §53
[408] W3920 §17
[409] W1988 §36, W1882 §35, 37, W1834 §25, W1868 §26, W1910 §23, W2637 §32, W1921 [ANON] §47, W1921 [ANON] §47, W1938 §46, 47, W2001 §15, W1992 §38, W1819 [ANON] §26, W1967 [ANON] §29, W2702 §33, W1998 §44, W1992, W1992, W2043 §37, W1826 [ANON] §25, W0622 §31, W1975 §28, W2034 §20, W2645 §38, GRO-D
[410] W1967 [ANON] §29
[411] W1882 §35, 37
[412] W1992 §38
[413] W1910 §23, W1953 §35
[414] W0622 §28 – 9, W1826 [ANON] §25
[415] W3713 §36, W2867 §17, 27

work.[416] This meant many parents felt unable to give their children what they wanted to, and children missed out on things like school trips and holidays.[417]

62. Some children became young carers, with all the responsibilities that this entailed, including caring for their parents, managing their health issues, calling ambulances and speaking to doctors, or helping out at home, doing the washing, cleaning and cooking.[418] Caring for a parent also causes the dynamic of a relationship to change, with the child becoming more like a parent themselves.[419] In one case, a child became his mother's advocate and was given the responsibility of making the extremely difficult decision as whether to agree to amputate his mum's leg to save her life.[420] In other cases, children may not have had to care for their parent, but for their siblings in the absence of their parent.[421]

63. This includes instances of having to care for the infected parent and the widowed parent after the loss of their partner.[422] When adults, they often had to continue to provide help and support including paying for care[423] or looking after them when they suffer with severe mental health issues.[424] This is mentally and emotionally draining;[425] it would require children to put their own life, career, and ambitions on hold[426] and prioritise their family over other relationships and friends.[427] For example, one CP describes that they did not have any romantic relationship until they were 22 because they equated sex with death.[428]

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[416] W1988 §36, W0072 §50, W1900 [ANON] §39, W2645 §43, W1910 §37, W2012 §73, W1111 §32, W0065 §45
[417] W0072 §50, W1900 [ANON] §39, W2645 §43, W1910 §37, W2012 §73, W1111 §32, W0065 §45
[418] W1994 §30, W1928 §49, W1925 [ANON] §22, 31, W1871 [ANON] §37, W0709 §46-47, W2634 §35, W1988 §36, W1834 §41, W2012 §75, W2035 §18, W2035 §27, 28, W2035 §32, W1819 [ANON] §31, W1877 §26, W2028 §41, W1981 §9, W2635 §24-28, W2991 §61, W1966 §13, W2635 §24-28, W1832 §29, GRO-D
[419] W2634 §35, W0580 [ANON] §41
[420] W2035 §27, 28
[421] W1954 §26, W2991 §60, W1817 §22
[422] W1814 §26, W2643 [ANON] §48, W1981 §19
[423] W0709 §35,
[424] W2643 [ANON] §47, W1981 §19
[425] W1928 §4
[426] W1925 [ANON] §31, W1814 §26, W2991 §61, W1926 §29, W2643 [ANON] §48, W1966 §13, GRO-D GRO-D
[427] W2035 §39, GRO-D
[428] W2643 [ANON] §48

64. Many parents' relationships with their children were affected by an overwhelming fear of what may happen to their child if they died, particularly if they were a single parent and the child was an only child.[429] GRO-D GRO-D GRO-D .[430] In other cases, parents worried about the risk of passing on the infection to their children.[431] This resulted in children being "*wrapped in cotton wool*", and parents and children feeling worried about kissing, cuddling, or touching.[432] Some parents would constantly watch their children to ensure they did not touch their razor or toothbrushes[433] or bought new towels, cups and cutlery after they were diagnosed.[434]

65. A foreseeable consequence of the changing dynamics of the parent/child relationship is that some of their children started rebelling or "*going off the rails*", behaving in ways which severely affected their life chances: skipping school, smoking, getting into debt, drinking, using drugs, getting in trouble with the police, self-harming, suffering mental breakdowns, becoming homeless, falling pregnant at a young age, being unable to get a job and over-eating.[435] One CP describes how her son tried to take his own life because he felt his quality of life was so poor as a result of his mother's infection.[436]

66. Some of our CPs lost their parents in childhood,[437] which in some cases lead to them growing up in the care of the state, with all the difficulties, problems and emotional trauma that this can cause.[438] Those who were young children when their parent was ill described finding it scary and confusing to witness the debilitating effect of the virus, especially if their parent suffered mood swings which they could not

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[429] W1999 §39, W1111 §21, W1820 [ANON] §27, W2853 [ANON] §23, W1857 [ANON] §35, W1859, GRO-D
[430] GRO-D
[431] W1988 §36, W1907 [ANON] §38, W1938 §46, 47, GRO-D W1947 [ANON] §57, W1857 [ANON] §16, W1876 §24, W2012 §20, W2639 §22, W2867 §17, 27
[432] W1907 [ANON] §38, W1938 §46, 47, GRO-D W1947 [ANON] §57, W1857 [ANON] §16, W1876 §24, W2959 [ANON] §23, W1846 §26
[433] W1876 §24
[434] W2012 §20
[435] W1925 [ANON] §31, W3915 §24, W1111 §35, W1826 [ANON] §35, W1834 §41, W2590 [ANON] §27, W1919 [ANON] §32, 38, W1919 [ANON] §39, GRO-D
[436] W1921 [ANON] §52, W2054 §24, W1817 §32, W1819 [ANON] §31, W1950 §45, W1962 §63, W1975 §33
[437] W1814 §26, W1825 §31, W1846 §24, W2057 §26, W1950 §45, W1832 §37
[438] W1824 §19-21, W2870 §22

understand.[439] Other children suffered the trauma of having to watch their parent's deterioration[440] and, in the worst cases, witnessing their death, often at a young age.[441] In one case, to shield her child from seeing her father in intensive care, a mother asked her child to make a tape telling her father that she loved him so that it could be played to him in the hope that it would help him wake up and recover.[442] Losing a parent when a child has had a number of consequences which are varied in nature for our CPs: it can lead to constant anxiety at the inevitability of death, it leads to sadness at parents not being there to witness life events, a sense of powerlessness at being unable to stop death or suffering, and a deep sense of loss at losing the person who you could talk to, trust and rely on, and also mistrust of medics.[443] As one CP explains:

> *"The impact of my mum's death has overshadowed my life since the age of five. I have lived with the continuous frustration, hurt and anger, knowing that nobody has ever acknowledged that my mum died from being given a blood transfusion of contaminated blood. I have missed out on the right to have a relationship with my mum. Not having the support, guidance and love from my mum affects my life daily. From the very young age of five and a half years I lived the very difficult life of growing up in and out of the care system. I missed out on the chance of a happy childhood, having to take on the role of the motherly figure to my siblings."*[444]

67. The parent-child relationship was particularly difficult for mothers who were infected during childbirth and therefore suffered symptoms during the early months of their child's life.[445] This meant instead of the first few months of the child's life being filled with time to bond, it was spent enduring illness and treatment.[446] GRO-D

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[439] W1817 §25, W1825 §31, W2057 §26, W2628 §16, W1883 §29, W1874 §20, W1950 §41-44
[440] W2637 §35, W2713 §31
[441] W2634 §37, W2869 §13-14, GRO-D, W1882 §35, 37, W1981 §14
[442] W1981 §14
[443] W1817 §25, W1825 §31, W2057 §26, W2628 §16, W1883 §29, W1874 §20, W2011 [ANON] §18, W1877 §26, W1917 §13, W2707 [ANON] §43, 44, W2707 [ANON] §46, W1926 §32, W1941 §60-62, GRO-D, W2052 §13-14, W2643 [ANON] §48, W1968 [ANON] §23, W1975 §33, W2635 §14-15, W2635 §24-28, W2052 §13-14, GRO-D, W1962 §63
[444] W1824 §19-21
[445] W1988 §36, W2853 [ANON] §12, W1895 §24
[446] W1988 §36, W2853 [ANON] §12, W1895 §24

GRO-D

GRO-D [447] In some cases, where mothers were infected due to a transfusion given following childbirth, the parent-child relationship would be affected by the guilt and trauma the child felt, believing that if they had not been born their parent would not have become infected.[448]

68. Sometimes, the infection caused a permanent rupture to the parent/child relationship. One CP had to make the agonising decision to place their child in foster care as they were not well enough to look after them.[449] One CP had to give up guardianship of her step-granddaughter having previously fought to look after her, being advised that there was no guarantee she would survive to look after her throughout her childhood. One CP's son took his own life because of distress caused by his parent's illness.[450] One CP's child would not speak to them after their diagnosis.[451] One CP was forced to stop IVF treatment following their diagnosis and thus lost the chance to have children.[452] GRO-D

GRO-D

69. Finally, a number of our CPs made the decision not to have children because of not wanting to risk the child being born with the infection.[454] In some cases, this involved sterilisation or a vasectomy.[455] In other cases, our CPs were unable to have a baby because they were physically too unwell[456] or because they feared they could not afford to have more children given their inability to work.[457] A number of our CPs describe being deprived of the opportunity to have children as the hardest part of

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[447] GRO-D
[448] W2702 §33, W3693 §59, GRO-D W2637 §36, W2035 §32
[449] W0622 §27
[450] W2690 [ANON] §38, W1988 §37
[451] W2631 [ANON] §28
[452] GRO-D §18
[453] GRO-D
[454] W2000 §32, W1822 [ANON] §22, W2053 [ANON] §14, W1860 §38, W1923 §16, W2648 §6-7, W1990 §57, W1908 [ANON] §38, W1879 §66, W2696 §27, W1814 §26
[455] W1923 §16, W2696 §27
[456] W1876 §28
[457] W1814 §26

living with the infection.[458] Some of our CPs describe feeling guilty that they never gave their parents any grandchildren.[459] GRO-D

GRO-D

GRO-D.[460]

Relationship with and impact on grandchildren

70. As with relationships between parents and children, the relationship between grandparents and grandchildren was impacted by infection in that grandparents would feel guilty and disappointed at being unable to look after or play with grandchildren.[461] Often, if grandchildren were young, they would struggle to understand the illness and why their grandparent was too tired to play with them.[462] Many CPs also describe grandparents becoming paranoid about physically close contact with their grandchildren, preventing them from kissing or cuddling, because of the fear of infecting them.[463] For some, the hardest thing was to acknowledge that they may never get to meet their grandchildren.[464] In other cases, grandchildren took on caring responsibilities for their grandparents, such as taking them to hospital appointments, doing a food shop, buying walking aids, helping them with their tablets or putting cream on their legs.[465]

Relationship with and impact on siblings

71. Only a few of our CPs commented on the impact of their infection on their relationship with their sibling. However, one CP commented that her relationship with her sister greatly deteriorated and became fractious and strained as a result of the infection, because she felt guilty and helpless and found her sister's health difficulties very

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[458] W1822 [ANON] §22, W1860 §38
[459] W1822 [ANON] §23, W1990 §57
[460] GRO-D
[461] W1947 [ANON] §58, W2039 §33, W1990 §55, W2869 §10-11, W1987 [ANON] §40, W2009 §43, W1878 §32
[462] W2039 §33
[463] W1987 [ANON] §41, W1977 §25, W2638 §24, W1829 §42, W1834 §37, W1886 [ANON] §40, W2639 §21, W2034 §30, W1907 [ANON] §38, W2690 [ANON] §37, W1829 §42, GRO-D W1913 §27
[464] W2819 §45, W3323 [ANON] §27, W1874 §24, W2710 §32
[465] GRO-D, GRO-D, W1927 §10, W1901 §46

distressing.[466] Another CP commented that her life was affected by having to drive every evening after school to visit her brother in the hospital.[467] Another CP describes how her sibling's infection caused her to lose her faith in the medical profession.[468]

Relationship with and impact on friends/social life

72. A number of CPs describe how their infection impacted their relationship with friends. Some CPs chose not to tell their friends about their infection out of fear of how they may react or how it would affect their relationship;[469] however, this means there is a huge part of people's lives which their friends do not know about.[470] Many of those who did tell their friends sadly lost them because they stayed away out of fear that they may become infected, leaving people feeling isolated and abandoned at a very vulnerable time.[471] Other CPs lost friends due to being too unwell to socialise[472] and eventually no longer being invited to things.[473]

73. A significant number of our CPs describe how as a result of their infection their social life completely disappeared.[474] Often people who were previously very sociable and active[475] withdrew from life,[476] because they were too tired, anxious, depressed or ill to socialise,[477] or because they were too embarrassed due to the physical symptoms

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[466] W2062 §45
[467] W3697 §31
[468] W1823 §45, 46
[469] W2690 [ANON] §40, 42, GRO-D, W2629 [ANON] §41, W2590 [ANON] §31 - 32
[470] W2590 [ANON] §31 – 32, W2006 [ANON] §32 - 34
[471] W2638 §25, W3916 §41, W2005 §37, W2590 [ANON] §31 – 32, W2631 [ANON] §28, W1962 §62, W1934 §55, W1893 §27, W1858, GRO-D
[472] W1999 §30, W3916 §42, W1899 [ANON] §38
[473] W0622 §36, W1913 §26, W2006 [ANON] §32 - 34
[474] W1907 [ANON] §39, W1970 §32, W2028 §22, 44, W2703 §60, W1926 §29, W1975 §27, W2643 [ANON] §37, W1848 §28, W0394 §20, W3697 §26, W2001 §11, W2819 §43, W2634 §32, W1992, W1997 §46, W2062 §48, W2059 [ANON] §36, W2644 §18, W1988 §31, GRO-D, W2059 [ANON] §24, W1996 [ANON] §34, W3713 §34-35, W1945 §50, W2645 §37, W1921 [ANON] §47, W1972 §34, W1982 §22, W1954 §27, W3915 §14, W1908 [ANON] §38, W2701 §26, W2637 §40, W1986 §25, GRO-D, W1857 [ANON] §37, W3916 §42, W1860 §23, W2629 [ANON] §27, GRO-D, W2690 [ANON] §40 W2005 §37, W2055 [ANON] §29, W1838 §48, W2853 [ANON] §24, W2019 §41, W1860 §30, W1888 §30, W2689 §26, 27, W1868 §12, 25, W1871 [ANON] §38, W1885 §24, W1885 §34, W1886 [ANON] §41, W1890 §29, W1891 §23, W1892 [ANON] §31, W1894 §32, W1900 [ANON] §40, W1926 §32, W1950 §30, W1848 §29, W2696 §25, W2694 §31
[475] W1994 §37, W2703 §60, W3697 §26, W2001 §11, W2062 §48, W2059 [ANON] §24, W1945 §50, W1986 §25, W2005 §37, W2689 §26, 27, W1871 [ANON] §38, W1885 §24, W1892 [ANON] §31, W1848 §29, GRO-D, §24
[476] W2028 §22, 44, W2644 §18, W1988 §31, W2059 [ANON] §24, GRO-D, GRO-D
[477] W1994 §37, W2703 §60, W1975 §27, W1848 §28, W0394 §20, W3697 §26, W1992, W1997 §46, W2062 §48, W2059 [ANON] §36, GRO-D, W1996 [ANON] §34, W3713 §34-35, W1945 §50, W1954 §27, W2637 §40, W3916 §42, W1947 [ANON] §58, W3916 §32, W1888 §30, W2689 §26, 27, W1890 §29

of the infection,[478] or because it was impossible to plan ahead due to the effects of the infection being so unpredictable,[479] or because they were unable to travel long distances to visit friends,[480] or because they were worried about the prejudice or stigma they would face,[481] in some cases, even fearing they would face physical or verbal abuse.[482] Some became reclusive and lost all physical contact with the world around them.[483] For many of our CPs the association between socialising and alcohol created difficulties, particularly as British social occasions are replete with alcohol,[484] with people finding socialising more uncomfortable when they were unable to drink,[485] or being concerned about the impact of drinking on their health.[486]

Stigma and shame

74. Only two of our 300 CPs explicitly said they were not affected by any stigma.[487] The overwhelming number of our CPs describe how the stigma associated with HCV, HBV and HIV made them feel dirty,[488] ashamed,[489] guilty,[490] unclean,[491] like a sewer rat,[492] poisonous,[493] and like a leper.[494] For some of our CPs the stigma is the worst part of

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[478] W1926 §29, W1860 §23, W2019 §41, W1900 [ANON] §40
[479] W1111 §32, W1838 §48
[480] W1878 §33
[481] W2028 §44, W1945 §50, W1875 §17
[482] W2643 [ANON] §37
[483] W2643 [ANON] §37, W2634 §32, W1862 §19, W2043 §34, W2059 [ANON] §36
[484] W1848 §28, W2819 §43, W1848 §28, W2629 [ANON] §27, W2853 [ANON] §24, W1875 §17, W1868 §12, 25, W1871 [ANON] §38, W2696 §25, W1832 §15, GRO-D
[485] W2819 §43, W1848 §28, W2629 [ANON] §27, W2853 [ANON] §24, W1868 §12, 25, W148 §29, W2696 §25, W1832 §15, GRO-D
[486] W1848 §28, GRO-D, W1875 §17 W1868 §12, 25, GRO-D
[487] GRO-D, W1838 §46
[488] W3103 §38, W1834 §37, W2009 §44, W1890 §15, W1892 [ANON] §26, W1919 [ANON] §34, W1954 §17, W1963 §10, W2644 §14, W0394 §16, W1901 §42, W2707 [ANON] §42, W0072 §53, W3916 §13, W1857 [ANON] §15, W1862 §20, W0671 [ANON] §29, W1888 §32, W2012 §15, W1890 §29, W0031 [ANON] §5.8, 5.9, W2634 §36, W1991 §34, W2707 [ANON] §42, W1848 §30, W1991 §20, W1919 [ANON] §29, W1954 §28, W2059 [ANON] §44, W1963 §22, W1932 §73, W1902 [ANON] §42, W0031 [ANON] §5.2, 5.11, W1905 §26, GRO-D, GRO-D GRO-D
[489] W1818 §35, W1859, W0031 [ANON] §5.8, 5.9, W3325 §26, W1893 §27, GRO-D, GRO-D
[490] W2690 [ANON] §27
[491] W1859, W0671 [ANON] §29, W2012 §15, W3710 §33, W1991 §34, W1925 [ANON] §25, W0031 [ANON] §5.2, 5.11
[492] W3712 §26
[493] W1871 [ANON] §24
[494] W1855 §49, W1910 §31, W1935 §13, W3713 §27, W1954 §12, W0031 [ANON] §5.8, 5.9, W1960 §36, W1822 [ANON] §24, W3713 §27, W2819 §8, W1877 §47, W1928 §42, W1932 §16, W1907 [ANON] §22, W2019 §42, W1871 [ANON] §35, W1893 §26, W1922 [ANON] §45, W0031 [ANON] §5.2, 5.11

the infection, whether it is perceived or real,[495] making them feel as if they have done the worst thing and do not have a right to exist.[496] Our CPs describe GRO-D GRO-D,[497] with very few people expressing any sympathy or offering to help them after their diagnosis.[498] This was felt particularly strongly by our CPs from minoritised ethnic groups, whose experience reflected those who gave live evidence to the Inquiry on this issue.[499]

75. Our CPs describe how the stigma manifested itself in a number of ways. One of the most prominent ways was through an (often yellow or red) sticker being placed on blood samples or medical notes saying, "*danger of infection*" or "*contaminated blood*" or "*hazardous*" with a warning sign or an image of a "*skull and cross bone*".[500] In some cases, this remained even after the person had been successfully treated.[501] These stickers were visible to everyone which CPs describe finding mortifying, making them feel dreadful and disgusting, and like a plague victim.[502] This was particularly difficult for those who lived in small areas as it meant everyone found out they were infected;[503] one CP describes local people crossing to the other side of the street when they saw him, banning him from the local children's nursery and sending hateful and threatening letters in the post.[504]

76. A number of our CPs state that they were explicitly advised by their GP or doctor not to tell anyone about their infected status because of the stigma attached to it which put pressure on people to hide it from friends and family; this meant the infection becomes a burden and a family secret and leads to a heightened fear and anxiety of people finding out.[505] In other cases, individuals themselves decided not to tell their

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[495] W1894 §19, 30
[496] W2643 [ANON] §40
[497] GRO-D
[498] W1896 §57, 58
[499] Transcript 30/09/2022
[500] W1886 [ANON] §44, W1868 §23, W2703 §56, W1919 [ANON] §34, W1960 §36, W1951 §36, W1988 §46, W1947 [ANON] §55, W1974 [ANON] §42, W1859, W1855 §45, W1876 §24, W1934 §51, W2028 §28, W1905 §48, W2638 §26, W2959 [ANON] §3
[501] W1947 [ANON] §55
[502] W1951 §36, W1826 [ANON] §28, W1859, W1855 §45, W1876 §24, W1934 §51, W2028 §28
[503] W1855 §45
[504] W1855 §45
[505] W0065 §20 (second statement), W1951 §15, W1977 §25, W2028 §20, W1965 §22, W1943 §32

family and friends.[506] This was for a number of different reasons: embarrassment at having been given contaminated blood,[507] paranoia and fear about how people may react or what they may think,[508] a desire not to be given special treatment,[509] concern that people will keep away, think differently of them and judge them,[510] worry that people will think they were sexually promiscuous or a drug user or an alcoholic,[511] scared of being labelled contaminated,[512] wanting to feel "*normal*" with other people,[513] worried about being trolled on social media or being bullied, harassed or attacked.[514] One CP reflected that having a brain haemorrhage helped with the stigma because it is a more socially accepted illness and it is something they could tell people about which they will accept.[515]

77. For those people who did tell their family and friends, they describe feeling embarrassed[516] and facing stigma[517] with some family and friends choosing never to speak to them again.[518] One CP describes telling their closest friends who were their neighbours and the very next day they moved out and they never saw or heard from them again.[519] Another CP describes how they were shunned by their family when

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[506] W2036 §35, W1963 §22, W2055 [ANON] §31, W1962 §61, W2031 §13, W2643 [ANON] §36, GRO-D, W0580 [ANON] §46, W2033 §40, W1882 §34, W2011 [ANON] §29, W2028 §29, W1926 §34, W1883 §20, W1821 §47, W2013 §20, W2057 §27-28, W1974 [ANON] §41, W2000 §57, GRO-D, W2042 §28, W1963 §31, W1867 §68, W1951 §34, W1814 §27, W2042 §43, W1943 §32, W1910 §34-35, W1902 [ANON] §38, W1900 [ANON] §41, W2055 [ANON] §30, W2690 [ANON] §35, W1822 [ANON] §25, W3325 §16, W1886 [ANON] §33, W1923 §30, W1818 §35, W3325 §26, W2053 [ANON] §31, W111 §33, W1820 [ANON] §22, W2004 [ANON] §47-49, 52, W1857 [ANON] §39, W1947 [ANON] §54, GRO-D W1820 [ANON] §22, W2009 §44, W1871 [ANON] §24, W1876 §34, W2012 §38, W2012 §60, 61, W1879 §50, 63, W1880 [ANON] §31 W1890 §29, W1886 [ANON] §35, W1891 §22, GRO-D, W0031 [ANON] §5.4, 5.5, W2637 §38, W2636 §13, W1907 [ANON] §22, W1908 [ANON] §39, W2827 §31, W1832 §15, GRO-D, W3712 §26, GRO-D GRO-D W2694 §32, GRO-D GRO-D, W2044 §21

[507] W2036 §35, W2031 §13, W1926 §34, W1883 §20, W1821 §47

[508] W2036 §35, W1963 §22, W2055 [ANON] §32, W2000 §57, W1963 §31, W1832 §44, GRO-D

[509] W2036 §35

[510] W2055 [ANON] §31, W0580 [ANON] §46, W1883 §20, W2000 §57, GRO-D, W1902 [ANON] §38, W1900 [ANON] §41, W2055 [ANON] §3 W2009 §44, W1876 §34, W2012 §38, W1880 [ANON] §31, W1907 [ANON] §22, W1908 [ANON] §39, GRO-D

[511] W2031 §13, W2033 §40, W1882 §34, W2028 §29, W1857 [ANON] §39, W1820 [ANON] §22, W2012 §38, W2012 §60, 61, GRO-D, GRO-D

[512] W1876 §34

[513] W2013 §20

[514] W1963 §31

[515] W1900 [ANON] §42

[516] W2031 §13

[517] W2013 §20, W2643 [ANON] §36

[518] W1910 §34-35, W1962 §58

[519] W2643 [ANON] §36

they told them as they were Methodists and assumed they had been sleeping around.[520] One CP describes how when he told his mum she told him to get out, leaving him shocked, scared and confused that the one person in his life who should love him no matter what was the first person to throw him out the door.[521]

78. The stigma associated with the infection also caused people to be treated differently. In some cases that different treatment was extreme and had severe consequences. For example:

a. People putting faeces in their letterbox and breaking their windows;[522]

b. Receiving an anonymous letter saying that the infected person should be taken to a field and shot, and their body burned like cows and badgers;[523]

c. Dead animals thrown onto their drive and red sauce spread on their car;[524]

d. GRO-D GRO-D[525]

e. Losing their job at a school because the school were worried about the damage to their reputation;[526]

f. GRO-D [527]

g. Hearing people talk behind their back;[528]

h. Being called a "*wee bleeder*" or "*the boy who bleeds*" in public;[529]

i. Being evicted and becoming homeless;[530]

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[520] W1867 §68
[521] W1962 §58
[522] W1906 §34
[523] W1921 [ANON] §49, 50
[524] W1921 [ANON] §49, 50
[525] GRO-D
[526] W1922 [ANON] §45-46
[527] GRO-D
[528] W1981 §23
[529] GRO-D
[530] W2643 [ANON] §4

j. Being prevented from working until supplying a certificate to show she was not a danger to her colleagues;[531]

k. Someone shouting across the bar in a pub "*stay away from [X], he has a disease*";[532]

l. Having colleagues hug them and then jump back and ask if they could catch it;[533]

m. A husband relying on the infection in divorce and family proceedings as late as 2003;[534]

n. Bullying due to others at school being told that if they spent time in their house, they would get the disease;[535]

o. School friends assuming their mother was a sex-worker and that her child also had AIDS;[536]

p. A teacher at school calling an infected child up onto the stage during assembly to announce that everyone must be careful around them;[537]

q. Friends requesting individuals to bring their own cup round to the house or not being able to use the loo or hand towel to dry hands;[538]

r. People washing their coffee cups and pointedly never touching the infected person's;[539]

s. People not assisting when an infected person cuts themselves at work;[540]

t. A person threatening to hit them while they were pregnant.[541]

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[531] W1966 §24
[532] W1882 §33
[533] W1923 §31
[534] W1988 §38
[535] W1855 §47
[536] W1917 §19
[537] W1860 §33
[538] W2690 [ANON] §41
[539] W1826 [ANON] §28
[540] W1829 §41
[541] W2712 [ANON] §17, 18

79. A number of our CPs describe that the stigma around the infection is fuelled largely because of the assumption that the infection can only be contracted through drug use, sexual promiscuity or alcoholism.[542] People had to explain to those they told that they were infected via a blood transfusion through no fault of their own.[543] One CP describes confiding in her friend at school about her infection but other kids finding out and accusing her of being raped, using needles, and injecting drugs.[544] Even amongst the medical profession, our CPs describe that there is a lack of awareness or sympathy about ways the infections could be contracted and a significant number of occasions where prejudice, lack of sympathy and lack of compassion was shown.[545] One CP describes an occasion when their mother was in hospital, and when an alcoholic drink was produced (for a celebration), one of the nurses said that "*you would think she would have learnt by now*".[546]

80. As well as misinformation about how the infection can be contracted, our CPs describe the misinformation about the different infections, with many people assuming that HCV and HBV were the same as AIDS.[547] Stigma also stems from misinformation about how the infection is transmitted, with people facing stigma from others afraid they will become infected.[548] Our CPs comment that the difficulties faced by stigma is compounded by the failure of the government and NHS to provide information or take public responsibility for the infected blood scandal, which means individuals themselves were held responsible for what happened to them.[549] This had two consequences. First it meant that unlike other debilitating and terminal conditions which people contracted through no fault of their own, people given infected blood faced judgment rather than sympathy, empathy and understanding.[550] Second, it meant individuals and their families did not realise that there were thousands of

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[542] W2709 §34, W1901 §43, W0709 §31, W0581 [ANON] §37, 38, W1822 [ANON] §25, W3916 §11, W1826 [ANON] §15, §26, W1953 §39, W0671 [ANON] §16, W1885 §40, W1871 [ANON] §40, W1823 §40, W2959 [ANON] §28, W2640 §29

[543] W1901 §43, W1885 §40

[544] W0671 [ANON] §16

[545] W2635 §21-23, GRO-D , W1823 §40

[546] W0709 §31

[547] W2702 §34, W0065 §49, W1818 §35, W2631 [ANON] §29

[548] W1905 §56, W1906 §33, W1820 [ANON] §23

[549] W1901 §40, W0581 [ANON] §37, 38

[550] GRO-D , W2637 §41, W3693 §50, W2009 §45

others affected like they were, making them feel isolated and depriving them of a support network of people going through the same thing.[551]

81. In a number of cases, the stigma affected not just the person infected but also their family members, friends and loved ones.[552] Where loved ones were made to keep the infection a secret this meant they became isolated and could not lean on friends for support.[553] The ways in which loved ones were affected by stigma are numerous: the wife of someone infected describes having their blood donation form ripped up in front of them,[554] the children of those infected describe being bullied, beaten up and teased at school,[555] with one child saying that another child said to her at school that she was glad her father was dead.[556] The stigma could still be faced by the family even after their loved one's death, as illustrated by one CP's story of when they attended the Registrar's office to report their father's death. They describe being kept waiting a long time, facing other people staring at them and spitting at them.[557] GRO-D

GRO-D

GRO-D

[551] W2959 [ANON] §23
[552] W2693 §21, W2959 [ANON] §13
[553] W2035 §31, W2959 [ANON] §22, W2854 [ANON] §16,W3324 [ANON] §31, W2696 §31, W2697 [ANON] §11, W2872 §28
[554] W2006 [ANON] §29
[555] W2035 §33, W2052 §16-20, W1981 §21
[556] W1981 §21
[557] W2643 [ANON] §44-46

GRO-D

Education and Work

82. A few of our CPs comment that it is very difficult to measure the impact of the infection on their education because they have always been infected.[559] However, other CPs comment that the infection and its side effects made it very difficult for them to concentrate on their studies.[560] Specifically, our CPs commented that they found it difficult to record information and recall it later, and in some cases would write a paragraph and then forget what they were writing about.[561]

83. Some people missed long periods of school, college or university education because of the effects of the infection and treatment[562] or because they were being bullied;[563] others held off treatment until after they finished to try to limit disruption.[564] A number of people described how they were unable to sit their exams because they were too tired or unwell,[565] or that they did not do as well in their exams as they should and could have done.[566] Others lost all motivation to study and ambition to progress to university or a career because of the debilitating and life-shortening effect of being infected.[567] Many never made it to university or college;[568] in one case, a young girl had her college place and had placed a deposit on a flat but passed away before getting the opportunity to attend.[569] Others were able to start their course or

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[558] GRO-D

[559] W2000 §58

[560] W1925 [ANON] §27, GRO-D, W1818 §37, W2629 [ANON] §44, W2709 §9, W1967 [ANON] §26, GRO-D §28, GRO-D, 19, 20, W3712 §27

[561] W1945 §52, W1967 [ANON] §26

[562] W1875 §13, W0671 [ANON] §42, GRO-D, 34 – 37, W2042 §45, W0671 [ANON] §37, 38, W1899 [ANON] §20, 21, W1902 [ANON] §43, GRO-D

[563] W0671 [ANON] §16

[564] W1875 §13, W0671 [ANON] §42

[565] W1963 §33, W1868 §29, GRO-D, W2959 [ANON] §39, GRO-D

[566] W2052 §24-29, W2828 §28, W1941 §64, 65, W1868 §29, GRO-D, 20W2959 [ANON] §39

[567] GRO-D, W1941 §64, 65, GRO-D

[568] GRO-D, W2828 §28, GRO-D

[569] W1823 §44

higher studies but were unable to finish them because they became too ill; this was particularly frustrating and disheartening, as they had to give up their dream career.[570]

84. Some of our CPs describe being treated very poorly by their school, college or university, who threatened to throw them out because they'd missed too much school time,[571] refused to let them re-attend after mental health problems leading to an overdose,[572] refused to take their infection or ongoing treatment into account as mitigating circumstances when awarding exam results,[573] or forced them to drop subjects or change classes because certain teachers refused to teach them.[574] One CP described how the school breached their confidentiality by telling all members of staff about their infection and calling their mum into school because there had been a rumour that they had kissed a boy.[575]

85. For those whose family member was infected, their education was affected by having to take time off school, university or college to travel home to see their loved one[576] and in some cases, care for them.[577] The mental and physical energy and time this took, as well as the emotional exhaustion derived from their concern for their loved one, also affected their ability to concentrate on their studies and keep up with the workload.[578] Some children even had to change their plans for where they studied in order to be closer to home so they could care for their loved one.[579]

86. A number of children had long periods off school, college or university during their loved one's treatment or after their death,[580] with some children refusing to go to school due to the fear of leaving their loved one in case they were not there when they returned,[581] or because they had severe separation anxiety with their remaining

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[570] W1991 §35, W1919 [ANON] §35, W2645 §40, W3713 §8, W0622 §38, W1967 [ANON] §26, GRO-D, W1899 [ANON] §42, W1902 [ANON] §43, W1819 [ANON] §28, GRO-D

[571] W1988 §39, GRO-D

[572] W2052 §24-29

[573] W2052 §24-29, W1962 §67

[574] W2643 [ANON] §43

[575] W0671 [ANON] §18

[576] W2052 §24-29, W2709 §9, W1961 §41, W2693 §22

[577] GRO-D, W1927 §16, W1832 §38

[578] W2052 §24-29, W2709 §9, GRO-D, W1927 §16, GRO-D, GRO-D

[579] W2643 [ANON] §49, W2709 §9

[580] W3326 §27-28, W1962 §67, W2959 [ANON] §39

[581] W2026 [ANON] §41, W1927 §16, GRO-D

parent after one parent had died.[582] In one case, the child's refusal was so adamant they became home schooled.[583] In contrast, in another case the parents made the decision to take the child out of their current school and send them to boarding school in the belief this would provide them with greater stability and safety.[584] One CP describes the far-reaching effect of their mother's infection on their education:

GRO-D

87. Our CPs describe how the symptoms of the infection and treatment also made work difficult; they could not retain information, could no longer do tasks they used to do

[582] W3326 §27-28
[583] W2026 [ANON] §41
[584] W1962 §67
[585] GRO-D

very quickly, and could not concentrate which caused them to worry and stress and make them feel inadequate.[586] Consequently, a large majority of our CPs had to give up work as a result of being infected,[587] because they were too tired, had no energy, suffered with brain fog,[588] were diagnosed with liver cancer,[589] could not cope with the stress,[590] suffered with depression,[591] were very self-conscious about what their colleagues thought,[592] or were just too unwell.[593] This came as a major blow to many of our CPs who loved their job.[594] Having to give up work effected people's sense of identity, dignity, self-worth, independence, sense of safety, confidence, freedom, well-being, sense of purpose and value;[595] as one person put it, it robbed their mother of her *"central source of pride"* and made her feel useless and purposeless.[596] Our CPs speak of the interest and social interaction they derived from work, the loss of which

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[586] W1932 §24-25, W3916 §45

[587] W2645 §41, W2062 §38, W2026 [ANON] §38, W3710 §35, W1962 §64, 65, W1867 §58, W3920 §15, W1994 §45-47, W3326 §33-34, W2635 §18, W2028 §22, W1977 §29, W2703 §63, W2031 §16, W2819 §52-54, GRO-D, W1877 §28, W1882 §38, W1901 §48, W1975 §37, W3697 §42, GRO-D, W1941 §42, W1981 §9, W1883 §20, W2013 §17, W1850 §50-51, W0580 [ANON] §43, W2991 §63-65, W1848 §20, W1819 [ANON] §30, W1998 §50, W1996 [ANON] §42, W1821 §39, W1967 [ANON] §27, W1814 §30, W1997 §52, W2043 §35-36, W1990 §25, W2041 §40, W1987 [ANON] §43, W1972 §37, W1982 §18, W1974 [ANON] §48, 49, W1963 §34, W2059 [ANON] §3, 41, W1960 §39, GRO-D, W5209 §31-32, W1947 [ANON] §62, W1951 §42, W1945 §53, W1943 §36, W1935 §37, W1943 §27, W1932 §75, W1943 §16, W1921 [ANON] §11, W1919 [ANON] §35-37, W1913 §17, W1908 [ANON] §42, W1906 §38, W1905 §62, 63, W1902 [ANON] §44, W1938 §54, GRO-D GRO-D, W1913 §33, W1896 §19, 28, GRO-D, 25, W2637 §42, W1899 [ANON] §23, W2055 [ANON] §33, W1907 [ANON] §41-43, W2055 [ANON] §33, W2690 [ANON] §43, GRO-D, W0065 §41, W1818 §2, 38, W1876 §36, W1822 [ANON] §2 and 27, W1838 §52, W3693 §53, W2005 §40, W2853 [ANON] §26, W2630 §29, W1923 §23, W1826 [ANON] §31, W1878 §37, GRO-D W3693 §57, W1111 §31, W1820 [ANON] §24, W1829 §27, W1824 §40, W2053 [ANON] §26, §27, W2053 [ANON] §28, W2053 [ANON] §29, W1868 §7-30, W0622 §39, W1855 §52, W2853 [ANON] §22, W1860 §46, W1862 §21, GRO-D, W0065 §52, 55, W0065 §55, W2631 [ANON] §32, W1880 [ANON] §22, W1886 [ANON] §42, W1889 [ANON] §70, W1891 §24, W1892 [ANON] §37, W1893 §28, W1900 [ANON] §6, GRO-D, W1832 §28, W2020 §35, GRO-D, GRO-D W2694 §33, GRO-D

[588] W2645 §41, W1962 §64, 65, W2819 §52-54, W1877 §28, W1882 §38, W1901 §48, W1975 §37, W1850 §50-51, W2634 §38, W2991 §63-65, W1998 §50, W2043 §35-36, W1974 [ANON] §23, W1972 §37, W1963 §34, W5209 §31-32, W1908 [ANON] §42, W1913 §33, W2690 [ANON] §43, GRO-D, W0065 §41, W1111 §31, W1820 [ANON] §24, W0065 §52, 55

[589] W2062 §38

[590] W1994 §45-47, W1963 §34

[591] W1966 §21, W1977 §29, W1943 §16, W1913 §33, W1818 §2, 38, W1111 §31, W1820 [ANON] §24

[592] GRO-D

[593] W1967 [ANON] §27, W1990 §25, W1987 [ANON] §43, W5209 §31-32, W2055 [ANON] §33, W1876 §36, W1822 [ANON] §2 and 27, W1838 §52, W3693 §53, W2005 §40, W2853 [ANON] §26, W2630 §29, W1923 §23

[594] W1962 §64, 65, GRO-D, W1848 §20, W1819 [ANON] §30, W1998 §50, W1821 §39, W2043 §35-36, W1987 [ANON] §43, W1982 §18, W1974 [ANON] §48, 49, W2059 [ANON] §3, 41, W3713 §41, W1951 §42, W1896 §19, 28, W1860 §46, GRO-D

[595] W1962 §64, 65, W2635 §18, W2991 §63-65, W1821 §39, W5209 §31-32, W1919 [ANON] §35-37, GRO-D GRO-D W3693 §57, W2053 [ANON] §26, §27, W2053 [ANON] §29, W1886 [ANON] §42

[596] W2635 §18

resulted in people becoming isolated and lonely.[597] Other CPs could not afford to give up work or were too scared to tell their employer about their infection so they forced themselves to continue to work through the pain and treatment.[598]

88. A number of our CPs indicated a lack of understanding by their employer of their ill health.[599] After having only one month off work due to depression, one CP – who worked at a hospital – was told he must either come back to work or hand in his resignation despite the fact that the company policy was to allow six months' sickness on full pay and six months' sickness on half pay.[600] Another CP had her employment contract terminated due to too many absences, despite explaining the reason for those absences.[601] One CP described how they felt invisibly monitored by their employer who repeatedly asked about infection control and requested they bring in blood tests to show that they would not contaminate students.[602] One CP describes how their employer put pressure on them to take early retirement and voluntary redundancy on the grounds of ill-health.[603] One CP who worked for the NHS was put down to nil pay after being on sick leave for too long.[604] One CP describes how their employer announced their diagnosis in front of all other employees and asked them not to use the staff kitchen.[605] One CP was made redundant by their employer and had to take them to court to win a constructive dismissal case.[606] One CP was told they hadn't passed their probation period due to "*non-performance*" just after informing their employer of their blood disorder.[607] One CP was told they were no longer able to teach because of the risk of infecting the children.[608]

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[597] W1821 §39, W2059 [ANON] §3, 41

[598] W1966 §21, W1950 §48, W1977 §29, W0394 §25, W2002 [ANON] §33, W1995 §39, W2000§59, W1814 §30, W2036 §27, W1974 [ANON] §48, 49, GRO-D , W1922 [ANON] §45, W2638 §14, 15,W2692 §18, W1857 [ANON] §23, 27, W1871 [ANON] §33, W1871 [ANON] §42, W1879 §68-69, W1894 §24, W1895 §35

[599] W1977 §29, W2991 §63-65

[600] W1977 §29

[601] W2991 §63-65

[602] W2634 §40

[603] W1814 §30

[604] W5209 §31-32

[605] W19334 §54

[606] W1826 [ANON] §31

[607] W2005 §39

[608] W1855 §52

89. Some of our CPs had to give up their job and move to a different job,[609] for example, a teacher who was advised that they would likely pick up illnesses from students which would affect their health.[610] This involved having to start again, which sometimes prevented them from ever progressing in a career or developing a clear career path.[611] For some of our CPs their infection affected their attempts to find a new job, as when they were honest about the infection and treatment, they found they failed to get offered a single job.[612] One CP described that they: "*have a law degree, [are] a partly trained chartered accountant, worked as a financial trouble-shooter in the City, a senior consultant and project manager in media and IT, and a legal head hunter*" but after diagnosis they tried to apply for various jobs, and no one would hire them.[613]

GRO-D

90. It was not just the person who was infected whose career was impacted by the infection; family members' careers were also affected. This could be because they had to take time off work, reduce their working hours, turn down opportunities at work or give up work to look after their loved one;[615] or because they were so devastated about the impact of the infection on their loved one, or in some cases the loss of their loved one, that they were no longer well enough to work themselves. [616] This meant family members too lost out on the chance to pursue their careers or opportunities for promotion[617] which affected their sense of self-worth, confidence, fulfilment and well-being.[618] The effect on people's confidence could be so severe that it could

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[609] W1988 §41-42, W1974 [ANON] §45, W1954 §232, W1922 [ANON] §45, W1826 [ANON] §31, W1868 §31

[610] W1988 §41-42

[611] W1943 §36, W1954 §232

[612] W2702 §35, W1922 [ANON] §45, W1938 §55, W1826 [ANON] §31, W0622 §40, W1860 §34, W0671 [ANON] §41, W0065 §57, W2631 [ANON] §32, W2012 §68, W1885 §43, GRO-D

[613] W1951 §46, W2631 [ANON] §29, 30

[614] GRO-D

[615] W1923 §23, W1998 §51, W2035 §37, W3326 §33-34, W1882 §39, W2693 §24, W1928 §47, W3324 [ANON] §38, W1858, W1891 §24, W1917 §22, GRO-D, W1900 [ANON] §37, W2697 [ANON] §13, W2636 §16, W2636 §16, W2712 [ANON] §19, W2827 §34, W2827 §34, W1990 §54, W2648 §20, 21, W0581 [ANON] §21, W1817 §21, 22, W3914 §55, W1961 §39-40, W1962 §68, W2039 §48, W2004 [ANON] §31, W2703 §63, GRO-D W2819 §52-54, W1832 §38

[616] W2689 §30-31, W2712 [ANON] §19, W1961 §39-40, W1975 §38-340, W2020 §45

[617] W1882 §39, W1858, W2827 §34, W1990 §54, W2648 §20, 21, W1814 §26, W3914 §55, W1962 §68, W1832 §38

[618] W2689 §30-31, W2827 §34

prevent them from applying for other job opportunities.[619] Some people were even advised that they would be better off financially if their partner gave up their job and became their full-time carer.[620]

Finances

91. The inability to work lead to much financial worry and a diminution in their financial circumstances[621] as it would often lead to significant financial loss,[622] would force families to be reliant on – at most – only one income stream,[623] or sometimes on state benefits and funding schemes.[624] This led to people losing their homes,[625] businesses,[626] financial independence,[627] and preventing them from being able to pay for food[628] or support their children through education.[629] It also meant a lot of individuals missed out on the pension they should have received[630] and they found themselves in terrible debt.[631] Unsurprisingly, due to many individuals losing their jobs and falling into debt they needed to use their savings to afford to live.[632] As one CP describes:

> *"My wife and children were plagued by bailiffs knocking at their door. It came to the point where my wife would not answer the door. I sent letters to everyone that I was in debt to, but that did no good at all. My wife went to Citizens Advice but*

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[619] W2959 [ANON] §39, W1832 §38
[620] W1817 §21, 22
[621] GRO-D, W1848 §20, W2004 [ANON] §34, 35, W0580 [ANON] §43, W1882 §40, W1825 §32, GRO-D §42, W1922 [ANON] §49, W1967 [ANON] §28, W2634 §41, W1988 §45, W1974 [ANON] §52, W2059 [ANON] §42, W1947 [ANON] §62, W1906 §39, W2637 §43, W1902 [ANON] §45, W1896 §29, W1822 [ANON] §27, W1885 §46, W1890 §31, W1900 [ANON] §44, W1908 [ANON] §43, W1826 [ANON] §32, GRO-D W3693 §54, W1860 §37, W1859, W2009 §47-48, W1880 [ANON] §33, W1892 [ANON] §39, W1893 §29, W1894 §33, GRO-D W1899 [ANON] §44, GRO-D W1905 §65, W1980 §26, GRO-D
[622] GRO-D
[623] GRO-D, GRO-D, W1947 [ANON] §62, W1905 §65
[624] W1848 §20, W2004 [ANON] §34, 35, W1882 §40, W1825 §32, GRO-D, W1922 [ANON] §49, W2059 [ANON] §42, W1880 [ANON] §33
[625] W1967 [ANON] §28, W2638 §27, W1896 §29, W1826 [ANON] §32, W1905 §65, W1954 §29
[626] W2638 §27
[627] W1947 [ANON] §62, W3693 §54
[628] W2634 §41
[629] W1967 [ANON] §28
[630] W1855 §54, W2853 [ANON] §27, W1960 §39, W0580 [ANON] §43, GRO-D W0065 §60, W1871 [ANON] §43, W1878 §38, W1900 [ANON] §44, W1905 §65, W1991 §35, W2638 §31, W2004 [ANON] §34, 35
[631] W2004 [ANON] §34, 35, W2631 [ANON] §33, W3323 [ANON] §45, W1876 §36, W1954 §29, W2694 §33
[632] W2055 [ANON] §35, W1891 §24, W1867 §58

they couldn't help her with the complexity of the case, contaminated blood was still virtually unheard of, and we found that no-one really cared. Over the years I have had to sell many of my possessions including football memorabilia and art that I had collected. I had to sell my Banksy print to pay for my daughter's wedding. That broke my heart but obviously family comes first."[633]

92. Having infected blood also affected or prevented our CPs' ability to get life insurance,[634] travel insurance,[635] home insurance,[636] business insurance,[637] medical insurance,[638] and a mortgage.[639] For one CP, this meant they were unable to travel to see any of their family in the US[640] and another CP was unable to visit their brother abroad before they died.[641] For those CPs unable to get a mortgage it meant they were never able to buy their own home.[642]

93. Very often the family standard of living hugely decreased: people were unable to afford to pay the bills, rent or mortgage;[643] they were forced to live hand to mouth;[644] they were unable to afford food[645] or a car, stripping them of their independence;[646] they became ashamed of their house as they did not have the money to maintain it;[647] they could not afford any luxuries[648] such as holidays;[649] they became fully dependant on benefits.[650] For many of our CPs it was very difficult for them to completely change the way they lived, having worked hard all their life, due to something that was no

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[633] W1972 §41-42
[634] GRO-D ; W1822 [ANON] §29, W1855 §4268, W2004 [ANON] §35, W1875 §21, W1817 §29, W2013 §25, W1935 §38, W2009 §46, W1880 [ANON] §33, W1893 §29, W1894 §33, W1821 §41, W1934 §73, GRO-D
[635] W1822 [ANON] §28, W1954 §34, W1934 §73, W1932 §72, W0709 §30, W1905 §67, W1906 §43
[636] W3326 §33-34, W2012 §69
[637] W1932 §76
[638] W3692 §47, W2643 [ANON]
[639] W1963 §35, W1826 [ANON] §27, W2643 [ANON], W1817 §29, W1848 §34, W2013 §25, W1954 §34, W1935 §38, W1862 §25, W1868 §27, W1880 [ANON] §33, W238 §30
[640] W1822 [ANON] §28
[641] W1932 §72
[642] W1963 §35, W1826 [ANON] §27, W2643 [ANON], W1817 §29, W1848 §34, W2013 §25, W1954 §34, W1935 §38, W1862 §25, W1868 §27, W1880 [ANON] §33
[643] W2638 §29, W1997 §42, W1913 §34, W1925 [ANON] §29, GRO-D , W0581 [ANON] §28, W2828 §27
[644] W2645 §42, GRO-D ; W1917 §22
[645] W1997 §42, W1913 §34, W1925 [ANON] §29
[646] W2033 §39, W1913 §34
[647] W2031 §17, W1997 §52
[648] W1994 §45-47
[649] W1994 §45-47, W2690 [ANON] §44, W1818 §39, W1829 §44, W1913 §34
[650] GRO-D ; W1963 §35, W1951 §45, W1818 §39, W1968 [ANON] §25, W1921 [ANON] §32

fault of their own.[651] In some cases, infected individuals' partners or loved ones had to take on more work or a second job to support the family financially.[652] Conversely, family members who cut down their hours or changed their career to care for their loved ones had their own salary and pension affected. [653] The financial impact was particularly difficult for those who lost their loved one and were forced to find a job to ease their financial difficulties at the point at which they were grieving;[654] as one CP explains:

> *"The impact on me is that I suddenly became a single parent and a widow. I was totally responsible for everything. I was responsible for the mortgage, for a debt of £50,000, for the care and support of my grieving children, for the running of my business which I had to build up in order to survive, for the financial support and care of my elderly mother, for my husband's burial, and the list goes on."*[655]

Treatment and care

Efficacy of treatment

94. Even those individuals who were given effective treatment and were "*cleared*" of the virus, describe the impact of the infection, whether this be that they have to continue to have liver scans or because they constantly worry that the virus could or has returned.[656] As one CP put it:

> *"It is as if you are put to one side once you have had the treatment. It doesn't matter if your skin is itching so much it bleeds, or if you are suffering mentally, constantly asking yourself whether it is going to come back. I am living in fear, how would I ever get through the treatment again?"*[657]

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[651] W1972 §40, W1899 [ANON] §48, W1908 [ANON] §68
[652] W2690 [ANON] §44, W2696 §35, W1877 §28, W2031 §18-20
[653] W1965 §23, W1817 §29, W2011 [ANON] §36, W1901 §49, W1980 §28
[654] W1950 §48, W2033 §35, W2004 [ANON] §39
[655] W1950 §32-33
[656] W2009 §29, W1876 §31, W2702 §24, W2019 §33
[657] W2019 §33

95. A large number of people were treated for HCV, HBV and HIV, but their treatment was not effective.[658] Our CPs describe how devastating it is to go through repeated courses of treatment, each time with painful and debilitating side-effects, which in the end are wholly ineffective;[659] some of our CPs went through treatment rounds as many as three,[660] four,[661] or five[662] times. They describe how each time a treatment failed they felt as if they had been infected all over again and they had to take time to recover physically and emotionally before being able to face another round of treatment.[663] Other individuals were simply not offered further treatment or were just told that nothing further could be done;[664] for others, treatment was abandoned because it was causing violent, damaging and potentially life-threatening side-effects.[665] Those who experienced failed treatment describe it as feeling like a death sentence,[666] engendering feelings of hopelessness, distress, worry and despair.[667] Some of our CPs were told they had successfully cleared the virus, but then later told that it was a false positive[668] or that the virus had returned.[669]

96. Our CPs describe that each time they underwent treatment their symptoms worsened permanently and they often felt more unwell during and afterwards, experiencing intense pain and suffering that was as bad, if not worse, than the infection;[670] this also had the knock-on effect that our CPs would have to take time off work causing additional stress and concern.[671] For many the treatment was unbearable[672] and soul

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[658] W1997 §28, W0622 §24, W1818 §30, W3693 §32 – 43, W1820 [ANON] §17, W2692 §17, 22-23, W2013 §16, W1998 §35, W1893 §20, W3326 §17, W1891 §17, W1974 [ANON] §27, W1895 §20, W2637 §22, 23, GRO-D GRO-D W1935 §24, W1834 §34, W1925 [ANON] §15, W0709 §40-41, GRO-D

[659] W1818 §30, W3693 §32 – 43, W1820 [ANON] §17, W2692 §17, 22-23, W2013 §16, W1998 §35, W1893 §20, W1891 §17, W1974 [ANON] §27, W1895 §20, W1899 [ANON] §30, W2637 §22, 23, W1982 §13

[660] W1899 [ANON] §30, W1982 §13, W1832 §25, GRO-D

[661] W2013 §16, W2692 §17, 22-23, W1998 §35

[662] W1876 §29

[663] W1974 [ANON] §27

[664] W1891 §17, W2637 §22, 23, W1882 §23-24, W0709 §40-41

[665] W3326 §17, W1882 §23-24, W1977 §20, W1947 [ANON] §32, W2059 [ANON] §33, W1997 §30, W1855 §31, W1842 §20-22

[666] W1997 §28, W2637 §22, 23

[667] W0622 §24, W1893 §20, W2637 §22, 23

[668] W1893 §25

[669] W2000 §39

[670] W1935 §24, W1111 §36, W2055 [ANON] §25 – 26, W1850 §33, W1885 §27, W1922 [ANON] §37, W1925 [ANON] §15, W2000 §40, GRO-D

[671] W2000 §39

[672] W1850 §33, W1818 §29, W1885 §27, W1925 [ANON] §37

destroying,[673] such that they chose to end the treatment prematurely or refuse further treatment.[674] For some, the effects were so unbearable that they say they wish they never had the treatment.[675] Other CPs describe it as being worse than their experience of chemotherapy,[676] requiring them to shut down completely to get through it[677] and endure the worst 12 months of their life.[678] As one person put it: "*the interferon and ribavirin treatment were like visiting Hell*".[679]

Side effects of treatment

97. A full list of all the reported physical and mental side effects of treatment identified in the evidence of our CPs for HCV, HBV and HIV can be found in Annexes 2, 3 and 4.

98. The two most common and severe side effects for our CPs infected with HCV and HBV were fatigue and depression. The fatigue was so extreme such that our CPs would sleep all the time and felt unable to do anything,[680] even lift their head off of the pillow.[681] As one CP described it, they felt like they had flu a thousand times over and as if their bones were being crushed.[682] Depression was severe,[683] causing suicidal ideation and attempts to take – or in some cases took[684] – their own life.[685] As one CP described it, they felt deprived of emotions, empty and isolated.[686] Another CP explained that they were told that if they went on the treatment, they would have to come off their anti-depressants and the treatment would likely worsen their

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[673] W2055 [ANON] §25 - 26
[674] W1818 §30, W0072 §44 – 45, W2059 [ANON] §33, W1855 §31, W1885 §27, W2638 §20, 21, GRO-D
[675] W1922 [ANON] §37, W1925 [ANON] §15, §37
[676] W1883 §26, W1820 [ANON] §17, W2000 §40, GRO-D
[677] W0065 §30
[678] W1820 [ANON] §17
[679] W1899 [ANON] §33
[680] W1923 §24, W1862 §22, W1968 [ANON] §20, W1998 §28, GRO-D, W1994 §28, W3693 §26, W1829 §32, W1888 §25
[681] W1923 §24, W2703 §25, W1998 §28, GRO-D
[682] W2638 §20, 21
[683] W1923 §24, W1968 [ANON] §20, W1966 §16, W1998 §28, GRO-D, W1997 §26
[684] W1968 [ANON] §20
[685] W1966 §16, GRO-D, W1996 [ANON] §24
[686] W1997 §31

depression.[687] For many, all they could do was take the tablets or injections and then go to bed and suffer the side effects until it was time to take the next dose.[688]

99. Specific side effects included fillings in teeth turning black,[689] the tongue feeling like it is burning,[690] a constant headache lasting months,[691] a rash on the face,[692] constantly itchy skin,[693] swelling in the face and eyes,[694] thrush in the mouth leading to the person spitting out lumps of skin,[695] black scabs which grow on the lips which burst and bleed,[696] seizure-like episodes at night and sleep paralysis,[697] extreme weight loss,[698] loss of the ability to swallow[699] and blurred vision.[700] The side effects were so debilitating that our CPs describe feeling as if years of their life had been taken away from them;[701] the treatment would make them dread the next day and wish they would not wake up,[702] and many people (and their loved ones) thought they were dying.[703] As one CP put it, the effect of treatment is like falling into a deep and terrifying abyss of pain and despair.[704]

Delay, refusal or unavailability of treatment

100. A number of individuals report that they were told that there was no available treatment or were offered no treatment,[705] either because at that point a treatment

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[687] W2043 §28
[688] W1970 §26, W1996 [ANON] §24
[689] W1935 §27-28
[690] W1935 §27-28
[691] W1935 §27-28, W1997 §31
[692] W1997 §30
[693] W1997 §30, 31,
[694] W1997 §30
[695] W1922 [ANON] §35
[696] W0072 §46
[697] W1990 §34
[698] W3693 §26, W1888 §25
[699] W0065 §13 (second statement)
[700] W0065 §15 (second statement)
[701] W1857 [ANON] §26
[702] W1859
[703] W1997 §30, W1922 [ANON] §35
[704] WTIN0622 §48
[705] W1997 §28, W2053 [ANON] §12, W1814 §20, 22, W1867 §52, W3323 [ANON] §26, W1862 §17, W2055 [ANON] §22, W1818 §41, GRO-D, W2853 [ANON] §7, W0709 §14, W3710 §19, W1928 29, W1906 §8, W3914 §21, W2641 §29, W1917 §14, W1950 §25, W1867 §54, W2000 §37, W1938 §12, W3325 §30, GRO-D GRO-D W1879 §24, W1902 [ANON] §17, 33, W1877 §20, W1913 §20, W2019 §10-11, W1919 [ANON] §23, W1929 §11, W1825 §10, W3697 §23, W1832 §9

did not exist or wasn't available,[706] or because the damage done was already so severe that treatment would not work,[707] or because the medical adviser told them treatment was not necessary,[708] or because the treatment was too expensive and there was no funding available,[709] or because of other health conditions which meant that treatment was not an option,[710] or because they were too old or unwell to receive treatment.[711]

101. A number of our CPs experienced delay in receiving treatment of varying lengths, including: 8 weeks;[712] 4 months;[713] 5 months;[714] 6 months;[715] 8 months;[716] 9 months;[717] 1 year;[718] 15 months;[719] 2 years;[720] 3 years;[721] 3.5 years;[722] 5 years;[723] 7 years;[724] and 11 years.[725] The delay was so long for one CP that they passed away before receiving any treatment.[726] Some of our CPs had no idea of the reason for the delay.[727] Other CPs were told the delay was due to a lack of funding[728] or because there were others more seriously ill than them who needed the treatment.[729] Some of our CPs were told that they did not yet qualify for new treatment schemes because the damage caused by the infection was not severe enough, despite research showing

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[706] W3710 §19, W1917 §14
[707] W2055 [ANON] §22, W2006 [ANON] §12 – 13, W2641 §29, W1950 §25, W1867 §54, W2000 §37, W2019 §10-11, W1825 §10
[708] W0709 §14, W1879 §24
[709] W1928 29, W1919 [ANON] §23
[710] W3914 §21, W1867 §54
[711] W1832 §9
[712] W1954 §10
[713] W5209 §25
[714] W1986 §31
[715] W1921 [ANON] §36, 37
[716] W2001 §11
[717] W1997 §25
[718] W1820 [ANON] §7, W1987 [ANON] §37, W2000 §37, W1832 §11
[719] W1972 [ANON] §30
[720] W1995 §32, W3692 §37, W2012 §53, W1871 [ANON] §27
[721] W1970 §28
[722] W1899 [ANON] §31
[723] W1893 §22
[724] W1848 §24
[725] W1963 §26
[726] W1977 §21
[727] W1963 §26, W1926 §27, GRO-D
[728] W5209 §25, W1850 §29, W1966 §15, W2648 §14, W1972 [ANON] §30, W1970 §28, W1954 §10, W1947 [ANON] §34, W1899 [ANON] §31, W1921 [ANON] §36, 37, W1934 §38, W1838 §56
[729] W1977 §21

that earlier treatment was more effective.[730] Others describe that when they tried to fight for treatment it was assumed that they contracted the virus because of their lifestyle choices.[731] One CP was told they would receive the treatment more quickly if they moved to a different postcode because the funding for treatment was dependant on the postcode; they moved house and received the treatment immediately.[732] Another CP describes that the doctor told them they were not "*worthy*" of treatment which made her feel like an inconvenience.[733]

102. Our CPs describe that the wait to receive treatment is particularly anxiety-inducing and stressful, leaving people scared that their condition may be worsening or they may die before treatment is made available, as well as making them feel disappointed, upset, angry and alone.[734] It is also very frustrating for those who were infected by the healthcare system to be told that there was not the funding available to treat and rectify the damage done.[735] Further, one CP commented that they were not offered any support while they were waiting for treatment but that they were left in the wilderness.[736]

103. Finally, some individuals refused treatment because they had lost all faith in the medical profession and did not trust the doctors' recommending treatment.[737]

Effect of treatment on family members and loved ones

104. As detailed above, a number of individuals had to fight and battle to receive treatment, and often their loved ones had to support them through this or fight on their behalf when they were not feeling well; this means loved ones also experienced the stress, anxiety and disappointment of treatment being refused, delayed, unsuccessful and/or unbearable.[738]

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[730] W0065 §26, 27, W1947 [ANON] §34, W1876 §30, W1893 §22, W1900 [ANON] §30-31, W1902 [ANON] §17, 33, W1919 [ANON] §23, W1934 §38
[731] W1900 [ANON] §30-31
[732] W2648 §14
[733] W1932 §50, 51
[734] W1963 §26, W1997 §25, W2012 §53, W1921 [ANON] §36, 37, GRO-D
[735] W1966 §15, W2012 §53
[736] W1921 [ANON] §36, 37
[737] W2031 §11, W1905 §46
[738] W0709 §27, W2691 §12

105. As shown in Annexes 2, 3 and 4, as a result of treatment people could become aggressive and suffer mood swings or personality changes. Family members who were unaware that this was a consequence of treatment express the guilt they feel at thinking this was part of their loved one's nature rather than it being as a result of the treatment.[739] For some the behaviour induced by those mood swings has irrevocably damaged relationships between loved ones.[740]

106. A number of our CPs commented on how difficult, scary and upsetting it can be to see your loved one so unwell, in pain and suffering, and feeling powerless to help.[741] This was particularly difficult for loved ones when they knew the treatment was important in order to try to increase their loved one's life chances while also observing the intense pain and suffering the treatment caused.[742] Those responsible for injecting their loved ones as part of the treatment found this was particularly difficult.[743] Family members also lived through the anxiety of waiting for the results of treatment and pinning their hopes on it, with the low likelihood of success hanging over them when the results were due, leading them to feel gutted when the treatment was not successful.[744] As one CP explained:

> "*For me, the worst part of his treatment came when he did not want to take the Interferon anymore because it made him so ill. I felt that I had to make him take it because I couldn't see any alternative to it: it was Interferon or liver cancer. I would be quite aggressive with him, telling him to take it, telling him he was not going to die on me and our son. He would stick the needle in and twenty minutes later would be shivering and shaking and would take himself to bed. I would sit and cry for a couple of hours because I felt so guilty. It was always on a Sunday, so that was our Sunday afternoon and evening for months and months.*"[745]

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[739] W2691 §14, W2958 [ANON] §16,
[740] W2691 §18, W2958 [ANON] §16
[741] W2006 [ANON] §36, W2958 [ANON] §13, W2959 [ANON] §14, W2872 §38-39
[742] W2958 [ANON] §14, W2872 §38-39
[743] W2691 §19
[744] W2960 [ANON] §14, W2959 [ANON] §17, W2691 §11
[745] W2696 §19

Liver transplants

107. Our CPs broadly relate negative experiences in respect of transplantation. Some of our CPs were never offered a liver transplant because their health had deteriorated so significantly that they were considered too weak to have the transplant.[746] Some of our CPs were told that because they had HCV they would not qualify for a liver transplant.[747] One CP was denied a liver transplant because they were told it was a *'waste'* of an organ as it would just get infected again by HCV.[748] Another CP describes that they went to the hospital on three separate occasions over two years in anticipation of having a liver transplant only to be told when they arrived that there had been an error.[749] GRO-D GRO-D GRO-D Indeed, a number of our CPs describe how their loved one was on the waiting list for a liver transplant but their health deteriorated such that they would not survive the operation or they passed away before a liver became available.[751] GRO-D GRO-D GRO-D.[752] During that time our CPs and their loved ones describe how they had to endure the stress and anxiety of not knowing if/when a liver may become available, requiring them to always have their bags packed ready to go to the hospital.[753] This was difficult for both the person waiting for the liver transplant and their loved ones as explained here:

> *"The transplant coordinators and nursing teams were supportive and compassionate but unable to protect us from the rollercoaster of fear, hope and disappointment. I lived with my phone never more than a metre away from me, frantic with anxiety at each text or call; anticipating news of her deterioration or*

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[746] W1953 §29, W1823 §36-37, GRO-D
[747] W1848 §15, W1882 §22
[748] W2062 §55
[749] W2634 §24
[750] GRO-D
[751] W1950 §26, W1823 §36-37, W1825 §19 GRO-D
[752] GRO-D
[753] W3693 §32, W1950 §26, W1823 §36-37

death. One memorable New Year's Eve a liver became available for transplant so I slipped out of the party and onto the underground tube train, sitting anxious and alone as midnight arrived and the groups around me hugged and cheered. I arrived just in time to hug my mum and wish her luck whilst hiding my fears that this could be our last conversation. Not long after she was sedated and taken to the operating theatre she was wheeled back to the ward as the nurses explained that the donated liver was not a viable transplant. It was yet another crushing disappointment. I hated leaving the hospital knowing that when she awoke from the anaesthetic, she too would have to learn the disappointing news and return to the anxious wait for a successful transplant."[754]

End of life

108. As previously highlighted, a number of our CPs died due to their infection with HCV, HBV and/or HIV.[755]

109. A number of our CPs faced difficulties following their loved ones' death, particularly in relation to funeral arrangements and death certificates. For example, funeral directors refusing to embalm their loved one's body or handle the body in any way, which was deeply upsetting and stressful for all the family to deal with at a time of immense grief[756] as once again it made it feel like their loved one was "*dirty*".[757] Others had undertakers insist on using a lead-lined coffin[758] or told people they had no choice but to opt for their loved one to be cremated.[759] One CP said that the funeral directors

[754] W2635 §20

[755] W1846 §2, W3693 §11, W3697 §32, W3326 §15, W1848 §30, W2689 §24, W2004 [ANON] §28, W2709 §27, W2703 §57, W1981 §18, W2643 [ANON] §44-46, W2643 [ANON] §44-46, W1817 §31, W3914 §32, W3710 §27, W1974 [ANON] §44, W3920 §8, W3918 §6-7, GRO-D W1966 §43, GRO-D W2039 §39, GRO-D §6, W2707 [ANON] §29, W2011 [ANON] §9, W1850 §46, 47, W2819 §3940, W2057 §15, 19, GRO-D W3326 §20, 21, W2033 §1, W2028 §48-49, W2019 §12, W1917 §21, W2869 §18, W0709 §43, 45, W1965 §15-17, GRO-D W1867 §50, W1941 §51, W1883 §22, W1832 §32, GRO-D W2710 §23, W1980 §20, W2044 §19

[756] W2703 §57, W1848 §30, W1883 §30, W2689 §29

[757] W1848 §30

[758] W2004 [ANON] §37

[759] W1981 §18, W2643 [ANON] §44-46

refused to dress their loved one and said they would bury him in a body bag.[760] As one CP explained:

> *"The stigma continues even after death. I went to Co-op to arrange my funeral plan as I had read that the Caxton Foundation would pay £3,500 towards it. I was informed by the funeral directors that due to the Hepatitis C they would not be able to touch my body or to embalm me. They said that I would be sealed in a black bag marked as an infection risk and that no family members would be able to see my body. I cannot begin to express how emotionally distressed this makes me feel. This has also had a huge emotional impact on my husband and my son".*[761]

110. In relation to death certificates, a number of our CPs describe that something other than HCV, HBV or HIV was listed on their loved one's death certificate despite their protestations;[762] for example, open verdict;[763] pneumonia;[764] liver failure and deconstruction of the liver by malignancy;[765] GRO-D GRO-D [766] alcoholic liver disease;[767] septicaemia and leukaemia,[768] even though, in a number of these cases, the families were refused a post-mortem.[769] Other CPs had their requests for HCV to be listed on the death certificate conceded to but were refused a full post-mortem.[770] In one case, the daughter of the deceased refused to sign the death certificate because it did not mention HCV but she was told her mother's body would not be released for burial if she did not sign it.[771]

111. Finally, those who lost a loved one describe the total devastation of watching them suffer and their health deteriorate.[772] As one CP describes:

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[760] W1817 §31
[761] W1974 [ANON] §44
[762] W1966 §43, GRO-D W3918 §22, W1848 §21
[763] W3710 §27
[764] W3920 §8, W2039 §39, W2819 §39-40
[765] W3918 §6-7
[766] GRO-D
[767] W2011 [ANON] §9
[768] W2057 §15, 19
[769] W3920 §8
[770] W1850 §46, 47
[771] GRO-D W2707 [ANON] §29
[772] W3326 §20, 21, W2033 §1, W2028 §48-49, W2019 §12, W2689 §18, W1917 §21, W2869 §18

"Hammersmith Hospital discharged [Y], within his final days, to die at home. [Y] was so distressed at this decision, the blunt result, he refused to allow them to remove the 'Hickman' line. I remember him crying, shaking his head, begging to be allowed to live; I felt his internal sob. I suppressed a scream. This anxiety will never leave me; evermore I will see this - sometimes totally overwhelmed by this vision, looking from the window in the hospital - the external wall clock partially in darkness as it was an early morning in October 1986".[773]

112. Death from the consequences of HCV, HBV and HIV is deeply distressing and often involves significant pain.[774] One CP was unable to be with their loved one in their final moments as they died in quarantine and alone.[775] Our CPs describe the accumulated cost to the mental health of affected family members following the early death of a loved one; how this left families fractured and mentally scarred and had a long-lasting mental health impact that redefined their lives.

Impact on treatment for other conditions

113. A number of our CPs commented that their HCV, HBV or HIV infection impacted on the dental care they received.[776] Many of our CPs describe being told by their dentist that they could only be seen at the very end of the day.[777] They describe that they were treated like a leper,[778] causing some of our CPs to stop going to the dentist at all[779] or changing to a different practice.[780] In other cases, dentists refused to treat those infected[781] or would make a point of putting on two masks and pairs of gloves to treat them and frantically sterilising equipment afterwards.[782] This was

[773] W3914 §29
[774] W2689 §23, W0709 §43, 45, W1965 §15-17, W3326 §20, 21, W1917 §21, W2869 §18, GRO-D, W2869 §18, W1867 §50, W2709 §27, W1941 §51, W1883 §22, W2709 §27
[775] W1846 §22
[776] W1818 §33, W1970 §30, W1814 §24, W1968 [ANON] §21, W1928 §42, W1901 §41, W1998, W1991 §32, W1966 §35, W1832 §27, W1980 §25
[777] W1928 §42, W1875 §15, W2702 §30, W1974 [ANON] §42, W1943 §37, W1885 §31, W1907 [ANON] §36, W1910 §31, W2641 §30-31, GRO-D
[778] W2036 §36, W1818 §33, W1893 §26
[779] W1818 §33, W1991 §32, W1966 §35, W1943 §30, W2631 [ANON] §27
[780] W1928 §42
[781] W1970 §30, W1814 §24, W1968 [ANON] §21, W1998 §41, W1901 §41, W2013 §27, W1988 §47, W3713 §33, W1974 [ANON] §42, W1943 §37, W1860 §39, W2631 [ANON] §27, W2012 §57, W1935 §34, W1906 §31, W1832 §27
[782] W2036 §36, W1834 §36, W1860 §39, W2631 [ANON] §27, W2641 §30-31

embarrassing and humiliating[783] and lead to severe consequences for their dental health; for example, one CP suffered a painful abscess for two years because they were unable to find a dentist who would treat them.[784] This was especially difficult for our CPs whose infection caused deterioration in their teeth therefore requiring dental treatment.[785]

114. In relation to treatment for other conditions, a number of our CPs commented that they are always at the end of the list for treatment at hospital,[786] the doctors were always wearing gloves and masks,[787] and all the equipment had to be double-bagged afterwards,[788] making people feel stigmatised.[789] One CP developed such a distrust of the medical profession because of the way in which they were infected that they did not seek help or treatment for other conditions and instead lived in pain for many years.[790] Another CP expressed a fear and belief that they would not get the right or necessary treatment because they would be regarded as "*damaged goods and not worth investing in.*"[791] Finally, a number of our CPs describe their concern that because their medical records had been "*lost*", they felt unsafe going for procedures and treatment because the treating professionals did not have details of their pre-existing medical conditions and surgical history.

Support

Attitude of healthcare professionals

115. A number of our CPs, particularly those who were diagnosed many years after they were infected, commented that they felt as if a deliberate decision was taken by

[783] W1875 §15, W1966 §35, W1943 §30, W2702 §30, W1988 §47, W1871 [ANON] §34, W2641 §30-31, W1832 §27
[784] W2013 §27
[785] GRO-D W2012 §57, W1902 [ANON] §48-49, W1925 [ANON] §36
[786] W2059 [ANON] §35, W1934 §52, W1966 §33, W2002 [ANON] §29
[787] W2042 §41, W1907 [ANON] §27, GRO-D
[788] W1966 §33
[789] W1934 §52
[790] W1879 §58
[791] W1908 [ANON] §36

healthcare professionals to keep the infection secret[792] and withhold information from them,[793] particularly those who were tested without being told what the tests were for or the outcome.[794] For many this led to them losing faith in the medical profession[795] and some stopped attending appointments altogether.[796] It also meant individuals would be unaware that they had a serious condition which left untreated would cause serious damage.[797] In other cases, individuals felt like they were unable to make an informed decision about treatment because they felt unable to get genuine advice from healthcare professionals.[798]

116. Our CPs describe how they have been treated differently and stigmatised by healthcare professionals due to their infected status and made to feel like they were bottom of the pile for everything.[799] Our CPs recall experiences of receiving dirty and judgmental looks from staff,[800] having the ambulance service refuse to come to the house,[801] nurses refusing to take blood or provide care,[802] hospital staff not providing them with food or drink,[803] organisations refusing to offer palliative care,[804] never being made to feel like a priority and instead being made to wait until the end of the day to receive care,[805] and being made to wait hours to receive care or treatment.[806] Individuals infected with HCV, HBV and HIV via contaminated blood also describe how they felt upset and stigmatised by always being placed on a bay in the hospital with those who had contracted HCV, HBV and HIV in other ways, such as through drug or alcohol misuse, and treated as if they had also contracted the infection in that way, often even when their medical notes clearly stated they contracted the infection

[792] W3103 §46, W1889 [ANON] §49, W1938 §26, W3323 [ANON] §31
[793] W1879 §44-45, W1905 §46-52
[794] W1879 §44-45, W1889 [ANON] §49, W1938 §26
[795] W1879 §44-45, W1905 §46-52
[796] W1879 §44-45
[797] W1889 [ANON] §49, W1938 §26
[798] W1905 §46-52, W2645 §32
[799] W1926 §36, W968 [ANON] §22, §14, W1896 §23, W1923 §8, W1922 [ANON] §20, W1832 §48, W3712 §25
[800] W1886 [ANON] §45, GRO-D , W1921 [ANON] §41, W1901 §42
[801] W2643 [ANON] §29, W2643 [ANON] §20-22
[802] W2643 [ANON] §29, W1947 [ANON] §61, W1934 §51, W1832 §48
[803] W2643 [ANON] §29, W2643 [ANON] §20-22
[804] W1867 §60-61
[805] W2819 §8, W1988 §46, W1921 [ANON] §41, W2690 [ANON] §35, W1832 §10
[806] W1832 §30

through blood transfusion or blood product.[807] This makes people feel humiliated.[808] A number of our CPs describe how it is only when they personally explained and educated medical staff about how they contracted the infection that they were treated with respect.[809]

117. A number of our CPs comment on the distinct lack of education, understanding, awareness and sensitivity about the fact that many individuals were infected because of blood transfusions or blood products given by the NHS rather than because they made risky lifestyle decisions; there was a presumption that they were at fault and somehow responsible for their illness.[810] One CP describes their loved one having alcohol gel removed from their bedside.[811]

118. Not only is there a lack of education and understanding about how individuals become infected but also about the infection itself and how to diagnose it.[812] The concerning consequence of the lack of understanding displayed by those in the medical profession is that the infection and its impact is trivialised, with people made to feel like there is nothing to worry about.[813] A number of our CPs describe the medical profession failing to correctly diagnose them, dismissing and trivialising their symptoms, and pointing to other causes of their symptoms (often suggesting they were psychosomatic), delaying them receiving the correct treatment and causing more damage.[814] Others describe how when they asked their GP (and sometimes even specialists) questions

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[807] GRO-D, W3326 §30, W968 [ANON] §22, W2819 §8, W1923 §8, W1996 [ANON] §38, W1901 §42, W1934 §51, W1966 §36, W2991 §57, 58, W5209 §26, 28, W3692 §28, W1963 §10, 22, W1974 [ANON] §40, W1982 §10, W2012 §62, W1880 [ANON] §29, W1889 [ANON] §28, W1899 [ANON] §9, W0031 [ANON] §4.1, W1921 [ANON] §17, 18, W1991 §15, W1932 §16, W0072 §25, W2009 §11, W1857 [ANON] §11, W3325 §15, W2009 §40, W2009 §41-42, W2012 §12, W1889 [ANON] §54, W3324 [ANON] §11

[808] W1947 [ANON] §61, W1908 [ANON] §35

[809] W3326 §30, W1996 [ANON] §38, W1901 §42, W1966 §36, W1966 §36, W3710 §12, W1901 §28, W1928 §40, W2009 §41-42

[810] W2635 §21-23, W1966 §36, W3710 §12, W1901 §28, W1928 §40, W2991 §57, 58, W1963 §10, 22, W1974 [ANON] §40, W5209 §26, 28, W3692 §28, W1982 §10, W2012 §62, W1880 [ANON] §29, W1889 [ANON] §28, W1899 [ANON] §9, W0031 [ANON] §4.1, W1921 [ANON] §17, 18, W1991 §15, W1932 §16, W0072 §25, W2009 §11, W1857 [ANON] §11, W3325 §15, W2009 §40, W2009 §41-42, W2012 §12, W1889 [ANON] §54, W3324 [ANON] §11, GRO-D GRO-D

[811] W2635 §21-23

[812] W3918 §13, W1838 §54, W1921 [ANON] §44, 45, W1829 §14, GRO-D W1820 [ANON] §5, W0065 §18 (second statement), W1868 §23, W3920 §7, W1945 §44, GRO-D

[813] W1111 §14, GRO-D W1871 [ANON] §31

[814] W3918 §13, W2001 §7, W1967 [ANON] §8, 10, W1934 §13, W3325 §25, W1871 [ANON] §7-8, 11, W2631 [ANON] §35, W1896 §7, W2696 §28

about the condition, they would not have the answers or seemed to know very little about the condition and were therefore unable to give them basic information about their prognosis and treatment options.[815] As one CP describes: "*Back in 1992 it felt like it was an unknown virus. I think that I learned as the medical profession learned.*"[816] This was described as particularly frustrating by CPs who knew that there was significant evidence available from organisations such as the Hepatitis C Trust about the link between certain symptoms and HCV, HBV and HIV, but it seemed the NHS were completely unaware of this and unwilling to engage with it or educate themselves.[817]

119. Our CPs would then often have to wait – while the sense of anxiety and uncertainty grew – until they were referred to a specialist who could provide them with more information.[818] Some of our CPs who tried to suggest to doctors that they had been infected with contaminated blood via blood product or transfusion – or that this possibility should at least be investigated - describe feeling ignored, dismissed and made to feel that the onus was on them to prove any links between the blood transfusions and HCV, HBV and HIV.[819] The lack of understanding and the inability to provide people with the information they so desperately needed made people feel frustrated and angry, completely alone and let down, and like they did not matter.[820] As has been previously highlighted, this inevitably caused many to lose faith in the health system,[821] and some of our CPs opted to pay for private treatment in order to try to get answers and care.[822] As one CP explains:

> *"Over the years, as I have learned more and more about this scandal, I have become angrier about it. I understand better now the seriousness of it. I was brought up to respect the National Health Service; our public health service. I cannot describe how angry I feel to know that it was this public health service that*

[815] W1987 [ANON] §9, W2013 §10-11, W2819 §10, W1963 §10, 22, W1963 §9, W2690 [ANON] §18, GRO-D
[816] W1826 [ANON] §14
[817] W5209 §14, 15 W1829 §14, W0065 §19 (second statement)
[818] W2702 §21, W2690 [ANON] §18
[819] W2991 §57, 58, W1823 §20, 34, 39
[820] W1963 §10, 22
[821] W1963 §10, 22, W1967 [ANON] §8, 10, W1921 [ANON] §44, 45, W1902 [ANON] §15
[822] W1934 §13

infected me with this disease. I am angry that the system did not protect me when it should have done. I have trusted that the system including the medical profession would have to take care of me for years. My mum did too. That trust has gone and I have been left feeling totally vulnerable as a person and completely let down. I feel particularly vulnerable because I now have to seek help from the system that has hurt me so badly. I simply cannot trust it now."[823]

120. A number of our CPs describe being treated with little or no respect, compassion and empathy by medical professionals.[824] Our CPs describe feeling that they felt seen as an infection and not a person,[825] that medical professionals did not want to take time to understand the history behind the infection,[826] and would frequently ignore or dismiss those infected.[827] For example, one CP was told that there was no point in her trying to have a child as she would be dead soon,[828] another person was shouted at by a nurse who said *"get out you are infectious"*[829] and another person recalls being rung by a consultant after her husband's death to ask if she was happy with the treatment he'd received, suggesting that they were more concerned about whether she would bring a claim against the NHS than whether she was coping.[830]

121. A number of our CPs commented on the fact that healthcare professionals repeatedly mentioned how expensive treatment was, making them feel guilty, angry and frustrated.[831] This was particularly so when the cost meant a delay in treatment which led to a deterioration in the person's condition.[832] One CP commented that a radiographer even said to them in a sarcastic tone: *"it's wonderful what the taxpayers' money is being spent on."*[833]

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[823] W1963 §10, 22
[824] W1988 §9, W1885 §33, W1991 §15, W2639 §25, GRO-D , W1859, W1905 §26, W1913 §20, W2696 §28
[825] W2639 §24
[826] W2639 §25, GRO-D W1859
[827] W2009 §41-42
[828] W1988 §9
[829] W1885 §33
[830] W1968 [ANON] §29, W2696 §33-34
[831] W2629 [ANON] §34, W2009 §36, W1890 §21, W1967 [ANON] §8, 10, W1941 §57, W1895 §20, GRO-D W0031 [ANON] §6.9, W1935 §22, W3324 [ANON] §22, W2696 §13
[832] W1895 §20, W1899 [ANON] §31
[833] W0031 [ANON] §6.9

122. Many CPs described that their experience of and treatment by the medical profession improved after they met their specialist HCV, HBV or HIV nurse; these nurses gave more informed advice, explained what the infection meant and what to expect, and set patients' minds at ease.[834] However, unfortunately, this was sometimes only arranged years after infection and diagnosis.[835] One CP even took it upon themselves to tackle the lack of understanding and empathy with her doctor:

> *"I also saw Dr [Z] at this time and was a year clear of HCV. Dr [Z] did not recognise me and appeared to be shocked by my fitness, weight loss and how well I looked. I felt she had assumed that I had previously just been fat and lazy and that the HCV had no impact on my life. I was much more confident at that appointment than when she had seen me in previous years because I was feeling so much better, and I was able to say how I felt about how she had treated me in the past. I told her how angry I was at how she did not listen to me when I was first in her clinic, and how she had made assumptions about my lifestyle from the way I used to look, which, as she could now see, where not valid. She apologised and said that she could see that now and said her opinions of people with HCV had changed over the past year. I asked her not to make assumptions and judge people who have HCV, and not to assume they were either alcoholics or drug users (not that this should matter). I asked her to see in me the direct impact of HCV on a person, as I had no other medical issues apart from HCV, so in me you can see the effects the virus has, both physically and mentally. I believe that, until that moment, she had not realised how much an effect the virus can have on its own. When I left the appointment, I was pleased to have been able to talk to Dr [Z] frankly about these issues and grateful to her for her apology and her change of heart."*[836]

[834] W1818 §50, W2631 [ANON] §16, W2041 §20 W2059 [ANON] §16
[835] W1818 §50
[836] W2000 §44

Access to psychological support

123. One of the most consistently recorded facts in evidence from IAP is that they were offered no psychological support or counselling after diagnosis or during treatment,[837] despite severe psychological symptoms being so common to be almost universal amongst IAP. A number of our CPs commented that they wished that counselling had been made available to them.[838] Similarly, a number of our CPs were not offered or provided with information about support groups.[839] Many felt isolated, knew no one else who had the virus, and therefore had no one to speak to who truly understood what they were going through.[840] Conversely, two CPs who were offered a support group to attend sometimes did not find it particularly useful, as the majority of people in attendance at the groups were those who became infected due to drug use, alcohol use or sex.[841]

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[837] W2055 [ANON] §36, W1820 [ANON] §29, W2009 §51, W1923 §36, W1817 §34, W2635 §11, W3103 §42, W2690 [ANON] §47, W1822 [ANON] §30, W1826 [ANON] §34 and 35, W3692 §48, GRO-D W3693 §62, W1111 §38, W1829 §47, W2005 §42, W0622 §55, W2853 [ANON] §30, W1857 [ANON] §43, W1860 §41, W1953 §48, W1820 [ANON] §29, W2009 §51, W3325 §33, W1868 §21, 33, W1871 [ANON] §45, W1876 §39, W1886 [ANON] §48, W1888 §39, W1890 §32, W1893 §31, W1895 §29, W1899 [ANON] §51, W1900 [ANON] §45, W1902 [ANON] §51, GRO-D W1905 §72, W2017 §49, W1906 §44, W1907 [ANON]§45, W1910 §17, W1913 §37, W2019 §47, W2641 §38, W1921 [ANON] §54, W1922 [ANON] §51, W1929 §16, W1934 §65, W1935 §43, W1943 §39, W1945 §57, W1951 §49, W3713 §30, W3713 §44, GRO-D W1960 §45, W5209 §35, W1963 §38, W2036 §39, W2701 §29, W1970 §40, W2645 §46, W1987 [ANON] §44, W1988 §54, W2059 [ANON] §48, W1990 §58, W2702 §37, W1991 §15, 38, W1992, W2062 §57, W1998 §58, W2000 §62, W2001 §17, W2002 [ANON] §37, W0394 §26, W1967 [ANON] §31, W2013 §28, GRO-D W1814 §31, W2689 §36, W3914 §63, W3915 §29, W1842 §32, W1846 §29, W2057 §29, W2628 §17, W1850 §60, W0709 §53, W1867 §83, W2819 §57, W1877 §30, W1882 §42, GRO-D, GRO-D, W2028 §18, 54, GRO-D GRO-D W1950 §50, W2033 §41, W1961 §42, W1962 §74, W2643 [ANON] §55, W1966 §37, W1968 [ANON] §28, W2039 §51, W1975 §42, W1977 §9, W2703 §70, W1994 §49, W2026 [ANON] §44, W1875 §25, W3710 §37, W2635 §30, W1987 [ANON] §44, W2028 §18, W1818 §42, W1963 §38, W2692 §51, W3713 §30, W1871 [ANON] §46, W1871 [ANON] §48, W2012 §79, W1907 [ANON] §47, W1867 §77-78, W2693 §25, W2691 §25, W2006 [ANON] §42, W2854 [ANON] §21, W3324 [ANON] §34, W2696 §38, W2820 [ANON] §33, W2712 [ANON] §20, W1846 §29, W2628 §17, W1848 §36, W1850 §60, W1867 §82, W2819 §57, W1877 §30, W1882 §42, GRO-D, W1917 §24, W3687 §44, GRO-D, W2028 §18, 54, W1942 §32, W2033 §41, W1961 §42, W2709 §36, W1962 §77, W2643 [ANON] §55, W2039 §51, W1975 §43, W1981 §26, W2703 §70, W1994 §49, W2031 §22, GRO-D, W3710 §37, W2635 §30, GRO-D W2960 [ANON] §24, W2959 [ANON] §40, W2872 §52, W3326 §37-38, W1846 §29, W2697 [ANON] §14, 15, W3323 [ANON] §50, W1824 §27, W1823 §48, W2012 §80, W1832 §22, GRO-D, W2020 §51, W3712 §29, GRO-D, GRO-D, W1980 §30, GRO-D GRO-D

[838] W1875 §24, 25, W5209 §37

[839] W2690 [ANON] §19, W1822 [ANON] §30, W1867 §77-78, W1891 §226, W1945 §47

[840] W2690 [ANON] §27, W1891 §226

[841] W1838 §58, W1829 §16

124. Those who did receive counselling often had to fight and actively seek it out,[842] had to wait months or years before being offered it,[843] or had to pay for it themselves,[844] only to find their counsellor did not have the relevant or appropriate experience[845] or that the set programme ended after a certain number of weeks despite them still needing support (often because the funding ended).[846] One CP commented that her counsellor failed to address the issues that had been caused by the infection, the consequences of the illness, or the damage to their sense of trust.[847]

125. Crucially, the few who did receive the right counselling and support describe the incredibly positive and helpful impact it had, helping them to come to terms with the infection, manage their anxieties, trust again, cope during the treatment and heal.[848]

Inaccurate or insufficient information or advice

126. An overwhelming number of our CPs describe that they were not given enough support or information to help understand, live with and manage the infection, for example what to expect, the treatment options available and the risk of infecting

[842] W3326 §36, W1966 §38, W1921 [ANON] §54, W2043 §45, W1910 §39-40, W1922 [ANON] §51
[843] GRO-D, W1932 §79, 80, W1996 [ANON] §49, W1921 [ANON] §54, W2043 §45, W2000 §63, W2630 §32, W2696 §22, W0065 §17, W1889 [ANON} §77, 78, W2869 §12, W1950 §50
[844] W2043 §45, W2000 §63, W1834 §45, W1947 [ANON] §67 W1889 [ANON} §77, 78, W1822 [ANON] §27, W2853 [ANON] §16, W3916 §47, W2692 §41 – 42, GRO-D, W2590 [ANON] §39, W2019 §36, 47, 29 (second statement), W1934 §65, W1883 §36, W2869 §12, W1950 §50
[845] W1997 §59, W1921 [ANON] §54, W0065 §17, W1871 [ANON] §46, W1885 §49, W1902 [ANON] §47, W1919 [ANON] §42, W2697 [ANON] §14, 15
[846] GRO-D, W3326 §36, W1997 §59, W2043 §45, W1838 §59, W0065 §63, W1834 §45, W1947 [ANON] §67, W1921 [ANON] §55-57, W1921 [ANON] §55-57, W1925 [ANON] §37, W1922 [ANON] §51, W1889 [ANON] §77, 78, W2019 §36, 47, 29 (second statement), W1892 [ANON] §41
[847] W0580 [ANON] §47
[848] W1855 §57, W2853 [ANON] §16, W1987 [ANON] §21, W1892 [ANON] §41, GRO-D, W1919 [ANON] §43, W2634 §48, W2041 §16, W2694 §36

others.[849] Some individuals felt the infection was downplayed[850] and were simply given a leaflet to inform themselves, which was often difficult to understand as it was in medical language.[851] Even those who did receive helpful information commented that it was only provided because they directly asked for it; it was not routinely offered.[852] For others the information they were given was not delivered with empathy and sensitivity and did not alleviate their concerns but just added to the trauma.[853] For others the information provided was limited to advising that they use a condom using sex, avoid drinking alcohol and/or avoid sharing toothbrushes.[854] As highlighted above, many found that medical professionals were unable to provide more information and they did not know the answers to questions asked.[855] As one CP put it:

> *"I didn't understand what hepatitis was at the time. There was no way to get information about it other than relying on what doctors told you, as there was no*

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[849] W1829 §15, W1953 §13, W1818 §16, W3103 §28, W1868 §11, W0065 §10, 18, W1876 §13, W2012 §12, W1879 §27, W1880 [ANON] §13, W1885 §17, W0031 [ANON] §2.47, W1900 [ANON] §15, GRO-D W1905 §22, W1906 §8, 9, W1097 [ANON] §10, 13, W1908 [ANON] §12, 15, W1913 §9, 10, W2019 §20,W2641 §17, W1921 [ANON] §19, W1922 [ANON] §15, W1923 §5, W1925 [ANON] §9, W1935 §10, W1938 §12, GRO-D W3698 §22, W1943 §6-7, W1947 [ANON] §18, 19, W1949 §12, W1951 §11, W1954 §11, GRO-D W1960 §20, 23, W5209 §10, 14, W1963 §10, W2036 §16, W2701 §12, W2644 §10, W1970 §11, W1974 [ANON] §9, W1982 §12, W1987 [ANON] §9, W2042 §15, W1988 §10, W1990 §39, W2702 §9, W1991 §15, W1992, W1995 §12, W1996 [ANON] §14, W1997 §15, W2062 §16, W1998 §16, W2000 §7, W2002 [ANON] §12, W0394 §12, GRO-D GRO-D W1814 §9, 10, W2054 §12, W1819 [ANON] §12, W1821 §16, W1825 §14, W3914 §24, W1846 §9, W0709 §17, W1867 §26, W2819 §24, W1882 §11, W1901 §19, GRO-D GRO-D §17, W2033 §17, W1961 §12, W2643 [ANON] §13, W1968[ANON] §10, W2039 §17, W1975 §8, W1977 §9, W2703 §8, W2004 [ANON] §16, W2026 [ANON] §16, W1875 §7, W3326 §11, W1922 [ANON] §19, W1886 [ANON] §18, W2000 §16, W2004 [ANON] §16, W1926 §21, W2055 [ANON] §14, W3915 §6, GRO-D W2644 §10, 11, W2712 [ANON] §9, W1822 [ANON] §9, W1826 [ANON] §13, GRO-D W2005 §10, W2853 [ANON] §7, W3916 §17, W2629 [ANON] §12, W1860 §9, W1859, GRO-D W2590 [ANON] §10, W1820 [ANON] §8, W3325 §16, W0065 §14, W1871 [ANON] §15, 16, W1880 [ANON] §13, W1885 §17, W1886 [ANON] §18, W1890 §9, W1945 §8, W1111 §9, W1829 §10, W0072 §37, W2630 §14,W1925 [ANON] §7, 8, W1876 §15, W2012 §17, W1880 [ANON] §16, W1890 §8, 9, W1900 [ANON] §14, W1902 [ANON] §20, W1910 §16, W2958 [ANON] §11, W1858, W2696 §12, W1832 §19, GRO-D W2020 §15, 16, W3712 §12, GRO-D §14, GRO-D W2710 §12, W1980 §8, W2694 §18, GRO-D GRO-D

[850] W1922 [ANON] §19, W1880 [ANON] §16

[851] W2028 §19, 23, W2055 [ANON] §14, W1925 [ANON] §7, 8, W2631 [ANON] §13, 17, W1890 §8, 9 GRO-D GRO-D GRO-D

[852] W3103 §28

[853] GRO-D 5, W2690 [ANON] §13

[854] W1818 §19, W2712 [ANON] §9 W1820 [ANON] §8, W1879 §27,W1890 §8, 9, W1899 [ANON] §14, W1902 [ANON] §20, W1832 §11, W2020 §11, GRO-D GRO-D

[855] W1818 §17, W1900 [ANON] §14, W1906 §9, W1907 [ANON] §10

internet. If you had a doctor who was good and explained everything to you, you were lucky; if you had one who was dismissive, that is just the way it was."[856]

127. The impact of not being provided with adequate information and advice meant that some considered the worst-case scenario.[857] Others describe feeling very angry at the lack of information which meant they were unable to prepare for later life.[858] As is described by one CP:

"It was frightening and I was anxious because I did not know what the infection was or what it meant for me. No one seemed to care about the bombshell that has been dropped. No one seemed to care that the shock of this news was life changing. No one took any time to talk me through anything about the infection. It is scandalous - the NHS infected me and then just left me high and dry with no information and no support."[859]

128. The lack of information had significant consequences in circumstances where a person is not informed of the possibility of the virus "*re-activating*" even after they have been "*cleared*"; this means someone may not realise they need to continue to be tested even after "*clearing*" the virus, and the virus could return without the person knowing.[860]

129. Due to the lack of information provided by medical professionals, a number of our CPs undertook their own research and became reliant upon information they found online or at the library to educate themselves about how to manage the infection and what to expect.[861] This caused people to become more frightened, terrified and distraught about their future and the impact the infection will have[862] and meant people were

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[856] W3915 §6
[857] W2958 [ANON] §12, W2958 §26
[858] W1876 §15
[859] W2644 §10, 11
[860] W2009 §31, W1890 §22
[861] W1907 [ANON] §11, 12, W1900 [ANON] §14, W2639 §8, W2645 §16, W2637 §9, W1850 §26, W1995 §12, W1829 §15, W1871 [ANON] §17, W0031 [ANON] §2.49, W2055 [ANON] §45, W1822 [ANON] §12, W0065 §12, W1963 §10, W1838 §15, W1871 [ANON] §48, W1111 §15, 18, W2019 §20, W1876 §16, W1891 §10, W1905 §27, W1910 §16, W1925 [ANON] §10, W2713 §26, GRO-D, W3712 §12
[862] W1907 [ANON] §11, 12, W2637 §9, W2055 [ANON] §45, W1838 §15, W1871 [ANON] §48, W1111 §15, 18, W1829 §15, W1905 §27, W1925 [ANON] §10

often reading information that would be limited, fearmongering and unreliable.[863] One CP also commented that healthcare professionals would make her feel bad and paranoid for looking at information online, despite failing to provide the information themselves.[864]

Financial support

Interaction with trusts and schemes

130. The shortcomings of the trusts and schemes are discussed at length in the chapter of our submissions dedicated to that issue, where we also highlight some of our CPs' experiences. We seek here to give a wider overview of the general experience of our clients.

131. A large number of people have never received any financial assistance from trusts and schemes as a result of being infected with contaminated blood.[865] Some CPs commented that they were never told about or made aware of the available financial assistance schemes[866] or they only found out from their solicitors at the start of the Inquiry,[867] from a fellow clinic friend,[868] or through their own online research.[869] Many individuals only found out about the financial assistance years after they were diagnosed,[870] by which time it was often too little too late as people principally needed the financial help when they were first diagnosed and undergoing treatment.[871] Others commented that information about the schemes was poorly disseminated,

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[863] W2639 §8, W2645 §16
[864] W1111 §15, 18
[865] W1818 §43-46, W2005 §44, W3103 §43, W2690 [ANON] §48, W2055 [ANON] §38 – 41, W2630 §34, W0671 [ANON] §45, W2590 [ANON] §41, W1953 §50 – 51, W1890 §33, W1894 §35, W2637 §46, W2638 §34, W2641 §40, W1929 §19, W3713 §45, W1967 [ANON] §32, GRO-D, W1814 §32, W2689 §37, W1823 §49, W2870 §25, W3914 §64, W3915 §30, W1846 §30, W2011 [ANON] §48, W1917 §25, W3697 §46, W2991 §68, GRO-D §35, GRO-D W3918 §23, 21961 §44, W2643 [ANON] §56, W2039 §52, W1975 §45, W1981 §27, W3920 §21, W1875 §26, W3710 §38, W3918 §23-24, W1829 §44, W3325 §34 – 38, GRO-D, W2009 §57, W1968 [ANON] §37-38, W5209 §40 – 42, W2693 §26, W2854 [ANON] §24, W2696 §43, GRO-D W2020 §52, W3712 §27, GRO-D, GRO-D W2710 §35, W2694 §38, GRO-D
[866] W3692 §51, W1951 §51, W1917 §25, W1980 §31, GRO-D
[867] W2055 [ANON] §37, GRO-D, GRO-D
[868] W1826 [ANON] §37 - 40
[869] GRO-D W3693 §66, W1980 §31
[870] W1818 §44, W1826 [ANON] §37 - 40
[871] W1826 [ANON] §42

leaving IAP unsure of what assistance they would be eligible for or how to apply.[872] Others who were infected with HBV or via Anti-D serum were told that there are no financial schemes for those infected with HBV through infected blood.[873] Similarly, those who have cleared the virus are not eligible for financial assistance regardless of the impact the infection may have historically had.[874] Some of our CPs were diagnosed before the Skipton Fund came into existence,[875] whereas others were told that because they were never granted Skipton stage 1 payments, they were unable to claim from the new England Infected Blood Support Scheme ("**EIBSS**") scheme.[876] Others were refused assistance because they received contaminated blood in 1992, after the September 1991 cut-off date when it is alleged that all blood was screened for infections.[877] Some of our CPs comment that they should have been given information about funds sooner, and that they find it incomprehensible that the funds were not made known to all patients automatically.[878]

132. A number of our CPs who did try to apply for financial assistance experienced difficulties, and in many cases rejection of their application, due to the lack of medical records or documentation which evidences how they were infected.[879] In a number of cases this is because the individual's medical records had been destroyed by the hospital or the relevant part of it is "*missing*".[880] In other cases, individuals have struggled to gain access to their medical records or track down the relevant record.[881] For some, their application has been refused despite having a note from their doctor

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[872] W3103 §43, W1876 §46

[873] W0671 [ANON] §45, W2590 [ANON] §41, W1951 §51, W1917 §25, W1906 §40, W3710 §3839, W3712 §32

[874] GRO-D

[875] W1829 §44

[876] W0622 §57 - 60

[877] W2005 §44, W0622 §57 - 60

[878] W1818 §49, W1826 [ANON] §42, GRO-D

[879] W1929 §19, W2042 §50, W0709 §58, W1967 [ANON] §32, W1838 §63, W2690 [ANON] §48, W2055 [ANON] §38 – 41, W1818 §39, W1826 [ANON] §37 – 40, W2630 §34, W1682 §30 – 31, W1818 §46, W3710 §38-39, W1892 [ANON] §43, GRO-D , W2011 [ANON] §49, W5209 §40 – 42, W1932 §82 GRO-D W2694 §38, GRO-D

[880] W0709 §58, GRO-D , W1967 [ANON] §32, W2690 [ANON] §48, W2055 [ANON] §38– 41, W1818 §39, W1826 [ANON] §37 – 40, W2630 §34, W1682 §30 – 31, W1818 §46, W3710 §38-39, W1892 [ANON] §43, GRO-D §44, W2011 [ANON] §49, W1932 §82, W1967 [ANON] §36

[881] W1838 §63, W2690 [ANON] §48, W2055 [ANON] §38 – 41, W1818 §39, W1826 [ANON] §37 – 40, W2630 §34, W1682 §30 – 31, W1889 [ANON] §82 – 84, 86

on the basis that this was not an official medical record;[882] others have only been successful in their application because of their own record retention.[883] In another case, one CP had their request for funding for a specialist bed refused because their GP was unable to confirm that the cause of their need for the bed was *definitely* HCV; they described this as deeply upsetting, that it is bad enough to have to beg for something comparatively minor, but then to have it refused is cruel.[884]

133. The time taken to track down the medical records and fill out the forms to apply for financial assistance to support their application not only took time and energy – often at a time when the individual was feeling unwell, suffering the side effects of the infection, or going through treatment – but also meant there was a delay in the individual receiving assistance when they often needed it most and without the payment being back-dated to the date of infection or diagnosis; this causes extreme suffering and hardship as well as resentment.[885] As one person said: *"you need the money when you're sick, not when you're dying."*[886]

134. Our CPs do not describe the experience of applying for financial support favourably; instead, it is described as time consuming, arbitrary, bureaucratic, confusing, humiliating, stressful, difficult and a demeaning process, requiring you to go cap in hand and jump through hoops.[887] They describe being made to feel like they were committing fraud,[888] being treated with contempt and disdain,[889] having a *"nerve-wracking"* wait while their application is determined,[890] being provided with no

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[882] W2055 [ANON] §38 – 41, W1818 §49
[883] W1826 [ANON] §37 - 40
[884] W1921 [ANON] §63-64
[885] W1954 §239, W1921 [ANON] §61, W1913 §41, W2043 §48, W2000 §70, W1819 [ANON] §41, W1991 §43, W0581 [ANON] §35, W2028 §50, W2645 §55-56, W1111 §44, 45, W1876 §46, W1900 [ANON] §47, W2959 [ANON] §26, GRO-D , GRO-D
[886] W2645 §55-56
[887] W2703 §78, W2028 §50, W0709 §61-63, W1968 [ANON] §37-38, W1967 [ANON] §36, W2000 §70, W1997 §65, W1998 §66, W1991 §43, W1970 §43, W1960 §49, W1988 §58, W1987 [ANON] §46, W2028 §50, W1922 [ANON] §55, W2629 [ANON] §50, W1963 §43, W2690 [ANON] §49, W1822 [ANON] §36, W1829 §51, W2692 §55, W0072 §58, W0622 §57 – 60, W2630 §34, W2629 [ANON] §50, W1860 §44, W1859, W2853 [ANON] §33, GRO-D W2629 [ANON] §50, W1111 §44, 45, W1858, W0065 §72, W1885 §54, W1889 [ANON] §82 – 84, 86, W1891 §29, W1892 [ANON] §45, W2696 §39, GRO-D , GRO-D
[888] W2644 §18, 26-28,
[889] W2644 §18, 26-28
[890] GRO-D

certainty,[891] having obstacles deliberately put in their way,[892] being made to feel like they were begging,[893] making them feel completely out of control,[894] and depriving them of their dignity.[895]

135. A number of our CPs state that they feel the funds made it difficult for them to apply by never volunteering any information, meaning people only found out things if they asked the right questions.[896] They also describe that people at the fund would refuse to accept the way in which they had contracted the infection and instead suggest they must have contracted the infection through drug use or alcohol misuse.[897] Our CPs also describe that when they speak to people at the fund, they make you feel like you are an inconvenience, are unsupportive, come across as uninterested and are slow to pick up the phone, which delays the process of applying even further.[898]

136. Our CPs have also expressed concern that the onus was entirely on them to be pro-active and persistent in applying and finding the necessary evidence when, as a member of the public, it is more difficult for them to contact and demand paperwork from hospitals than a public funding scheme.[899] Further, our CPs describe their particular frustration that the burden of all the administration and evidence gathering to apply falls to them when they were infected through no fault of their own; instead it is suggested that compensation should be provided to all those infected automatically.[900]

137. Some of our CPs have received some financial assistance from the Skipton Fund and/or EIBSS and/or the Caxton Fund and/or the McFarlane Trust.[901] For many, those

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[891] W2703 §78 GRO-D

[892] W1998 §66

[893] W1925 [ANON] §41, 42, W2028 §50, W1900 [ANON] §47, 49, W0072 §58, W1876 §46

[894] W1963 §43

[895] W1889 [ANON] §82 – 84, 86

[896] W0709 §61-63

[897] W0709 §61-63

[898] W2692 §56, W2009 §56, W1868 §34, W2696 §39

[899] W0709 §61-63, W2853 [ANON] §33, W1859, W2630 §34, W1868 §37, W1892 [ANON] §45, W1962 §88-89

[900] W1997 §65, W2853 [ANON] §33, W1859, W2630 §34, W1868 §37, W1892 [ANON] §45, W1962 §88-89

[901] W1822 [ANON] §36, W1826 [ANON] §37 – 40, GRO-D W1838 §63, W3693 §66, W1829 §51, W2692 §55, W1820 [ANON] §31, W2631 [ANON] §37-41, W1871 [ANON] §52, W1876 §40, W1878 §43 – 45, W2012 §84, W1879 §72, W1885 §52-53, W1886 [ANON] §50, W1888 §43, W1889 [ANON] §81, W1892 [ANON] §42, W1893 §32-33, W1895 §31, GRO-D , 46, W1899 [ANON] §53, W1900 [ANON] §47, W1902 [ANON] §52,

payments have made a substantial difference, and are described by some as lifesaving and a saviour, helping to ease the stress of being on a low income and, in some cases, preventing individuals from losing their home or business.[902] They have also helped people to build a safety net after their finances have been destroyed by the infection[903] and mean some of our CPs are not forced to work when they are unwell or undergoing treatment.[904] Successful applicants rely heavily on the financial support they receive[905] and some would not know how they would survive without the money.[906] Conversely, the consequence of having received no financial assistance is grave, with many living on state benefits[907] or being unable to afford carers despite suffering severe health conditions.[908]

138. However, even those CPs who have received payments state that while they are grateful for them the fact they have to re-apply on an annual basis and receive monthly payments – on a "*drip-fed*" basis – without any guarantee of whether and for how long they will continue, deprives them of any sense of financial security, reassurance, independence or control; their income hangs in the balance and payments could go up, down or just be taken away with no warning or explanation, leading to a constant heightened sense of anxiety, forcing them to live hand-to-mouth, and preventing them from making any independent financial investment

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W1905 §72-76, W1907 [ANON] §49-52, W908 [ANON] §56-58, W1910 §42, W1913 §38-39, W2019 §48-50, W1919 [ANON] §44, W1922 [ANON] §5, W1923 §237-38, W1925 [ANON] §38, W1932 §83, W1934 §68, W1935 §45, W1938 §58, GRO-D, W1943 §40, W1945 §60, W1947 [ANON] §71, W1954 §39, GRO-D, W1960 §46, W5209 §42, W1963 §39, W2036 §40, W1970 §41, W2645 §48, W1972 §48, W1974 [ANON] §55-57, W1982 §26, W2041 §43-44, W1987 [ANON] §45, W1988 §55, W2059 [ANON] §17, W1990 §60, W2043 §47, W0580 [ANON] §50, W2702 §38, W1991 §41, W1992, W1992 §54, W1996 [ANON] §50, W1997 §64, W2062 §62, W1998 §66, W2000 §67, W2001 §16, W2002 [ANON] §38, W0394 §27, W1999 §46, W2013 §30, W2634 §49, GRO-D, W1819 [ANON] §41, W1821 §52, W1825 §36, W1842 §33, W1848 §38, W1850 §62, W1867 §84, W2819 §59, W1877 §31, W1882 §44, W1901 §56, W2028 §55, W1928 §57, GRO-D, W1950 §53, W2033 §43, W1962 §85, W1977 §34, W2703 §72, W1994 §51, W2004 [ANON] §70, W3326 §39, W1896 §33, W1822 [ANON] §36, GRO-D, W1383 §53, W2692 §48, W1832 §51, GRO-D, GRO-D

[902] W1990 §64, W2000 §68, 9, W1822 [ANON] §36, W1889 [ANON] §86, W1892 [ANON] §48, W1892 [ANON] §48, W1919 [ANON] §46, W1919 [ANON] §46, W1900 [ANON] §50

[903] GRO-D, W1892 [ANON] §48, W1900 [ANON] §50

[904] W2692 §48

[905] W1880 [ANON] §33

[906] W2696 §21

[907] W0622 §57 - 60

[908] W2012 §87

decisions.[909] Some of our CPs have to make a new application each time they want additional assistance and are obliged to provide multiple quotes to evidence the value they were requesting before waiting weeks or months for the application to be processed.[910] For example, our CPs who rely upon their car describe that when it needs repairs they have to find three quotes and then wait weeks for approval of the application during that time either going without a car or being forced to pay for it themselves.[911] Another CP describes how she had to provide three quotes and receipts to buy socks for her children.[912] Another CP describes supplying three quotes, and the fund choosing the cheapest one and then providing only half the amount.[913] Our CPs also describe how the fund is not set up to work in an emergency. For example, one CP's hot water and heating system broke, and they had to wait seven days before EIBSS approved the funding to pay for the repairs;[914] GRO-D

GRO-D

GRO-D As another CP explains:

> *"To have to apply for funding every time you want or need something, and then having to wait a month for a response which may not be what you hoped to hear, is not really how people want to operate. It would be much better to move towards a more regular income so that people can just live their lives rather than having to beg every time they need a new appliance. I do not believe that this kind of financial assistance is the right way to compensate people for what happened. I think that they should be provided with full and proper compensation, a sum which they can invest to give them income for the rest of their lives. These ex-gratia payments are not sufficient. There are people who are injured through medical*

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[909] W2028 §50, W1871 [ANON] §53, W2000 §68, 9, W1965 §24, W1954 §45, W2033 §46, GRO-D, W1999 §49-50, GRO-D, W1871 [ANON] §54, GRO-D

[910] W1987 [ANON] §46, W2645 §53, W1922 [ANON] §53, W1111 §44, 45, W1885 §54, W2026 [ANON] §50, GRO-D

[911] W1987 [ANON] §46, W1885 §54

[912] W1111 §44, 45

[913] W1922 [ANON] §53

[914] W1858

[915] GRO-D

negligence, and you hear of them getting half a million pounds. Ollie wanted proper compensation for what had been done to him and others. The monthly payments are not compensation, they are ex gratia payments. It had affected the lives of his children and may have contributed to the breakdown of his first marriage. If people infected with contaminated blood were given enough money to invest, this would mean that their families would be able to benefit from this money after their death. At the moment there is lots of discussion about whether the ex-gratia payments should be made to widows, parents, children. If proper compensation was paid in the first place all of these issues would fall away, it would be up to those infected, or their estate, to distribute the money how they saw fit."[916]

139. Our CPs have further commented that while they are grateful for the money received, the amount provided is inadequate and insulting, and that no amount of money can compensate for what has happened to them and the damage and loss it has caused;[917] this is particularly so for those who lost a loved one who question how value can be placed on someone's life.[918] Indeed, our CPs comment that the amount received seemed arbitrary and does not reflect the stress, anxiety and devastation suffered or their loss of earnings.[919] Others have commented that the amount of money they receive from the payments is not sufficient to enable them to catch up after years of poverty, and the cost of the damage done to their health and life opportunities, and that after they have paid their bills there is very little left.[920]

140. Other issues highlighted with the current compensation system include:

    a. The letter received offering financial assistance makes clear that there would be limits and certain pre-conditions put on the money they would be sent, and that

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[916] W1850 §70

[917] W1855 §65, W1888 §44, W1919 [ANON] §46, W1919 [ANON] §46, W1889 [ANON] §86, W2001 §16, W1962 §88-89, W2033 §46, GRO-D GRO-D W1842 §35, W1867 §89, W1825 §39, W2702 §39, W1960 §49, W1938 §63, W3693 §66, W3916 §53, W1857 [ANON] §46, W1860 §44, W1896 §35, W0031 [ANON] §7.9, W1907 [ANON] §53, W1934 §70, W2026 [ANON] §50, W2709 §38, W1935 §50, W2854 [ANON] §23

[918] W1900 [ANON] §50 GRO-D W2033 §46, W1842 §35, W1825 §39

[919] W2028 §55, W0580 [ANON] §50, GRO-D

[920] W2043 §51, W1889 [ANON] §86, W2001 §16, W1982 §27, W1960 §49, W1987 [ANON] §47, W3693 §66, W3916 §53, W1857 [ANON] §46, W1860 §44, W1857 [ANON] §46, W1935 §50, W2854 [ANON] §23

the money did not mean they were admitting fault; this made people feel like the money was a cheap solution and that no one had actually taken responsibility for what had happened to them and their loved ones;[921]

b. Only those whose infection developed into liver cancer could qualify for stage 2 Skipton Fund payments, when other individuals suffered equally severe and life-altering loss and harm by virtue of their infection and treatment;[922] one CP commented that even though their partner died of cancer it was not the right kind of cancer i.e. liver cancer, to qualify for stage 2 payments;[923]

c. That there are discrepancies in payments between those with HIV, HCV and HBV which seem to them to be unfair and arbitrary;[924]

d. Those affected by the contaminated blood scandal – rather than infected – also highlight that despite often being as affected by the tragedy as those infected, and suffering equal loss and financial hardship, they have been unable to qualify for any financial assistance.[925] In some cases, families who relied upon these payments were left in a difficult financial situation at a time when they were grieving, if their infected loved one passed away as the financial payments stopped.[926]

Access to welfare benefits system

141. For some, the lack of funding via trusts and schemes meant they had to rely on government benefits for a number of years.[927] A number of our CPs commented that they had a negative experience with the Department of Work and Pensions ("**DWP**").[928] Many people describe the assessment process to qualify for allowance (particularly employment support allowance and personal independent payments) as humiliating and degrading and they were treated with contempt and a complete lack

[921] W1938 §59, W2033 §46, W1901 §58, W1965 §26-27, W3323 [ANON] §54
[922] W1994 §53-54
[923] W1994 §53-54
[924] W1965 §26-27, W1825 §39
[925] GRO-D W2028 §57, W1821 §71, W3323 [ANON] §54, W1850 §53, W0709 §64
[926] W2028 §57, W1821 §71, W1850 §53, W1961 §49
[927] W0622 §41
[928] W1829 §39, W3326 §35, W0622 §60, W1867 §5971, W2059 [ANON] §43, W2013 §21, W1996 [ANON] §43-44, W2043 §46, GRO-D, 53, W0065 §35-37, W1889 [ANON] §71

of empathy. They describe it as a process that crushes people and leaves lasting damage.[929] They also describe the DWP as having no understanding of HIV, HCV and HBV and how it affects someone such that people were often judged and assessed to be "*work capable*" (and therefore ineligible for disability benefit) when they were clearly not capable and suffered severe and debilitating side effects.[930] Indeed, one person was assessed as fit to work on the same day that they were admitted to A&E to be resuscitated.[931] Another CP said they received a nasty letter after requesting reconsideration of their application insinuating that they were lying and there was nothing wrong with them.[932] Two CPs commented that they took their loved one to a DWP doctor's assessment who told them they were so ill they should not be attending the appointment, and then had the DWP administrators declare that they were perfectly fit and capable of working.[933] One CP had their application rejected on the basis that the symptoms of the treatment would come to an end when the treatment stopped and were therefore not indefinite.[934] For many this meant expending precious time and energy fighting to appeal the decision, often while they were unwell.[935] For some, the energy required to appeal the decision was an insuperable obstacle.[936] Others commented that the debilitating effects of the infection and treatment, or the need to care for their infected loved one, meant they were unable to work or apply for jobs rendering them unable to qualify for Job Seekers Allowance.[937]

142. Even those who did receive support from the DWP describe that it was offered in a way that was degrading and humiliating and the process made them feel as if they were begging;[938] for example, one CP describes being given £10 vouchers to pay for a

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[929] W1996 [ANON] §43-44, W1998 §52, W0065 §35-37, W2631 [ANON] §33, W1899 [ANON] §48, 56,
[930] W1829 §39, §44, W0622 §60, W3326 §35, W1945 §54, W1867 §71, W2590 [ANON] §42, W2013 §21, W1996 [ANON] §43-44, W1998 §52, W0581 [ANON] §34, W2631 [ANON] §33, W1889 [ANON] §74, W1832 §28
[931] W3326 §35
[932] W2059 [ANON] §43
[933] W1867 §5971, W1996 [ANON] §43-44
[934] W1934 §71
[935] W3326 §35, W0622 §41, W1901 §48, W1934 §71, W2012 §66-67, W1922 [ANON] §38
[936] W1996 [ANON] §43-44, W2013 §21, GRO-D, 53, W1832 §28
[937] W1829 §44
[938] W1111 §43, W0622 §41, W2638 §28, W1932 §77

washing machine which they had to stand and count at the counter in the store.[939] Others commented that the benefits they received were wholly insufficient, and they were still forced to rely on foodbanks.[940] Others also commented that the process to apply for benefits was impossibly difficult, stressful and long-winded, often with long delays between applying, being assessed, receiving a decision and eventually receiving the payments.[941]

Other issues

Failure of organisations, individuals and the Government to accept responsibility and take action

143. Our CPs describe the numerous ways in which they felt let down and ignored by those in a position to help and take responsibility:

    a. Receiving no support from the government or the NHS since being diagnosed.[942]

    b. Being treated with disregard compared to the support and compassion shown to those with other life-threatening conditions, making people feel under-valued by those in a position to help.[943]

    c. Having to battle with the authorities and governmental and NHS officials constantly to try and get the care and support they need, never feeling like the authorities were on their side and perpetually facing ignorance about the infection.[944]

    d. Writing to MPs for help but receiving nothing in reply.[945]

[939] W1111 §43
[940] W1868 §16, W2012 §66-67
[941] W1901 §48, W1966 §22
[942] W2055 [ANON] §45
[943] W1822 [ANON] §38
[944] W1829 §37
[945] W1829 §38

e. Feeling as if there was no way to right the wrong that had been done and carrying the burden alone.[946]

f. Feelings of injustice that the government denied accountability and then set some arbitrary cut-off to the fairly meaningless compensation.[947]

Research

144. A number of our CPs were – or suspected they were – involved in research in some way, including for example being entered on the HCV Register[948] which for some involved samples of their liver being taken and examined.[949] Some of our CPs consented to being involved in research, whereas others subsequently found out they had been involved in research without knowing; making people angry that they were not asked.[950] For one CP, they were required to take part in research in order to be part of a treatment trial.[951] Some of our CPs said they did consent to being part of a research study but they were never told what would happen, kept updated with progress or told the outcome:[952] "*I would occasionally ask about the progress when I came into give blood, and they would give vague answers, saying that the study was still ongoing, or thanking me for my participation, but without any update*"[953] One CP describes being subject to repeated consecutive liver biopsies for research without being offered pain relief which was incredibly painful, degrading and humiliating: "*it was as if I was not in the room but a body that they were working on. They were not talking to me, but talking about me, around me. It felt like I could have been a mannequin on the desk.*"[954] As another CP explained:

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[946] W2853 [ANON] §13
[947] W2960 [ANON] §22
[948] GRO-D , W2062 §33, W2853 [ANON] §3, W2002 [ANON] §23, W0065 §5-10 (second statement), W1871 [ANON] §27, W1922 [ANON] §18, W1945 §28, W1878 §28, W1879 §12, 32, 33, W1987 [ANON] §17, W1889 [ANON] §40-43, W1988 §17, GRO-D , W1832 §20, GRO-D GRO-D & GRO-D
[949] W2853 [ANON] §3, W1871 [ANON] §27, W1889 [ANON] §40-43
[950] W0065 §5-10 (second statement), W1879 §12, 32, 33 W1987 [ANON] §17, W1889 [ANON] §40-43, W1988 §17, GRO-D
[951] W1871 [ANON] §27
[952] W1945 §28, W1878 §28
[953] W1945 §28
[954] W1889 [ANON] §40-43

"I believe that Dr [Z] was using me for research without my family's informed consent. I knew that he was very interested in my condition and the fact that I was a female haemophiliac. When I was 15, he took me to a lecture hall in front of students to discuss my haemophilia. It was clear to me that I was part of a research study, but I don't remember being told any details about this. I do not know if my mother consented to my participation in the study, but she was not very well educated about these issues and would have gone along with what the doctors advised. […] My family certainly did not consent to Dr [Z] taking my medical records to America for his research, leaving my treating hospital without a copy to refer to. In addition to making it difficult for my new doctors to treat me without knowledge of my condition, taking these records abroad and using them in research without notifying me or my family was a breach of my privacy. I would not have let him do that if he had asked."[955]

Conclusion

"Unless you have been directly affected by this tragedy, it is impossible for anyone to understand the impact. It changes everything. You feel like a nothing, a nobody no matter what profession or position you hold. You tolerate unacceptable behaviour from medical professionals as you know that you are now classed as a contaminated being and no one else will probably take you on. Your life as you knew it is no more, a black cloud will follow you around for the rest of your life. You can blank it out and carry on as best you can but eventually it will eat you up."[956]

[955] W1879 §32, 33
[956] W1908 [ANON] §18

CHAPTER 2: THE ROLE OF THE BLOOD SERVICES

"He told me that there was no chance that the factor VIII was contaminated, he said it was 100% safe and that he would even give it to his 7-year-old-daughter."[957]

Introduction

1. In the chapters on the Role of Medical Practitioners and Haemophilia (centres, clinicians, the UKHCDO, and Haemophilia Society), we explore the role that our CPs' medical practitioners played in administering the blood, blood components or blood products that infected them or their loved ones. Many of these infections were, for reasons we explain in those chapters, clinically unjustified and therefore avoidable. The discussion of failures to implement what we might now term "*haemovigilance*"[958] or "*Patient Blood Management*" systems to manage and audit use of blood demonstrates, however, that clinicians do not work in a vacuum. If proper haemovigilance systems had been in place and had operated effectively, this malpractice would have been noticed and action could have been taken.

2. In this chapter we explore the parts of the haemovigilance chain that were or should have been operated by the NBTS,[959] namely the safe[960] collection, processing and provision of blood and blood components to clinical settings for patient treatment, as well as the audit and monitoring of the use of that blood, including the operation of reporting systems for TTIs, which includes HIV, HBV, and HCV. We also discuss the vital educational function that the NBTS should have played, but omitted to, which

[957] **WITN1885001, §6**

[958] Professor Mark Bellamy gives the JPAC definition at §8 of his witness statement [WITN7312001_0006] as follows: "*Haemovigilance is the `systematic surveillance of adverse reactions and adverse events related to transfusion' with the aim of improving transfusion safety*."

[959] Given the time period that is relevant to the Inquiry and our CPs, the term, "NBTS", is used throughout to refer collectively to the disparate national blood services in England and Wales (formed of a system of RTC and their directors ("**RTDs**"), which were operationally separate but making some strategic decisions in consultation with each other). It is used as a catch all for the precursors to and the early form of the National Blood Authority, which was established in 1993. The Scottish NBTS is referred to as "**SNBTS**".

[960] As reasonably safe as it could have been.

contributed to and compounded the failures of other NHS bodies[961] and clinicians, as well as the inadequate safety measures taken by the NBTS regarding testing and donor exclusion. These failures were, undoubtedly, compounded by the organisational and structural problems with the NBTS, which should have operated as a centralised system with statutory powers and/or duties at a much earlier stage. Finally, we explore the inadequate and problematic lookback programme conducted by the NBTS in 1995 in respect of seeking to find those infected with HCV via blood transfusion. This chapter, therefore, largely focusses upon the transmission of HCV, HBV and HIV via blood transfusion, and what steps should have been taken to adequately protect against that risk.

3. In short, we submit that the way in which domestic blood collection and blood supply was organised undoubtedly both led directly to, and contributed to other causative factors for, avoidable infections. The issues related to fractionation of blood products are explored in a separate chapter, although there is inevitably some crossover.[962]

The absence of a haemovigilance system

4. As discussed in the chapter on the Role of Other NHS Bodies, Better Blood Transfusion ("**BBT**"), spearheaded by the UK Chief Medical Officers in the late 1990s, heralded a new era for blood safety. Supported by structures such as the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee ("**JPAC**"), National Blood Transfusion Committee ("**NBTC**") and its associated regional committees, and Serious Hazards of Transfusion ("**SHOT**"), the NBTS naturally took a lead role in implementing BBT.[963]

[961] Those bodies and the role they played are addressed in the chapter on the Role of Other NHS Bodies.
[962] Particularly in relation to the provision of plasma for fractionation by the NBTS, and the organisational and structural problems with the NBTS, which led to inefficiency and impacted on the ability to make sufficient domestic blood products.
[963] This was highlighted clearly in the evidence of Dame Professor Marcela Contreras: Transcript 02/12/2021, in particular pp156-164.

5. Prior to this, however, there was no proper haemovigilance system that spanned the entire "*history*" of a blood component. There was a serious failure on the part of the NBTS, and RTDs, to develop and operate such a system.

Knowledge of risk and haemovigilance

6. A haemovigilance system should have been brought into force much earlier. The risks of blood-borne infections, such as hepatitis, were known decades before the inception of BBT. No adequate explanation has ever been given for why this did not happen. Haemovigilance came, to some degree, after the event (namely after testing developments), whereas it should have been embedded in the system since at least the 1970s.

7. Many RTDs gave evidence of their serious underestimation of non-A non-B hepatitis, and then HCV, in terms of its prognosis and significance.[964] This contributed to a severe and entrenched attitude of complacency around the risks non-A non-B hepatitis posed to recipients of blood and blood products, which in turn perpetuated the misjudgement of the virus in broader clinical and government circles.

8. While the entire NHS and public health system was, undoubtedly, affected by what Sir Liam Donaldson described as a *"post war optimism that* [the] *conquest* [of infectious diseases] *was near",*[965] we consider that, this justification cannot excuse the failings of the NBTS in circumstances where it occupied a unique position in terms of its access to knowledge about blood-borne viruses ("**BBVs**"), and the importance of this scientific expertise to its duties to operate a safe blood collection and processing system.[966]

9. The field of haematology became increasingly aware of non-A non-B hepatitis over time. The risks of serum hepatitis, and later non-A non-B hepatitis/HCV, from transfusions were highlighted in multiple important transfusion guidance and

[964] E.g. Dr Napier, transcript 30/11/2021, pp85-87 and transcript 01/12/2021, p132, where he expressed his regret at this fact; Professor Dame Contreras, transcript 02/12/2021, pp65-66.
[965] Explored in the Role of Medical Practitioners at §35 and the Role of Other NHS Bodies at §15.
[966] Please see the Role of Medical Practitioners at §31 for a fuller discussion of what clinicians should have known about the risks of non-A non-B and blood-borne viruses and the evidence relied on (which includes CTI's Knowledge of Risk of Infection Chronology: INQY0000006).

textbook documents from the early 1960s onwards. These textbooks would, as a matter of medical ethics, have been essential reading for any practitioner operating in the sphere of blood transfusion medicine.

10. Moreover, the reason why the risk of serum hepatitis from transfusion was well known from the WWII/post-war period was because of transfusion medicine and the activities of the NBTS and its predecessor bodies. For example, following the implementation of testing for HBV in the early 1970s, there is ample evidence before the Inquiry that it was known that a form of hepatitis was, nonetheless, being transmitted.

11. Crucially, it was known from the mid-1970s, and certainly by the end of the 1970s, that, while non-A non-B hepatitis may be associated with less severe acute illness than HBV, its long-term prognosis could be similar, with patients developing chronic hepatitis and cirrhosis in the same way.

12. This was something that hepatologists were increasingly aware of and were attempting to highlight to other clinicians.[967] However there is little, if any, evidence of information sharing between the NBTS and the hepatology field, or of a routine hepatological presence within the NBTS.[968] This, we consider, was a failure on the part of the NBTS given the growing knowledge about blood-borne hepatitis. This "*silo*" of expertise is reflected too in the limited knowledge of those involved in blood policy, as is set out in the chapter on the response of government.

13. Finally, it was especially harmful that the NBTS failed to heed this knowledge because of the role that it played in terms of influencing other clinical fields, public bodies, and the Government with regards to their understanding of the risks of transfusion. The NBTS's failure to put into place a haemovigilance system to attempt to mitigate the

[967] For example, by the time the HCV test wasavailable, Professor Geoffrey Dusheiko, in the 1995 BBC Panorama documentary, "*Bad Blood",* suggested that: *"hepatologists and liver specialists were at loggerheads with services responsible for the provision of blood"* because the serious risks were well known, and had been well known for a significant period of time, in the field of hepatology: approximately 10:00 in BBCO0000003.

[968] We note that the absence of structures for information sharing is a theme that reemerges throughout our submissions – not only in relation to the NBTS and the absence of effective structures– explored below – but also in relation to haemophilia treatment with blood products, in relation to clinical guidance and in relation to the management of our CPs' multi-systemic disorders as a result of their TTIs.

risks of TTIs meant that there was a dearth in the epidemiological understanding of BBVs, but particularly of non-A non-B hepatitis, and the scale and significance of the problem. The absence of this epidemiological picture reinforced the perception that infectious disease had been "*conquered*".

What went wrong?

14. Notwithstanding that the NBTS published in one form or another from 1949 onwards the Notes on Transfusion/the Handbook of Transfusion documents,[969] which set out guidance on haemovigilance processes for clinicians and hospitals (including blood banks), it both:

    a. failed to implement important steps of the process that were wholly within its control; and

    b. failed to supervise and audit other parts of the haemovigilance chain to ensure the safe and appropriate use of blood in hospitals.

15. The NBTS failed to put into place and/or operate surveillance and record-keeping procedures, which covered the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up.

16. Nor did it put in place systems for the monitoring, reporting, investigation and/or analysis of adverse events related to the donation, processing and transfusion of blood, in order to take action to prevent their occurrence or recurrence by improving, or suggesting improvement, in blood services processes.

17. In this vein, the NBTS had a duty not only to be aware of and to disseminate the latest research and science on BBVs and TTIs, but through an effective haemovigilance system it could have made a meaningful contribution to research and epidemiological

[969] As set out in INQY0000328 - Presentation by CTI about the guidance available to clinicians regarding the use of blood transfusions.

data gathering in relation to the emerging risk of non-A non-B hepatitis and other BBVs, such as HBV and HIV.[970] There is no evidence that it did this or sought to do this.

18. To operate such a system required that the NBTS coordinate the actions of a number of stakeholders and other NHS Bodies, including, hospital clinical staff and transfusion laboratories, hospital transfusion committees, as well as the NHS more generally and Government. It also required the NBTS, once it had identified problems, to learn from them and to distribute that knowledge in the form of guidance or other educational resources. In order to fulfil the functions described above, there needed to be mechanisms in place for information sharing and communication between the relevant bodies.

19. In our submission, the systems operated by NBTS were seriously inadequate and did not come close to proper haemovigilance.

20. Instead, the NBTS record keeping system (including when a formalised system was introduced after the creation of the National Directorate) only extended to the process history of a product up until its issue by a RTC to a hospital. This was where the surveillance chain ended. The RTC record keeping was not joined up with the hospital record keeping process, meaning there was an effective tracing "*gap*".[971] Therefore there was no harmonised system to investigate post-transfusion infections (assuming clinicians made reports in the first place),[972] link them to a particular donor to prevent them donating blood again and/or to trace other recipients of potentially infected blood. Instead, the loose system in place relied solely on the creation and retention of effective records of blood transfusion within hospitals. As explored fully in the chapters on the Role of Medical Practitioners and the Role of Other NHS Bodies, record keeping systems in hospitals were extremely poor. If a record was made of transfusion at all, it would likely be incomplete (lacking blood batch numbers and/or

[970] For example, this could have been conducted with key clinician stakeholders such as UKHCDO or hospital-based haematologists.

[971] See e.g. Professor Dame Contreras, transcript 02/12/2021, p111.

[972] Regarding which, please see the section on education below. We also note that there was no statutory requirement to notify public health authorities of "non-A non-B" hepatitis prior to its identification as HCV. However, we submit that this placed a particular onus on the NBTS to operate its own TTI notification system separate given the lacuna in public health surveillance and epidemiology.

clinical reasons for transfusion) and/or later misfiled, lost or destroyed. This was demonstrated starkly by the 1995 lookback programme, the effectiveness of which was significantly curtailed because of inadequate and incomplete records at various points in the chain.[973]

21. These failings were noted contemporaneously and are not asserted simply with the benefit of hindsight:

    a. For example, in 1982 the Department of Health tasked Central Management Services ("**CMS**") with studying the existing controls on the movement of blood. The CMS report[974] noted serious deficiencies.

    b. In Scotland, in February 1983, SNBTS directors recommended that RTCs accept a formal responsibility for encouraging good practice in those hospital blood banks for which they were responsible for supplying blood and blood products; that this should involve meeting at least annually to discuss transfusion practices in the hospitals; and that that meeting should be attended by representatives of the medical staff of the RTC, haematologists, and consultants representing divisions of surgery, anaesthetics, paediatrics, medicine, and obstetrics and gynaecology.[975] It is unclear to us the extent that this recommendation was adopted in Scotland, but we consider that this demonstrates the issues we raise were live, understood, and yet were not grappled with by the NBTS.

    c. A Health Circular issued in March 1984[976] provided that: "*For medical reasons and from the point of view of accountability for a valuable resource, records kept at RTCs, hospital blood banks and at ward level must permit the tracing of any unit of blood from collection to transfusion or disposal. Health authorities are asked to* ***ensure that the systems employed at Transfusion Centres and hospital blood banks do so.***" (emphasis added).

[973] Regarding which, please see the section on lookback below.
[974] DHSC0002221_011. Also referred to in the chapter on the Role of Other NHS Bodies.
[975] PRSE0000525.
[976] CBLA0001819, §7.

22. A direct consequence of the absence of a haemovigilance system was that the medical malpractice explored in our chapter on the Role of Medical Practitioners was not audited or monitored and therefore allowed to continue unchecked. This link was made by Dr B T Williams, director of the Medical Care Research Unit of the University of Sheffield, who produced a review for the Department of Health in November 1991 titled, "*The use of single unit blood transfusion* ".[977] He noted that:

> "*Our present state of knowledge of blood product transfusion practice in this country is incomplete and not accurately ascertainable using existing routine information systems. The National Blood Transfusion Service Directorate's Management Information System receives its datasets from Regional Blood Transfusion Services. These in turn, describe only the nature and volumes of products donated, processed and distributed to hospital blood banks. No routine data exist at regional level on transfusion practice in the institutions served which would allow the incidence of single-unit transfusions to be measured.*"
>
> ...
>
> "*Neither the overall pattern of transfusion practice in this country nor any variations in it are at all well known. The issues of safety, effectiveness and resource conservation which are involved, along with the more stringent requirements imposed by recent legislation imply that there may now be a 'need to know'.*"

23. As Dr Williams suggested, if the NBTS had been operating a proper haemovigilance system, which traced blood components from start to finish, they would have realised that there was widespread and near total non-compliance with the guidance in its own publications and "*raised the alarm*", resulting in appropriate steps being taken.

24. This lack of audit was self-reinforcing. It led to the delay of initiatives like BBT and SHOT, because the scale of the problem was not sufficiently appreciated. This was noted by haematologist, Dr Mike Murphy: *"[These initiatives] could have been*

[977] DHSC0025270.

introduced but the imperative to do so, the evidence that they were really needed, wasn't there."[978]

A failure to provide better blood education

25. While disseminating education and guidance is undoubtedly part of "*haemovigilance*", its importance is heightened in a landscape where there is (even still today) a lack of knowledge among clinicians of the risks of transfusion and BBVs. The failure, therefore, of the NBTS to provide adequate education and guidance to key clinicians and to hospitals on safe blood transfusion practice (so they could in turn transmit this through structures like hospital transfusion committees) merits specific discussion.

26. The NBTS should have been the most important body in terms of disseminating guidance to other clinicians on safe transfusion practice, and its risks, given its unique position and clinical expertise.[979]

27. It clearly did consider one of its functions to be to provide advice and education, hence its publication of Notes on Transfusion/ the Handbook of Transfusion. However, the NBTS appears to have made no effort to promote these documents, to monitor compliance with them or to enforce its own guidance. As explored in the Role of Other NHS Bodies, many clinicians whose practices involved administering blood transfusions could not recall ever having seen the Notes on Transfusion/the Handbook of Transfusion documents.[980]

28. The NBTS's attitude is best summed up by Dr Murphy, who said in his oral evidence: "*I'm not sure that [the NBTS/RTC] saw it as their role to give us advice about appropriate use of blood.*"[981]

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[978] Transcript 24/02/2022, p131, ll4-9.
[979] This remains the case today, and the reinforcement of this statutory role is addressed in our recommendation regarding the role of NHSBT.
[980] The Role of other NHS Bodies at §19(d).
[981] Transcript 24/02/2022, p124, ll18-19. Although with some notable exceptions, such as Dr George Galea, p22.

29. This meant that valuable advice on transfusion was not appreciated or applied by clinicians. One striking example of this was demonstrated again by Dr Murphy, who in his oral evidence referred to a 1999 paper on the Transfusion Requirements in Critical Care Trial ("**TRICC trial**"), as displacing a widely held view that a patient should generally receive red cell transfusions if their haemoglobin was less than 10g/dl. On the contrary, over a decade earlier, the 1988 edition of the Handbook of Transfusion Medicine[982] advised clinicians that:

> "*Surgical and anaesthetic practice has tended to be guided by the belief that a haemoglobin level below 10g/dl (haematocrit below 30%) indicates a need for peri-operative red cell transfusion. There is little or no firm evidence supporting this belief and experience in recent years suggests that patients with severe anaemia may tolerate anaesthesia and operation without major morbidity or mortality resulting from the anaemia itself. Evidence from clinical and physiological studies does not support the necessity for the '10g/30% rule'.*"

30. However, in his oral evidence, Dr Murphy told the Inquiry that prior to the TRICC trial, "*we didn't have the evidence for anything different…we had nothing to go to other clinical teams and say, you know, 'This is what you should be doing'.*"[983] This suggests both that the NBTS's up-to-date, evidence-based guidance gained insufficient traction and demonstrates a widespread missed opportunity to avert avoidable infections. As a haematologist, Dr Murphy is exactly the kind of clinician who was well placed to disseminate NBTS education within his hospital.

31. It was vital that the NBTS put in place structures to ensure that information on safe blood transfusion practice was passed between the NBTS/RTCs and hospital clinicians (or their own bodies such hospital transfusion committees). The evidence of clinicians such as Dr Bogod was that no such structures existed on any systemic level.[984]

32. By contrast, Dr Wallis gave evidence concerning his membership of the NBA Zonal Blood User Group from 1995 to 1999, which he described as being founded because

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[982] NHBT0099310_002.
[983] Transcript 24/02/2022, p127, ll18-20.
[984] Dr Bogod, Transcript 23/02/2022, p116, ll5-7.

"there would need to be some form of feedback to help the clinicians at the coalface to feed back their information to much larger groups, and the Zonal Blood Group was part of that"[985]. He later sat on the NBTC.[986]

33. He referred generally to the role of these committees and noted that they acted as a forum for discussing and coordinating audit of new guidelines.[987] In terms of the composition of these groups, he said, *"When it started we had a very good representation from consultant haematologists and from laboratory managers, blood transfusion laboratory managers, throughout the region".*[988] Increasingly there was representation from clinical nurse specialists or transfusion nurses, who acted as excellent conduits for information sharing.[989] Once or twice a year there were educational meetings that focused on a particular area, like obstetrics and peri-natal medicine, at which a guideline might be discussed.[990]

34. In our submission, these education and information sharing structures were vital for the promotion of safe blood management. They should have existed at national, regional and hospital level throughout the history of the NBTS, with the NBTS playing a lead coordinating role.

35. There are two important consequences of this failing:

    a. Many of our clients would not have been infected had the educational advice in Notes on Transfusion/the Handbook of Transfusion, and other best practice guidelines, been translated into clinical practice *"on the ground"*; and

    b. Crucially, there is cogent evidence that improved education about safe blood use had an impact on demand for blood.[991] This decreased when it was understood,

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[985] Transcript 24/02/2022, p6-7, ll24 – 2.
[986] Whose terms of reference are found in: WITN7001026.
[987] Transcript 24/02/2022, p9, ll21-25.
[988] Transcript 24/02/2022, p10, ll5-8.
[989] Transcript 24/02/2022, p10, ll22-24.
[990] Transcript 24/02/2022, pp11-12.
[991] DHSC0004205_005 states that: "*Since the second CMO's seminar 3 years ago, and the publication of the more detailed Health Services Circular HSC 2002/009, there has been a fall in the demand for red cells of 11%. As a result of efforts to use blood more appropriately, red cell demand fell by 5.7% in 2004, and by another 4.7% in the first 10 months of 2005/06.*"
See also witness statement of Dr Murphy, in which he states that there has been a 30% reduction in the use of red cell transfusions in England and a stabilisation in the growing demand for platelets §113(b).

for example, that "*two was not always better than one*", when red cell concentrates were preferred over whole blood, or when there was better knowledge around haemoglobin levels and clinically appropriate levels for transfusion. Had this reduction in blood use occurred earlier, this would have had an overall net benefit in terms of blood plasma supply for fractionation, and, therefore, domestic blood product self-sufficiency.[992]

Testing

General testing decision-making flaws

36. In our submission, testing technology for HIV, HCV and HBV was introduced too late by the NBTS. Some of our CPs were infected during periods of unnecessary delay to testing. These infections were likely to have been avoidable.

37. We have identified the following themes in the decision-making of the NBTS around testing technologies:

    a. The NBTS, and some RTCs in particular, were affected by a lack of funding, meaning they sought to delay the costs inherent in rolling out testing and putting in place the necessary infrastructure around it (for example counselling for positive or potentially positive donors).[993] There was an attitude of "*maximum benefit for minimal cost*";[994]

    b. The NBTS made decisions about testing based on an insufficient epidemiological picture of the prevalence of the BBVs in question. As we argue above, this was substantially contributed to by the NBTS's own failures to implement a system of haemovigilance;

    c. Between 1983-1984 there was an underestimation of the nature and seriousness of HIV (or Human T-lymphotrophic virus type 3 ("**HTLV-III/AIDS**")). The same

[992] See chapter on Self-sufficiency, fractionation and pharmaceutical companies.
[993] See regarding RTC funding concerns about introducing HCV tests earlier in 1991, §85 in Dr Gunson's HCV litigation statement (NHBT0000025_001).
[994] NHBT0000044_095.

occurred in relation to non-A non-B hepatitis/HCV. This underestimation of the chronic and serious nature of non-A non-B hepatitis/HCV persisted until testing was introduced, and indeed even continued afterwards;

d. The NBTS system was overstretched and inefficient (with a lack of focus on blood economisation for patient safety purposes), meaning that decisions about testing were made in a context where its primary focus was to provide enough blood and blood components to feed NHS needs for transfusion medicine, and enough plasma to meet its targets for fractionation.[995]

38. We acknowledge the evidence of multiple RTDs that the most important factor in delaying the introduction of HIV and HCV testing technology was the fallibility of early generation testing technologies and the absence of (effective) confirmatory testing. These directors emphasised the ethical ramifications of causing potentially unnecessary distress to the donor if they gave a false positive result.[996]

39. For both HIV and HCV testing, however, we submit that improved technology was very much on the horizon at the points when the early technology was fallible and/or in a trial phase. In other words, if an early test had given a positive result, donors would only have needed to be deferred for a short period before improved and/or confirmatory testing could corroborate, or not, the first result. The reasonable ethical concerns could have been dealt with in a way that respected both donors' *and* recipients' interests, by ensuring that deferred donors were carefully and sensitively advised of the reasons for their deferral and reassured by the offer of further and/or more effective testing as soon as it became available.

40. We submit that it is with the benefit of hindsight that former RTDs have emphasised the ethical concerns for donors as tipping the decision-making balance. Instead, the factors set out above weighed heavily in the risk-benefit assessments of whether to introduce testing technologies at the earliest possible stage.

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[995] See further discussion below.

[996] See for example, Dr Napier, transcript 01/12/2021, pp54-56. And indeed, the witness statement of Dr Gunson (NHBT0000025_001), §38, where he suggests that a confirmatory test was required for HCV because there would be too many false negatives and false positives in low risk population, like donors.

41. In any event, when it came to testing, we submit that the incorrect balance was struck. The assessment should have been weighted heavily towards patient safety, the protection of lives and the reduction of morbidity (and indeed, on an economic level, long term savings for the NHS by minimising infection). The consequence of not doing so was that many of our CPs suffered infections that were avoidable and experienced harm and suffering, as is explored fully in the chapter on Impact.

HIV testing

42. In this context, we consider that HIV testing was introduced too late. By mid-July 1984, various reliable tests for HTLV-III were available.[997] We rely on the evidence of Professor Tedder that, by this stage, there was an urgent need for screening to detect HIV infection: *"[It] showed that the virus was present in the UK population, and therefore, even though prevalence in healthy donors was very low, we couldn't say how long that was going to remain low"*.[998]

43. This was underpinned by earlier failures of the Government to provide funding for HIV testing research and to scale up the technology so it could be rolled out in public health settings beyond the NBTS, such as Genito-Urinary Medicine ("**GUM**") and sexual health clinics.[999] This failure was important, because it led to delay while the NBTS was concerned about a "*magnet effect*" (donors giving blood for the purpose of discovering their HTLV-III status). The fear of this effect, we consider, was misguided and not a reasonable justification for delay. It could have been mitigated and minimised with good donor information and education.

HCV testing

44. The flawed decision making explored above was especially demonstrable when it came to the introduction of routine HCV testing. Such was the controversy around the delay that the Newcastle RTC took the step of introducing routine HCV testing over

[997] Professor Tedder, Transcript 13/10/2022, p107: discussion with the Chair.
[998] Professor Tedder, Transcript 13/10/2022, p108, ll13-15.
[999] Professor Tedder's witness statement at §69: *"The sense I got was that DHSS did not regard testing as a problem. She indicated that they would not provide the necessary funding."* And at §70: *"…we knew that we needed to do something quickly… but the DHSS was saying that it was not really their business to fund it"*.

four months prior to the national commencement date of 1 September 1991- something which (we suggest, wrongly) caused concern amongst other RTDs and central government at the time.[1000]

45. Similarly, Dr Lorna Williamson, a haematologist at the East Anglia RTC, recalled, in a manner which the Chair recognised as refreshingly clear and simple, thinking, *"If we are ready, why not go? What would be the point of delaying any longer than we had to?"*.[1001]

46. In short, we endorse the judgment of Burton J in *A & Others v the NBA* [2001] 3 All ER[1002] that:

> *"…. routine screening ought to have been introduced by 1 March 1990. That in my judgment would have allowed sufficient time for pilot studies and evaluation, particularly if, as I conclude should have been the case, rather more work had been done prior to Rome, but even if it had not been. If pilot studies had been more promptly carried out, even in the context of a wider evaluation, I am satisfied that a decision could have been taken which would have given at least three months lead time for implementation by the Centres before the introduction of routine screening. This date would accord with Dr Gunson's "certainly early in 1990"; would be slightly before the date of "sometime after April 1990", which Dr Cash had gambled on on 3 August 1989, in the course of his own evaluation of the assay; and would accord with the date of implementation of routine screening by France and new donors in Luxembourg, and would post-date Japan, Australia and much of Finland. This would mean that the RIBA test would be known to be relatively imminent and would in fact have followed some two months later. In that interim period, either there could have been deferment of donors, for what even Professor Zuckerman would have accepted to have been a short period of*

[1000] See NHBT0000062_054, minute from Andrzej Rejman to Dr Mettersand Dr Gunson's letter to Dr Hugh Lloyd on 29 April 1991, in which he expressed his disappointment regarding the "*unilateral decision*" to proceed with screening "*without first discussing the issue, not only with me, but with your colleagues in other RTCs*": **NHBT0000074_008**

[1001] Transcript 08/12/2021, p63, ll8-10.

[1002] DHSC0011771 at §172.

time, or for that short period of time an extra burden on the newly instituted counselling procedures."

47. There is also a linked issue about the failure to implement a proper infrastructure around testing to ensure the highest level of safety for patients. Blood began to be screened at RTCs for the presence of HCV antibodies from 1 September 1991. However, the NBTS (Dr Harold Gunson) was warned by Dr John Cash[1003] that, unless a programme was undertaken to remove blood collected prior to 1 September 1991 from the NHS system (such as frozen blood components, we suggest), untested blood would continue to be used in the NHS system after 1 September 1991. The effect of this evidence was summarised by the Chair as follows:

> *"So he's raising the possibility that after -- if, as we've seen, it is likely that on 1 September what was happening was testing of all new supplies, the supplies currently in the system might very well have been infected because they hadn't been tested"*[1004]

48. Moreover, the evidence before the Inquiry suggests that no programme to test blood which had been taken from donors prior to 1 September 1991 and was unused at that date was ever introduced.

49. It is reasonable to infer, therefore, that untested blood remained in the NHS system for use after 1 September 1991. The issues this raises in relation to eligibility for financial trusts and schemes, and the validity of current National Institute for Health Care Excellence ("**NICE**") guidelines for HCV testing are fully explored elsewhere.[1005]

Surrogate testing

50. Regarding surrogate testing, we endorse the judgment of Burton J in *A & Others v the NBA*[1006]:

[1003] PRSE0002763.
[1004] Transcript 11/11/2021, p53.
[1005] See Trusts and Schemes chapter and Role of Other NHS Bodies chapter.
[1006] DHSC0011771 at §141.

"I am clear that the scales have come down in favour of the introduction of these surrogate tests, and indeed of both kinds of surrogate test, both ALT and anti-HBc. The United States and France, the major countries who introduced surrogate tests at that time, introduced them both, and I am clear that, notwithstanding the lesser expert support for the latter test, once ALT testing is to be introduced, the addition of anti-HBc adds little by way of extra disadvantage, cost, blood loss or inconvenience, and may be of substantial advantage. It was, in my judgment, at least very likely to decrease the number of donors who were in any event unwanted, a factor which does not seem to have been discussed at any ACVSB or ACTTD or other meetings to which my attention has been drawn. Further, if the US research was right, the two tests did not, or not materially, overlap, and in any event the combined efficacy of the two together, on the basis of the predictive studies, was clearly greater, and there may additionally have been advantages, as discussed in paragraph 133(iii) above, in relation to counselling and diagnosis. It is both difficult, and, in my judgment, unnecessary, for me to decide a particular time for such introduction. I am however satisfied that ***it ought to have been at some stage after the introduction of the surrogate tests in the United States and the subsequent consideration given to them in the United Kingdom, and before, or at any rate by, 1 March 1988***." (emphasis added)

51. We submit that this surrogate testing would have had an impact in relation to both non-A non-B hepatitis and HBV if introduced by 1 March 1988, although we explore the specific issues around Hepatitis B core antibody testing ("**anti-HBc testing**") for HBV below.

HBV testing

52. In comparison to the developments in testing of donated blood for HIV and HCV, the Inquiry heard significantly less evidence in relation to testing for HBV.

53. In December 1972 the UK introduced screening of donated blood for HBV surface antigen ("**HBsAG**"). It soon became clear that the tests were not sufficiently sensitive to prevent post transfusion HBV. In as early as 1974 Lord Owen confirmed in answer to a parliamentary question that an expert group examining results from the North-

West Thames Regional Transfusion Centre had agreed that the test in general use across the NBTS "*is likely to fail to detect Australia antigen in a significant proportion of carriers*", and recommended the introduction of a more sensitive test as soon as possible.[1007] A study published in 1983, "*Incidence of infection with hepatitis B virus in 56 patients with haemophilia A 1971-1979*"[1008] found that in as late as 1979 haemophiliacs were still at high risk of infection despite screening of individual donors for HBsAg.

54. The fallibility of these tests is borne out by the evidence of clinicians. Professor John Barbara described the early tests as "*accurate but not sensitive*";[1009] Professor Contreras acknowledged that she and her colleagues "*realised that the sensitivity wasn't as good as it could have been.*"[1010]

55. The report of the Inquiry's Statistics Expert Group found that:

> "*7.4 Risks remained post-1970, although these are difficult to quantify. It was claimed in 1976 that the available tests for HBsAg would detect no more than about 50% of HBV carriers, and so there would have been 'breakthrough' HBV infections.*"[1011]

56. At least 10 of our clients contracted post transfusion HBV after 1972.[1012] This is a direct result of the fallibility of the early screening tests employed by NBTS.

57. Despite the sensitivity of the HBV surface level antigen tests apparently improving over time, post transfusion HBV continued to occur. The Inquiry heard that some individuals, often those late on in their infection, described by Dr Barbara as "*tail end carriers*,"[1013] produce a very low level of surface antigen however their blood may still transmit the infection. Several clinicians gave evidence that there were ongoing discussions regarding the introduction of routine anti-HBc testing of donations which

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[1007] DHSC0001788.
[1008] MACK0001033.
[1009] Transcript 26/01/2022, pp101-102, particularly p102, ll9-10.
[1010] Transcript 02/12/2021, pp54-56.
[1011] Expert Report to the Infected Blood Inquiry: Statistics, p96, referring to PRSE0000799.
[1012] Please note that this constitutes 11 out of 14 clients of Leigh Day who were infected with HBV and submitted statements to the Inquiry: W2641; W3103; W1951; W1906; W2638; W3710; W2870; W3914; W0671; W2689.
[1013] Transcript 26/01/2022, p82, l15.

may carry the virus but are HBV surface level antigen negative. It was described by Dr Brian McClelland as a "*recurring theme*" amongst virologists.[1014]

58. These discussions continued into the early 1990s. Thus, it is clear that even by this late stage, and despite reliable tests for HIV and HCV having been developed (although with some limited capacity for window period donations to slip through the net), the HBV surface antigen tests were comparably less sensitive, and thus less likely to prevent occurrence of post transfusion HBV.

59. The Advisory Committee on Transfusion Transmitted Diseases ("**ACTTD**") met on 7 May 1992. In preparation for this meeting Professor Contreras and Dr Barbara wrote a paper[1015] which stated:

> "*The question of the likely benefit of anti-HBc screening of blood donations continues to reappear, especially so in the light of the introduction of anti-HCV screening. The attitude towards transfusion safety has veered away from the concept of 'maximum benefit at minimal cost' towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced.*"

60. In her oral evidence to the Inquiry Professor Contreras agreed that the concept of "*maximum benefit at minimal cost*" described the approach she and her colleagues had taken previously in relation to issues such as surrogate testing and anti-HCV testing.[1016] She explained that by 1992 there had been a shift in her own thinking and in general thinking to an attitude that "*we had to introduce any testing, regardless of cost*".

61. The ACTTD agreed in May 1992 that "*the introduction of anti-HBc donor screening had a high priority.*"[1017] At a meeting of the same committee in January 1993[1018] it was agreed that a recommendation to Advisory Committee on the Virological Safety of

[1014] Transcript 28/01/2022, pp81-88.
[1015] NHBT0000044_095.
[1016] Transcript 03/12/2021, pp116-118.
[1017] NHBT0017532.
[1018] DHSC0006982_049.

Blood ("**ACVSB**") for the introduction of routine anti-HBc screening of donations should be made on the basis that

> "*(i) the knowledge from the trials to date have revealed that potentially infectious donations for hepatitis B were being transfused. "(ii) that patients who had suffered from transfusion associated hepatitis B (when the blood was HBsAG negative) were being reported.*"

62. However, in October 1993 all RTDs were informed that the DH Advisory Committee on the Microbiological Safety of Blood and Tissues from Transplantation had decided that the routine anti-HBc testing of blood donations could not be justified. Despite the dismay of those who had advocated for this testing it was never introduced and was eventually superseded by Polymerase Chain Reaction ("**PCR**") testing for HBV which was rolled out in the early 2000s.

63. Professor Contreras explained that the PCR test was a "*very sensitive test that would have excluded those donations that were carriers for hepatitis B -- most, not -- most but not all.*"[1019]

64. In our submission there was a failure by NBTS to keep up to date with the developments in tests and to ensure that the most sensitive tests available were employed.

65. Further it is our view that anti-core HVB testing should have been introduced earlier, particularly as the inadequacy of the HBsAG tests was well known. The failure to do so was as a result of the factors listed above and resulted in avoidable infections for our CPs and others.

66. As above, the issues this raises in relation to eligibility for financial trusts and schemes, and the validity of current NICE guidelines for HBV testing are fully explored elsewhere.[1020]

[1019] Transcript 03/12/2021, pp118-122.
[1020] See Trusts and Schemes chapter and the Role of Other NHS Bodies chapter.

Other safety measures

Donor exclusion criteria

67. There are a number of other safety measures, beyond testing (and crucially, in the absence of routine testing), that were available to the NBTS in order to reduce the risk of infectious donations entering the system. We consider that donor selection criteria and other donor exclusion measures used by the NBTS were inadequate in screening out "*high risk donors*", who may have been infected, thus leading to avoidable infections.

68. The advent of the AIDS pandemic marked a step change in donor exclusion criteria, when, from September 1983, various iterations of a donor information leaflet advised certain groups not to donate blood. This action, however, was inadequate in multiple regards:

    a. The criteria themselves[1021] were insufficient in highlighting the risk factors for AIDS and therefore the donors who should defer. We fully endorse the position of Professor Richard Tedder in his written and oral evidence, that the donor exclusion criteria for AIDS during the Relevant Period should have, from the inception of the leaflets, excluded all men who have, or who have ever had, sex with men ("**MSM**"), as well as their sexual contacts. The criteria also should have excluded anyone who had ever injected drugs at any time. Instead, the language and criteria used was purposefully vague and overly cautious.[1022] It is reasonable to infer that it would have led to some donors, who should have self-excluded, continuing in good faith to give blood (for example because they did not have multiple sexual partners or were not a *current* drug "*abuser*" or had only "*dabbled*" in drugs in their youth).[1023]

[1021] Summarised in Table 3.1 of the Expert Report to the Infected Blood Inquiry: Statistics, p34.

[1022] We contrast the early leaflet language with drafted by SE Scotland Blood Transfusion Service in May 1983, which had a broader list of donors invited to self-exclude (PRSE0000984); the SNBTS donor information leaflet in mid-1984, which was significantly more proactive and clearer (PRSE0000286), and the American Red Cross suggested leaflet appended to the Council of Europe recommendation of 23/06/1983 (PRSE0000526).

[1023] Professor Dame Contreras's personal view was that, "it could have been clearer…I think it took too long.": transcript 02/12/2021, pp175-176.

i. As a separate, but linked point, we rely on the evidence of Professor Tedder that effective donor exclusion criteria for HIV/AIDS would have also reduced the numbers of donors who were HBV or HCV positive (because of an overlapping risk factor of parental exposure to other people's blood). That this is the case is demonstrated by evidence in the Statistics Expert Group report, at §7.7. which states: "*Between 1983 and 1986, the HBsAg count per 100,000 donations halved, at a time of enhanced self-deferral of donors to reduce HIV-related risks and the introduction of HIV antibody screening of blood donors.*"[1024] The Statistics Experts also rely on expert evidence from blood transfusion experts that the HIV/AIDS exclusion criteria and routine testing had an impact on the number of donors who were HCV positive. Notwithstanding this, and the fact that (as Professor Tedder's evidence showed), there was a clear understanding from an epidemiological and virological perspective by the early 1970s that men who had sex with men and their sexual contacts were at risk from viral hepatitis, the evidence of RTDs did not demonstrate that there was any discrete analysis of which exclusion criteria may be effective to reduce the risk of transmission of viral hepatitis, and particularly non-A non-B hepatitis. There could and should have been earlier exclusion criteria put in place to recognise the higher risk of those individuals, along with injecting drug users.

b. Secondly, the evidence before the Inquiry demonstrates that RTCs were too reticent in the way that they promoted this donor exclusion information and managed the process of donor deferral. For example, many RTCs were reluctant to send the AIDS Donor Information Leaflet to their donors with "*calling cards*", and instead chose to have the leaflet merely available at donation sessions.[1025] We agree with the position of Professor Tedder that it was preferable that these donor information leaflets served to prevent donors turning up in the first place, because of sociocultural considerations and the risks occasioned by the need to

[1024] Expert Report to the Infected Blood Inquiry: Statistics, p97.

[1025] See for example CBLA0001755, which demonstrated that by 14 October 1983, half of the RTDs were distributing the leaflet with the call-up card, whilst others had the leaflet available at sessions or were actively handing them to donors at sessions.

turn a donor away at the session itself.[1026] Not only was it vital, therefore, that the donor information leaflet exclusion criteria were correct, but also that donors received and processed the information prior to attending a session. Professor Tedder's conclusion was that *"not everybody got the questionnaire"*.[1027] Moreover, it was vital that the information leaflet was coupled with a "*proactive*" approach to questioning donors, which required a sensitive and controlled environment for a question and answer session between the examiner and donor.[1028] With the exception of a minority of RTCs, notably North London, the evidence demonstrated instead that RTCs were not in favour of "*too close*" questioning of donors as to their sexual activity, out of concern that it might be counterproductive.[1029] Blood donations often took place in workplaces and other large industrial settings, where it is unlikely that individuals would have wished to have revealed private or personal information.

c. The evidence, however, shows that these fears were unfounded. To the contrary, parallel work engaging with the gay community could lead to the "*buy-in*", understanding and support of the communities the NBTS were seeking to exclude or defer. Professor Tedder described this a "*meaningful and useful interrelationship, and exchange of views and advice, bilateral advice, on how to find the best way forwards.*"[1030]

d. Crucially, as those with ministerial responsibility for these leaflets accepted (notably Lords Fowler, Clarke and Glenarthur), their publication was improperly delayed. This delay appears more starkly when contrasted with Scottish approach.

69. In relation to donor exclusion more generally, we also consider that:

[1026] Transcript 13/10/2022, p73, ll4-8.
[1027] Professor Tedder, Transcript 13/10/2022, p71, ll3-4. See also Professor Dame Contreras, Transcript 03/12/2021, p4, ll406.
[1028] Professor Tedder, Transcript 13/10/2022, p71-l4-7.
[1029] See for example, Advisory Committee of The NBTS Working Group on Aids, 27 November 1984, DHSC0002251_011.
[1030] Professor Tedder, Transcript 13/10/2022, p74, ll2-4.

a. It was wrong for the NBTS to revoke the exclusion criterion of having a history of jaundice after the introduction of HBV testing (because this remained a risk factor for viral hepatitis generally and non-A non-B hepatitis)[1031]; and

b. The NBTS system relied on an outdated system of donor cards, coupled with inadequate information sharing between centres, which allowed donors that had been excluded in one centre to (in theory) give blood at another.[1032]

c. Blood donations also took place in some areas where the likelihood of individuals being infected was also higher, for example in prisons, until a relatively late period of time. In Northern Ireland, blood donations took place amongst serving soldiers who, it is suggested, were more likely to have had TTIs.

The organisation and structure of the NBTS

70. In short, we endorse the position of Public Health Expert, Professor Pollock that a serious weakness of the NBTS was that it was not a genuinely national transfusion service.[1033] We consider that it was clear that a centralised, national service, with executive powers, should have been in place in the 1970s-80s. Instead, the NBTS was in fact a confederation of independent RTCs run as "*fiefdoms*" by individual RTDs, answerable to their respective health authorities, with differing practice and policy. The system of RTD meetings was unwieldy in terms of reaching consensus and not nimble enough to ensure that the whole NBTS responded rapidly and proactively to emerging public health crises.

71. The organisational and structural weaknesses were identified by the RTDs themselves at a meeting in 1970: "*DHSS might think that NBTS worked efficiently and smoothly*

[1031] A risk considered by the Royal College of Physicians in 1976: PRSE0001579_0005.

[1032] See Professor Dame Contreras, transcript 02/12/2021, pp120-121: "*there was no mechanism for a centralised database shared with other RTCs about excluded donors.*"

[1033] Transcript 04/10/2022, pp56-57, in particular: "*If there had been, you wouldn't have had the problem, you would have had a National Blood Transfusion Service, with funding, a proper system and programmes -- systems and programmes and expertise there. It could be organised, of course, through regions but you wouldn't have had the problem of regions constantly battling against each other, battling for funding within the region and this, you know, this issue of top slicing of funds and some regions being more successful than others in competing for funds, for the service. So that, to me, is a big part of the problem, that lost opportunity.*"

under the present system. This was in fact, not so. There were in reality 14 quasi-independent regional centres and 2 central laboratories trying to provide a uniformly efficient service of high standard without any central coordinating body apart from the Regional Transfusion Directors' Meeting which had no formal authority."[1034]

72. The particular consequences of the way the NBTS was organised and structured were, we consider, as follows:

    a. A genuinely national service (as the advent of the National Blood Authority ("**NBA**") demonstrates) would have more easily facilitated the implementation of a proper system of haemovigilance and epidemiological surveillance;

    b. The decision-making structure of the NBTS relied on attempts to seek consensus among RTDs and implement broadly uniform policy at different RTCs. However, it lacked an executive body with executive powers to implement change proactively and speedily when it was required in the interests of patient safety;

    c. The forums for information sharing between different RTDs and centres were insufficient to share "*best practice*" and knowledge of innovative safety measures between different centres. For example, the North London RTC obtained expert knowledge on the risk of AIDS and donor exclusion measures but this was not adequately shared or, crucially, applied among all centres;

    d. The NBTS system was inefficient, both economically and in terms of the efficiency of blood collection and supply. This meant that the virological safety of blood was not prioritised as much as it could have been, and instead there was a focus on simply supplying *enough* blood to the NHS system.[1035] A nationalised system with executive powers would have allowed the sharing of blood across regions and nations, both for the NHS system for transfusion, and to meet plasma targets. This may also have facilitated other safety measures, such as the increased production

[1034] See this and general discussion at DHSC0002371_010_0005-6.

[1035] See for example the decision by UK BTS Working Party on Transfusion Associated Hepatitis on 24 November 1986 not to recommend introduction surrogate testing for NANB hepatitis(PRSE0003140_0001) and the noted concern that there would be a loss of "innocent blood".

of cryoprecipitate, had that been requested of RTCs[1036], and the eradication of collection of blood from penal institutions.[1037] Nationalised funding would also have allowed for economies of scale. While we consider that the NBTS system as a whole was underfunded, the inequality of funding among RTCs[1038] (coupled with the need for consensus in order to take important new safety measures such as routine testing) acted as a barrier to the whole of the NBTS taking a more precautionary approach to patient safety; and

e. It would have been easier to ensure donor exclusion across the system as a whole rather than just within centres.

Inadequate lookback attempts

73. There were a number of "*lookback*" exercises on a local and national level. The success of such exercises was severely compromised by the absence of a haemovigilance system that followed blood components throughout the entire chain and by the near-universal poor record keeping around blood transfusion. This was articulated, for example, by Dr Wallis, who described the difficulties inherent in searching through old paper records when trying to conduct a lookback exercise.[1039]

74. Particular criticism should be made of the NBTS's (by this point, the NBA's) national lookback programme conducted in 1995 in respect of HCV. We submit that, while it could have been a hugely valuable exercise, it was ineffectual and insufficient to protect patients for the following reasons:

[1036] Dame Professor Contreras said, if her centre had been asked in 1983/1984 to increase cryoprecipitate production, they could have done so "To a large extent, but we were not asked to do it. But we had the capability to do it.": transcript 02/12/2021, pp149-150, ll19-12.

[1037] Please see for example the discussion of this issue by RTDs in on 23/08/1983 (PRSE0004729), when it was recorded, "*Nevertheless, although most Regions, especially those with no shortage of donors, may not need to use prisons, there is at least one which has to view them as a major source of donations in order to meet targets*" and noted that a blood transfer system between regions would be needed to "*compensate for the loss of that source of donors.*"

[1038] See for example Dame Professor Contreras witness statement (WITN5711001), §131 and transcript 02/12/2021, pp28-31.

[1039] Transcript 24/02/2022, pp24-25, ll13-12.

a. It was too late. Given HCV testing was introduced nationally on 1 September 1991, and so donors with infections were being identified from that point onwards, there was a massive, missed opportunity to conduct lookback between 1991-1995 of these donors' previous donations. This had very real and practical consequences, we submit:

i. The evidence from the lookback programme shows that only 8% of recipients of infectious components, where it was possible to trace them, had received a diagnosis.[1040] This shows that routine monitoring or testing, for example in general practice, was failing to pick up infected recipients' infections,[1041] and that a targeted exercise was needed and would have made a difference.

ii. By 1991, there were interferon-based treatments for HCV, even though their effectiveness was limited.[1042] Notwithstanding, the success and risk profile of these early treatments, it should have been a patient's choice whether to proceed with them.

iii. In any event, the knowledge that an individual was infected could have made a difference in mitigating the effects of the disease through lifestyle changes, for example reducing alcohol intake, and given people crucial information that they might pose a transmission risk to others.[1043]

iv. These points above undermine the muddled justifications for delay given by the NBA that HCV was both not serious enough morbidity-wise for there to be an ethical duty to inform the recipients of infectious donations, while at the same time serious enough for them to be unnecessarily distressed if they

[1040] NHBT0097156_004.

[1041] This is entirely consistent with our submissions in the chapters on the Role of Medical Practitioners and Other NHS Bodies.

[1042] See Hepatitis Expert Report, p41, which demonstrates that early interferon treatments achieved a small, but nonetheless significant, number of SVR results even from 1991 and that this number grew consistently even prior to the introduction of DAAs.

[1043] This is something which, naturally, has caused huge distress to our CPs: see in the chapter on Impact. Indeed, this was something that the Lookback Collaborators recognised themselves: see NHBT0097156_004.

were informed they may be at risk of having contracted HCV at a point where there was, supposedly, no effective treatment.[1044]

b. Any donations from donors who were in fact HCV positive prior to 1 September 1991, but had not had not donated blood after this point, were not included in the lookback programme, since there were not stored samples to retrospectively test. This was recorded by the lookback collaborators as a weakness of the programme.[1045]

c. The lookback programme failed to identify the fate of 31% of components that were transfused from donors found to be infected.[1046] Poor record keeping at some or various points in the chain, we infer, is the reason for this.

   i. As an aside, recipients were identified for 97% of transfused components which *were* traced, demonstrating the effectiveness of lookback where records were kept properly, and also the utility of hospital blood bank records as a source of information.

   ii. Similarly, whilst it was not reported in this 31% of cases whether information was unavailable at RTCs or hospitals, inability to trace the fate of a component was significantly associated with the donation being made at an earlier point in time. This supports our submissions earlier in this chapter, and in the Role of Other NHS Bodies, that haemovigilance and audit of blood use works to improve safe practice. Although haemovigilance was inadequate throughout the Relevant Period, as explored in that chapter, the evidence before the Inquiry suggests that a minority of hospitals were beginning by the late 1980s to make inroads into haemovigilance. We submit that it can be inferred that it was tentatively beginning to work.

d. However, 76% of components with identified recipients did not result in recipient testing.[1047] This was a severe weakness of the lookback programme.

[1044] Dr Angela Robinson first witness statement, second witness statement and BBCO0000003.
[1045] NHBT0097156_004.
[1046] NHBT0097156_004 and NHBT0097156_005.
[1047] NHBT0097156_004 and NHBT0097156_005.

e. One of the reasons for a significant proportion of traced recipients not being tested,[1048] is the fact that clinicians who were informed of their patient's potential infection and asked to refer them for testing were given an option to indicate, without telling the patient themselves, that they were "*unsuitable for testing*". For example, if it might have a negative psychological impact on their patient. There is no available evidence of exactly how many clinicians exercised this option, or the reasons why they did so (again because of data limitations and design flaws of the exercise itself).[1049] However, it can be inferred that a significant number of doctors took this approach, for reasons that fall far short of what the law and medical ethics would now understand as a legitimate "*therapeutic exception*". It may be that some doctors felt uncomfortable or insufficiently informed to take on the role of counselling their patient through testing and a potential diagnosis. This meant that a significant number of infected recipients may have fallen through the net, for reasons which, we submit, are not ethical.

75. In short, lookback exercises, including the 1995 programme, were inadequate and overly delayed, meaning infected recipients of blood transfusions were not identified, which led to avoidable deaths and illness.

[1048] It is not possible to determine from NHBT0097156_004 and NHBT0097156_005 exactly how many, because of design flaws in the lookback information forms.

[1049] See W1988001, §14, whose doctor was sent a lookback letter in July 1995 asking them to approach the patient with a view to counselling and testing to determineher HCV status. This witness was diagnosed in 1994, but in any event her doctor never contacted her to inform herthat she had been identified by the lookback programme has someone who had potentially received infected blood.

CHAPTER 3: THE ROLE OF MEDICAL PRACTITIONERS AND THE MEDICAL SYSTEM IN THE UK

"I have trusted…the system, including the medical professionals... My mum did too. That trust has gone and I have been left feeling totally vulnerable as a person and completely let down. I feel particularly vulnerable because I now have to seek help from the system that has hurt me so badly. I simply cannot trust it now."[1050]

Introduction

1. The description by Professor Lord Robert Winston of the infected blood scandal as "*the worst treatment disaster in the history of the NHS*" is oft quoted. Sadly, however, the evidence to this Inquiry confirms that it remains as accurate and perspicacious a characterisation as ever.

2. The role played by medical practitioners[1051] in administering infectious blood, blood components and blood products to patients is an essential element of the harm suffered by our CPs.

3. This initial harm, however, was thereafter compounded by treatment (or lack of treatment) from medical practitioners, which was unethical or clinically unjustified: when our CPs' TTIs were not diagnosed; at the point of diagnosis; and when seeking care and treatment for their viral infections.

4. Worryingly, evidence to the Inquiry has shown that much of this wrongdoing continues to the present day. Therefore, as well as identifying what went wrong for our CPs, these submissions look to the future. They invite the Inquiry to make recommendations to improve the care and treatment available to our CPs, to alleviate the suffering caused by their infections (with benefits for the patient population at large). They also focus on improving patient safety at a systemic level to reduce the risk that a similar disaster could reoccur in the future.

[1050] WITN1963001

[1051] Generally, in this chapter, unless otherwise stated, the term "*medical practitioners*" is construed to include all clinicians providing care to patients, not just doctors.

5. While this chapter (and the fundamental ethical principles governing practitioners' conduct) applies to all CPs, the role of haemophilia doctors and the UKHCDO necessitates specific discussion given the idiosyncratic issues it raises. It is therefore addressed in a chapter that goes into greater depth on the harm caused to our CPs with haemophilia and bleeding disorders. In a similar vein, the first part of this chapter focuses on blood transfusion malpractice.

6. Secondly, as is explored below, medical practitioners do not operate simply as individuals, but exist (particularly in the NHS) in the context of many other systems and structures that purport to govern, audit, regulate and educate them. There is further discussion of these systemic issues (especially around blood transfusion) in the chapters on the Role of Other NHS Bodies and the Role of the Blood Services.

7. Thirdly, the submissions in this chapter set out the conclusions on the role that Medical Practitioners have played in the harm and suffering our CPs have experienced. It sets out "*what went wrong*" on a thematic level. In general, the submissions do not draw on specific client cases, except where there are particularly egregious or instructive examples. Instead, the full spectrum of the impact the infected blood scandal has had on our CPs is explored in detail in the chapter on Impact, in which there are many individual examples of the malpractice explored below.

Summary

8. In summary, the following submissions are made in relation to the Role of Medical Practitioners:

   a. The NHS is (still) in need of wholesale cultural and systemic change and this has a serious impact on patient safety and upon the approach towards the use of blood;

   b. The NHS is radically under resourced- both in terms of people and money - and this similarly has a serious impact on patient safety;

   c. Blood transfusion practice was, and to some extent still is, characterised by unnecessary and over transfusion of blood components, a fear of innovation, and

a prioritisation of the clinical freedom of clinicians over compliance with clear evidence-based guidelines. This was and is particularly prevalent in the field of obstetrics and gynaecology, which is where many of our CPs received the blood that infected them;

d. There were and are still serious shortcomings in relation to consent for blood transfusion. More generally, there is a cultural misunderstanding among medical practitioners of the importance and substantive requirements of informed consent. There are particular issues around consent in obstetrics and gynaecology, and in emergency settings;

e. There have been serious and systemic issues in terms of making and retaining records of blood transfusions, with significant consequences for our CPs;

f. Medical practitioners failed to diagnose our CPs' TTIs without, in many cases, substantial delay. At the point of diagnosis, there were multiple other failings in terms of communication and information giving;

g. Medical practitioners have failed to provide appropriate care and treatment to our CPs, in relation to viral treatment for HCV, follow-up and monitoring care, management of HCV as a multi-systemic disorder, psychological care and treatment and palliative care. In some cases, there have been obstacles to obtaining treatment altogether;

h. Some of our CPs have been subjected to research (notably the HCV Register) without their knowledge or consent, which has serious ethical ramifications; and

i. Our CPs with blood disorders, who are disproportionately from minoritised ethnic groups, have suffered additional systemic and individual discrimination and stigma, including barriers to obtaining diagnosis, adequate resourcing, and appropriate care and treatment for their TTIs.

A health system (still) in need of wholesale cultural and systemic change

9. Notwithstanding the debate between the Public Health and Administration Experts on whether the NHS requires "*cultural*", "*systemic*", or "*structural*" reform,[1052] a consideration of the role of medical practitioners in the infected blood scandal would be incomplete without first addressing the context within which medical practitioners have practised and continue to practise, and its inherent incompatibility with achieving the best outcomes for patients.

10. Much of the avoidable harm suffered by our CPs was not only a product of individual clinicians' actions, but of a system, or culture, that, ultimately, failed to put patients first. Much of that harm stemmed from paternalistic attitudes which have not yet been eradicated from the health system. Patients were given unnecessary "*top ups*" of blood without discussion of risks. Our CPs with haemophilia and bleeding disorders were not advised of the material risks and alternatives to factor concentrates and other human-derived blood products; instead, they were treated in a blanket fashion (regardless of the severity of their condition) and assumptions made about their choices and personal values. For many of our CPs with bleeding disorders, they were given factor concentrates when this treatment was not needed.[1053] Reports of decades-long symptoms of hepatitis were dismissed or baselessly treated as signs of alcoholism.[1054] Women's complaints were often dismissed and instead put down to the strain of various life stages (women, in many cases for clinicians, seem to have to suffer without complaint), for example to being a "*new mum*", without a link being made to a transfusion given during childbirth.[1055] Patients who, in a vacuum of publicly accessible information, and desperate to educate themselves on their symptoms, researched on the internet, were labelled "*neurotic*" or criticised by their doctors.[1056] A misguided attachment to a notion of the "*clinical freedom*" of doctors took

[1052] Transcript 04/10/2022, p171, ll14-25. Please see the debate between Lord Bichard and Professor Pollock.
[1053] As stated above, this malpractice is explored in the chapter on Haemophilia Doctors and the UKHCDO.
[1054] Please see the chapter on Impact, particularly §17-20.
[1055] Ibid.
[1056] Please see the chapter on Impact, particularly §126-129.

precedence for too long over patient autonomy, individualised medical treatment and, fundamentally, respect.

11. This Inquiry would not be the first to suggest that there are pervasive cultural problems within the NHS. The Francis Report identified "*an institutional culture which ascribed more weight to positive information about the service than to information capable of implying cause for concern*" and a "*failure to tackle challenges to the building up of a positive culture.*" The report recommended that the NHS "*foster a common culture shared by all in the service of putting the patient first.*"[1057] Those criticisms and that recommendation remains valid and have been reinforced by the evidence given to this Inquiry, which has had a chance to examine practice in a range of clinical disciplines over a long period of time.

12. Indeed, the repetitive quality to the findings of the various recent inquiries and reviews that have been tasked with investigating medical malpractice was encapsulated by the oral evidence of Dr Melinee Kazarian, one of the Medical Ethics Experts:

> *"I think there... are common themes to different healthcare failing episodes that we've seen in different inquiries… the lack of information given to patients, the lack of transparency, the lack of openness, the failure to actually listen to patients and listen to their concerns, that's something that has come back in almost all inquiries that have addressed a particular failure, a particular episode…."*[1058]

13. This Inquiry can equally draw the same conclusions.

14. The NHS has already been recognised as having attitudes and approaches towards women that need to be the subject of a systemic culture change. In *First Do No Harm*, the report of the Independent Medicines and Medical Devices Safety Review

[1057] Francis Report, p4: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf. We consider that his recommendations numbers 2, 12, 220 and 290 are all relevant.
[1058] Transcript 27/01/2021, p156, ll12-23.

("**IMMDSR**"),[1059] Baroness Cumberlege noted numerous reports of medical complaints from patients being "*fobbed off*" consistently by medical professionals. She commented "*… patients – almost universally women – spoke in disbelief, sadness and anger about the manner in which they were treated by the clinicians they had reached out to for help. The words 'defensive', 'dismissive' and 'arrogant' cropped up with alarming frequency*".[1060] She also noted the damage that these dismissive attitudes caused to patient faith in those treating them. The same report records repeated failures to obtain informed consent. Baroness Cumberlege concluded that "*put simply, the system has not been listening as it should*". She recommended that a Patient Safety Commissioner be recruited. This recommendation has been fulfilled recently by the appointment of Dr Henrietta Hughes, who commenced her post on 12 September 2022. The remit of this post, however, constitutes a significant missed opportunity, given it is limited to medicines and medical devices rather than care and treatment more broadly.

15. That report was issued in 2020 and its recommendations were substantially accepted by the Government in its response in 2021.[1061] There is no reason to be confident that this dysfunctional culture has changed or improved since that time and there is certainly no room for complacency. The publication of the Ockenden Review into maternity services at the Shrewsbury and Telford Hospital NHS Trust in March 2022, once again, raised similar themes. These findings reflected earlier investigations into maternity care in the Morecambe Bay Investigation – an independent investigation into the management, delivery and outcomes of care provided by the maternity and neonatal services at the University Hospitals of Morecambe Bay NHS Foundation Trust from January 2004 to June 2013. Dr Bill Kirkup, who led that review, found that "*there were repeated failures to be honest and open with patients, relatives and others*

[1059] Available at: https://www.webarchive.org.uk/wayback/archive/20200721101148mp_/https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf.

[1060] *First do no harm*, p17.

[1061] Government response to the Report of the Independent Medicines and Medical Devices Safety Review, 26 July 2021. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf.

raising concerns. The Trust was not honest and open with external bodies or the public."[1062]

16. The accounts of our CPs and of other IAP in this Inquiry regarding their recent experiences of late and/or misdiagnosis, combined with poor communication and follow-up, demonstrates that these systemic and cultural issues around honesty and candour persist throughout the NHS.

17. The Inquiry should also recognise the specific and additional discrimination and burden experienced by our CPs from minoritised ethnic groups, particularly those who are female and for whom the discriminatory treatment described above intersects with the discrimination they experience because they have been racialised as an "ethnic minority". Disproportionately worse health outcomes have been the subject of various recent reports, including MMBRACE.[1063] The Chair is invited to consider the experiences of all IAP from minoritised ethnic groups. While exploring the psychosocial impact of the stigma of having a TTI within these communities has been a focus of the Inquiry's work in this regard, it is vital that the Inquiry considers the impact of stigma and racially biased resource allocation, care and treatment, and communication *within* the NHS and other governmental systems and structures, not merely outside them. Professor Dame Sally Davies' evidence on sickle cell treatment (explored below) raised such themes.

18. None of the above exculpates individual clinicians entirely. It is at the core of medical ethics that doctors, as individuals, are required to act ethically. Those actions are discussed in detail below. It would be unreal and unhelpful, however, to deny that clinicians work within systems and cultures, and that these can fundamentally influence how individuals behave.

[1062] See §25 in report available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf.

[1063] https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/maternal-report-2022/MBRRACE-UK_Maternal_Report_2022_-_Lay_Summary_v10.pdf and https://www.gov.uk/government/news/new-taskforce-to-level-up-maternity-care-and-tackle-disparities?msclkid=ce3c98f6a5de11ec9733c0ba172e1260 etc.

A health system radically under resourced

19. The NHS can only function properly where it is adequately funded and resourced. The malpractice that is the subject of the submissions in this chapter arose, at least in part, due to a lack of proper resources and funding in the NHS.

20. It is trite to say that a consent process, and effective, personalised communication of risk, is only as good as the time available to conduct it, and doctors who are perpetually "*firefighting*" may not have the space in their schedule to do the vital work to keep up to date with guidelines and research.

21. This important barrier to the delivery of effective patient care and was emphasised by those who gave expert evidence to the Inquiry – including most notably the Public Health and Administration Expert Group and the Medical Ethics Expert Group.

22. "*On the ground*" Professor Philip Steer, a distinguished obstetrician who ran a central London maternity service and taught many junior doctors, gave oral evidence of how a lack of funding impacted the training of junior and senior staff, meaning that they are not up to date with the latest guidelines and clinical practice. He referred to his own attempts at developing training programmes for junior doctors in his Trust being curtailed because of resources.[1064] As a result, charities were obliged to plug this vital education gap. Baby Lifeline, for example, he said, "*raises millions of pounds a year to do training for obstetricians and midwives. So they are a substantial part of the training effort.*" He summed up the perversity of this situation when he said: "*I have always thought it odd -- I mean, if you went to an airport and you saw a pilot shaking a collecting box and you said, 'What are you collecting for?' and he said, 'It is a charity for pilot training', you might be slightly surprised. And yet a lot of the training in maternity in the UK is still done on a charitable basis. I personally felt that is not adequate.*"[1065]

[1064] Transcript 23/02/2022, pp80-81.
[1065] Transcript 23/02/2022, p90, ll10-17.

23. The "*catch 22*" of a lack of funding was captured by Professor Bobbi Farsides, who referred to an "*unreasonable*" system that "*has been denuded of finances or where attention hasn't been paid to organisational, systemic issues*", which inevitably leads to things going wrong and patients being put at risk. Professor Julian Savulescu referred to "*radical underinvestment in the NHS… [as] a significant part of the problem*", suggested that doctors were still "*operating in a system that isn't fit for purpose*" and urged the Inquiry to "*take a courageous step and encourage politicians to invest properly in their healthcare system*".[1066]

24. As well as the level of resource available, the way resources are allocated and planned in the NHS is also problematic. Professor Charles Vincent highlighted the flawed logic of the annual financial cycle of the NHS; making it a "*nightmare to get anything done*".[1067] We set out issues concerning planning and the cycle of the NHS funding in the Government chapter which reflects similar concerns.[1068]

25. We strongly endorse these views, and respectfully submit that any recommendations made by the Chair will be ineffective if they are not supported by proper funding and investment. Any such investment should be actively cognisant of existing health disparities and ensure that any possible bias in the investment in or delivery of NHS services is actively eliminated. The Inquiry has identified at various junctures the gaps in quantitative and qualitative evidence regarding racial discrimination and its impact on IAP.

26. What is required is radical reform, both in terms of the amount of funding and the self-defeating short-termism in the NHS's annual financial planning cycle.

Blood transfusion practice

27. We set out in this chapter the ways in which medical practitioners' actions have led to avoidable harm and suffering on the part of our CPs. An essential element of this harm

[1066] For Professors Farsides and Savulescu's comments, see Transcript 27/01/2021, pp190-194.
[1067] Transcript 04/10/2022, p15, ll4-6. For a pertinent example of this, please see discussion in the chapter on the Role of Other NHS Bodies on the introduction of DAAs.
[1068] See Government chapter.

is, undoubtedly, the transfusion (or transfusions) that transmitted their infection(s) in the first place.

28. The evidence to the Inquiry from practitioners across the field of medicine demonstrates that blood transfusion clinical practice in the Relevant Period was characterised by the administering of clinically unjustified blood transfusions. Blood was both over-transfused, in these sense that more units were given to patients than were necessary; and unnecessarily transfused, in the sense that blood transfusions were given to a patient when it was either clinically inappropriate in the circumstances and/or where a less restrictive alternative (such as some kind of iron treatment or rest) would have achieved the desired outcome.[1069] For practitioners across the clinical spectrum, their propensity to transfuse was reckless and widespread.

29. Indeed, this is not merely a historical phenomenon. A recent 2021 NHS Blood and Transplant ("**NHSBT**") audit of four important NICE Quality Standards (on iron supplementation, tranexamic acid, appropriate haemoglobin levels indicating transfusion, and consent) found widespread non-compliance.[1070] It is logical to infer that many transfusions in the present day are unnecessarily given and avoidable and that these practices continue.

30. The evidence from medical practitioners on this phenomenon is borne out by the CP evidence, and indeed by evidence to the Inquiry from IAP more generally. Counsel to the Inquiry's ("**CTIs**") presentation on the experiences of infected persons receiving blood transfusions[1071] was entirely consistent with our CPs' experiences.

31. The logical conclusion is that a significant proportion of our CPs' infections were avoidable. This does not follow simply in cases where blood transfusion was clinically unjustified *per se*. It follows because evidence to this Inquiry shows that over-transfusion was the norm, yet each additional unit of blood came with a greater risk

[1069] The question of clinical appropriateness in this section is treated as something distinct to the issue of whether a patient gave informed consent, which is dealt with in the following section. It is our submission that if patients were given the chance to give their informed consent to treatment, even more of our CPs' infections would have been avoided.

[1070] RLIT0001824_004. Please see also the oral evidence of Professor Ian Roberts, pp82-86.

[1071] INQY0000327 - Presentation by Counsel to the Inquiry on blood transfusion on the perspectives of infected individuals and their families.

that a patient would contract an infectious disease. That a CP required *a* transfusion does not mean their infection was inevitable. To the contrary, when it came to risk, every unit mattered.

What should medical practitioners have known about the risks of blood?

32. To support our submission that many of our CPs' transfusions were clinically unjustified, it is necessary first to address the question of what medical practitioners knew, or reasonably should have known, about the risks of blood transfusion.

33. First, it has always been a very clear and established principle of transfusion medicine that a transfusion of whole blood or blood components should never be given without a definite indication, because of the associated risks for the patient. Dr George Galea pithily described this principle as "*the safest blood is the blood that is not given*".[1072] Such principles were enunciated as early as the 1958 edition of *Notes on Transfusion*.[1073]

34. If Dr Galea's principle – the lynchpin of blood transfusion clinical practice – had been adhered to by medical practitioners, many individuals may not have been infected.

35. Second, the risk of serum hepatitis, and later non-A non-B hepatitis/HCV from transfusions was explicitly set out for clinicians in multiple important transfusion guidance and textbook documents from the early 1960s onwards.[1074]

36. The risk of serum hepatitis from transfusion was well known from the WWII/post-war period. Following the implementation of testing for HBV in the early 1970s, there is ample evidence before the Inquiry that it was known that a form of hepatitis was, nonetheless, being transmitted. This hepatitis, as a result termed non-A non-B hepatitis, may have been responsible for a significant proportion of what was

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[1072] Transcript 07/12/2021, p25, ll11-12.

[1073] WCAS0000008.

[1074] For example, Dr Discombe's Textbook, *Blood Transfusion*, 2nd edition from 1960, RCSE0000002; *Mollison's Blood Transfusion*, fourth edition published in 1967, RLIT0001570; *Blood Transfusion - A Guide to the Formation and Operation of a Transfusion Service*, edited by Bowley,CC et al on behalf of the WHO, the International Society of Blood Transfusion and the League of Red Cross Societies, 1971, PRSE0002035; 1973 edition of *Notes on Transfusion*, **HCDO0000861** (and subsequent editions of *Notes on Transfusion/the Handbook of Transfusion*).

previously understood to be "*serum hepatitis*". Crucially, it was known from the mid-1970s, and certainly by the end of the 1970s, that, while non-A non-B hepatitis may be associated with less severe acute illness than HBV, its long-term prognosis could be similar with patients developing chronic hepatitis and cirrhosis.[1075]

37. Third, from the early to mid-1960s, key guidance and practitioner texts were already warning clinicians against the use of peri-operative transfusions, including to correct "*anaemia*". They were warned to consider whether other effective and safe treatment, such as pre-medication with iron, or no treatment at all may have been appropriate.[1076] It is not repeated here, but as CTI's presentation to the Inquiry demonstrated, such guidance was only reiterated and strengthened with further clinical evidence and advice throughout the 1970s, 80s and 90s.[1077]

38. Notwithstanding this wealth of evidence-based guidance, it is striking that the significant majority of doctors that gave evidence to the Inquiry regarding blood transfusion practice[1078] did not appear to have had adequate knowledge about non-A non-B hepatitis, later HCV, until the mid to late 1980s. Some did not know about this form of hepatitis until even later. Crucially, these practitioners were not aware that non-A non-B hepatitis/HCV was a chronic condition with serious consequences and could progress to cirrhosis and hepatocellular carcinoma ("**HCC**"). The point at which they gained knowledge appears to have coincided with the identification of the virological agent responsible for non-A non-B hepatitis and the subsequent development of testing technology – far too late. A conspicuous example was Dr Dafydd Thomas, who said the first time he became aware of HCV was in "a*bout*

[1075] We do not repeat CTI's Knowledge of Risk of Infection Chronology (INQY0000006), but rely on it, in particular: article entitled 'Long-incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis-B virus' by Prince et al, published in The Lancet on the 3 August 1974, PRSE0001431; letter from Dr J. Garrott Allen, Stanford University, to Dr Maycock, BPL, 06/01/1975, CBLA0000249; and a report in The Lancet in September of 1978 by Professor Preston, Dr Underwood, Dr Mitchell and others looking at the position of chronic liver disease in haemophiliacs, PRSE0003622.

[1076] See *Notes on Transfusion* 1963 update, JPAC0000162_021; Dr Discombe's Textbook, *Blood Transfusion*, 2nd edition from 1960, RCSE0000002; Article published by Dr Jean Grant, director of the Oxford Regional Transfusion Centre, published in The Practitioner in August 1965, PRSE0003897.

[1077] INQY0000328 - Presentation by CTI about the guidance available to clinicians regarding the use of blood transfusions.

[1078] A trend that was also reflected generally among haemophilia doctors.

1990"[1079] from a Panorama documentary - a news programme designed for a lay population - notwithstanding that he had undergone anaesthesia training (a clinical role with notable responsibility for transfusions) throughout the 1980s and became a consultant in 1989. Similarly, Ms Emma Prescott, who qualified as a registered general nurse in 1988 does not recall being taught anything about viral hepatitis.[1080]

39. There can be no doubt from the totality of this evidence that there was a huge education systems failure in the NHS in relation to BBVs in the 1970s and 80s, especially with regards to non-A non-B hepatitis. This may have been caused by what former CMO, Sir Liam Donaldson, referred to in his 2002 report, Getting Ahead of the Curve, as *"post war optimism that* [the] *conquest* [of infectious diseases] *was near"*; a mindset that he rightly identified, "*proved dramatically unfounded*"[1081], which was echoed wholeheartedly by the Public Health and Administration Expert Group. This systems failure will be addressed in the chapter on the Role of Other NHS Bodies.

40. However, this educational lacuna cannot be a complete answer when assessing the role medical practitioners played in the infected blood scandal. As the Medical Ethics Expert Group Report makes clear, it is a fundamental principle of medical ethics that "*clinicians are required to act on sufficient information*". Clinicians are required to keep abreast of developments, with current guidance from the General Medical Council ("**GMC**") requiring doctors to be competent in all aspects of work and to *"keep your professional knowledge and skills up to date*". As a matter of law, it was established as early as 1950 (see *Whiteford v Hunter* (1950) 94 Solicitor's Journal 758, HL) that, although a practitioner is not expected to know of every published research paper in their field, they may be found negligent if they have not followed general and approved current practice.[1082]

41. The risks of BBVs, including non-A non-B hepatitis, were known and were the subject of guidance in the Relevant Period. For practitioners for whom transfusion was a significant part of their role, knowledge of these risks was necessary to ensure that

[1079] Transcript 02/03/2022, p79, ll10-16.
[1080] Transcript 03/03/2022, p88, ll6-8.
[1081] RLIT0001745_0009.
[1082] Medical Ethics Expert Group Report, p46.

they were acting on sufficient, up to date knowledge. A failure to do so was, we submit, unethical.

Blood transfusion sub-issues

Blood top ups and the "*two not one*" policy

42. Arguably the most significant of failures in relation to blood transfusion was the practice of giving "*top ups*" of blood to patients – namely a transfusion with the goal of making a patient recover quicker (whether pre-, peri- or post-operatively) and often based on a misguided notion of what constituted "*anaemia*".[1083] This was linked to the practice of giving "*two not one*" units of blood – a perverse practice based on the belief that "*if you are going to give any blood, you might as well give two units rather than one*".

43. In both cases, these are clear examples of either altogether unnecessary or over transfusion of blood and an approach that subjected patients to unnecessary risk. These practices were especially common in the obstetrics and gynaecology context (discussed in further detail below), meaning that a disproportionate number of our infected CPs are women.

44. The ubiquity of these practices was reflected in the near universal reference to them by practitioners in their written and oral evidence to the Inquiry.

    a. Dr Thomas said that in the early 1990s "*top ups*" and "*two not one*" transfusions were still "*undoubtedly…occurring quite a lot.*"[1084] His experience was that there was an ongoing issue in the Cardiac ITU with the giving of "*top up*" transfusions. He described this as a reluctance in this field of medicine, to have their "*safety blanket*" removed.[1085]

    b. Dr David Bogod, who practised as an obstetric anaesthetist, caveated his initial evidence that he could not recall a single patient to whom he gave a transfusion

[1083] Professor Steer Transcript 23/02/2022, and INQY0000328 - Presentation by CTI about the guidance available to clinicians regarding the use of blood transfusions.
[1084] Transcript 02/03/2022, p111, ll17-25.
[1085] Transcript 02/03/2022, pp108-110.

that he would not now transfuse, by saying, "*I would perhaps not have transfused as many units of blood and I have said that perhaps in the postpartum period, in the very rare occasions when I was involved in transfusing patients postpartum, I might have decided not to transfuse a patient rather than to transfuse them*".

c. Dr Jonathan Wallis, from his perspective as a Consultant Haematologist, explained how the "*two not one*" mantra became a substitute for patient-specific clinical judgment:[1086]

> "*There was a general belief among many clinicians, not, possibly, haematologists, that if you are going to give any blood, you might as well give two. And there was no real logic to that. Subsequently some people changed dramatically and said, 'We should never give more than one unit at a time without re-checking'. I think both of those positions are not really tenable. And the important thing is to give the blood that you think is going to be required to achieve the benefit that you think is necessary.*"[1087]

d. The illogicality of this mantra was encapsulated by Dr Thomas:

> "*…if you are going to try and restrict transfusion to a transfusion trigger or a target of 90g, then it would be valid to give a one-unit transfusion in that situation because it gets you over the line, over the 90. You don't need to give two, because the inherent risks of giving two units are double the risk of giving one. And if you have set a target of 90 and one unit will take you over 90, then there is a justification for a one-unit transfusion.*"[1088]

e. The practices of "*top ups*" and "*two not one*" transfusions are examples of malpractice that took hold culturally among clinicians. They took precedence over guidance-driven, evidence-based medicine. They were perverse policies, whose logic does not withstand scrutiny. They meant that patients were subjected to

[1086] This was also corroborated by the evidence of Dr Bogod, Transcript 23/02/2022, p128, ll10-19.
[1087] Transcript, 24/02/2022, p68, ll6-15.
[1088] Transcript 02/03/2022, p111, ll2-11.

unnecessary viral risk, where they should never have been given a transfusion at all, or where only one unit was clinically necessary for their recovery.

f. It should be of grave concern to the Inquiry that Professor Mark Bellamy gave evidence of modern-day malpractice in relation to blood transfusion and "*top ups*": "*Dr X will wander in to see his patient who has been admitted to critical care and sneakily prescribe two units of blood to bring them back up to 113, completely unnecessarily, but he thinks he's a doing the right thing because he's correcting the numbers, not based necessarily on evidence*".[1089] He suggests that there needs to be a "*lightbulb moment*" – for example a pivotal study – to create cultural change around such practices. We submit, however, that the evidence on safe transfusion is plentiful and has been since the Relevant Period. This Inquiry's report, including its recommendations, must act as a "*lightbulb moment*" for practitioners in this field and precipitate the cultural change that is so urgently required.

Obstetrics and gynaecology

44. More of our CPs were infected in the obstetric and gynaecological context than any other single field of medicine (60 of the primary infected CPs).[1090] It therefore merits specific emphasis. There are various examples of women being given transfusions for anaemia associated with pregnancy or childbirth and also in emergency circumstances, such as obstetric haemorrhage.

45. Of course, childbirth and other obstetric/gynaecological events are likely to be associated with a risk of blood loss and associated blood transfusion. In our submission, however, the disproportionate number of CPs who were infected this way does not simply reflect that heightened risk but intersects with gender discrimination against female patients, both in relation to the initial transfusion and subsequent care

[1089] Transcript 16/11/2022, pp160-165.
[1090] Please see the chapter on Impact, particularly Annex 6.

and treatment. Such cases are often associated with a disproportionately long period before diagnosis and misdiagnoses of HCV-related symptoms (discussed below).[1091]

46. The practices of "*topping up*" and "*two rather than one*" appear to have been as – or more - prevalent in obstetrics and gynaecology.

47. In the case of peri-partum women in particular, a driving force of this malpractice was a phenomenon that Professor Steer discussed extensively in his evidence[1092] of widespread misunderstanding among obstetrics and gynaecology practitioners (a misunderstanding that persisted until he retired) that the standard medical threshold for "*anaemia*" needed to be adjusted for pregnant women. He provided detailed evidence and studies which showed that women in pregnancy have lower levels of red blood cells but that these studies have not been translated to "*on the ground practice*". Even though his evidence was that it was unlikely that this would have led to unnecessary transfusion, we submit that a number of our clients received transfusions in this context for anaemia and it is reasonable to infer that this widespread misunderstanding was to blame.

48. Moreover, Professor Steer referred to the common, but unscientific, practice of "*topping up*" postpartum patients, to "*pep them up*" temporarily; often with the aim of aiding breast feeding or precipitating hospital discharge.[1093]

49. Moreover, his evidence was that the illogical "*two not one*" practice was prevalent in obstetrics/gynaecology as in medicine more widely.[1094]

50. Professor Steer's evidence correlates with the experiences of our CPs with remarkable exactitude. There are some striking examples of inappropriate blood transfusion in the obstetrics/gynaecology context:

    a. W2043– was given a blood transfusion in 1989 at the Queen Elizabeth Hospital, Gateshead for anaemia after the birth of her fourth child.

[1091] We invite the Inquiry to consider the additional intersection with discrimination on the grounds of race for male and female IP.
[1092] Professor Steer, Transcript 23/02/2022, Professor Steer written statement, in particular pp5-8.
[1093] Transcript 23/02/2022, pp25-26.
[1094] Transcript 23/02/2022, p32, ll4-8

b. W1913– was given a blood transfusion for anaemia after labour on GRO-A 1980 at St David's Hospital in Bangor – she was informed she was a "*bit anaemic*" and would be "*bouncing*" after a blood transfusion.

c. W2009– was given a blood transfusion postpartum (but was not anaemic at the time) on GRO-A 1981 in Peterborough Hospital. She recalls being told that she would be getting a bit of blood to help her recover and to prevent her from feeling tired and becoming anaemic. Her GP said six weeks later that she would likely have been able to recover without the transfusion of blood. She does not recall any alternative options for recovery, including the option of no treatment at all, being explained to her.

d. W2059– was given a blood transfusion on 14 June 1984 at Northern General Hospital in Sheffield. Blood was given after stitches burst the day after the operation. Although their blood pressure had dropped, it is not clear that there was a clear clinical case for a transfusion and that alternatives were not appropriate.

e. W0394– was given a blood transfusion several days after birth in GRO-A 1984 at Blackpool Victoria Hospital. It is unclear whether the transfusion was required.

f. W1910 - was given two transfusions for anaemia following the birth of her son on GRO-A 1985 at the Dryburn Hospital. Her notes record that haemoglobin levels were 9.1 gm/dL and that 2 units of blood were transfused. Professor Steer's evidence would suggest that these levels may not have been sufficiently low for a blood transfusion to be required.

g. W1921– was given a blood transfusion for prenatal anaemia on 23 May 1986 at GRO-B Her evidence is that she was told she had to have the transfusion because the doctor had said so, and that she was a young mother and so did not question the medical advice given. She recalls that a nurse took a very sharp tone with her.

h. W1896– was given a blood transfusion for postpartum anaemia on 30 January 1978 at St Mary's Maternity Hospital, Rugby. Her evidence is that she was offered

two units of blood or iron tablets for six months. A midwife advised her that it was better to stay overnight and have the transfusions. Her haemoglobin levels were 8.9 gm/dL. She was not offered any information about the risks of blood transfusion.

51. Professor Steer suggested that these misguided practices persist even in contemporary blood transfusion medicine.[1095] This was demonstrated by his 2017 research, "*Retrospective surveys of obstetric red cell transfusion practice in the UK and USA*". This research concludes that:

> "*Current transfusion practice deviates from evidence-based guidelines. Either by default or longstanding tradition, more women receive two rather than one unit despite similar [estimated blood loss].*"
>
> …
>
> "*Despite evidence demonstrating the clinical benefit of a restrictive transfusion policy in most settings, current transfusion practice in maternity care continues to deviate from recommended guidelines both in the two UK centres and in the US centre studied. However, the unfounded belief that 'two units is better than one' is not unique to obstetrics.*" [1096]

52. Professor Steer described a recent conference he had attended where colleagues in the field clung to the notion of "*two not one*", even where evidence clearly did not support it; something that perplexed him:

> "*…it would almost need a psychologist to work out why they are not convinced by the data. It's something which, as an academic, I have always been intrigued by, why clinical practice sometimes seems at odds with what the scientific evidence suggests to me is appropriate.*"[1097]

53. We invite the Inquiry to conclude that:

[1095] Transcript 23/02/2022, pp30-31.
[1096] WITN6977008.
[1097] Transcript 23/02/2022, pp30-31.

a. Not only did inappropriate transfusion occur disproportionately in the obstetrics/gynaecology context, and thus to women; but that,

b. Doctors are still operating in a culture characterised by inappropriate "*clinical freedom*" to practise in an idiosyncratic way, dependent on their own biases and preferences, even where such practices are contradicted by clinical evidence.

54. These ongoing systemic and cultural issues should be of real concern to the Inquiry. Given that obstetrics and gynaecology are likely to be the most frequent place where women under the age of 50 encounter hospital or specialist care, it is particularly important to recognise the disproportionate impact transfusion transmitted infections have had on women in this context and the absence of consideration or focus upon this to date. (Please see also the submissions on "*clinical freedom*" more generally below and suggested recommendations).

A paradox: an increase in transfusions as more is known about non-A non-B hepatitis/HCV

55. Another theme from our CPs' evidence is that the "*apex*" of infectious blood transfusions was 1981-1985, with large but growing numbers in the five-ten years before, and large but declining numbers in the five-ten years following.[1098] This may demonstrate that despite there being knowledge of non-A non-B hepatitis, there was an increase in infection-causing transfusions at a point in time where the risks of non-A non-B hepatitis hepatitis/HCV were increasingly known. This may not reflect actual infection, as the Statistics Expert Group identified it is simply impossible to know how many infections may or may not have occurred, and of course this is a sample of those transfused who would be young and healthy and so more likely to have survived to be able to become our CPs to this Inquiry. Similarly, those transfused before 1980 may not have had non-A non-B hepatitis diagnosed and/or not been aware of the link between transfusion and their liver dysfunction (and sadly may have died).

[1098] Please see the chapter on Impact and Annex 6.

56. We consider that there was a particular ethical imperative as more was known about non-A non-B hepatitis/HCV, and testing technology was on the horizon, for practitioners to consider whether transfusion could be avoided. At the very least, it created a heightened duty to explain the risks, and, when testing was envisaged in the near future, to offer a patient the chance to postpone elective surgery. There is no evidence from our CPs that this occurred. To the contrary, Professor Steer could not recall any advice or information being given to patients on this issue.[1099]

A fear of innovation

57. The evidence to the Inquiry also shows a reluctance on the part of medical practitioners to use innovative methods that would have reduced the risks of blood transfusions and, therefore, led to fewer infections. Such technologies include using red cell concentrates rather than whole blood,[1100] cell salvage, pre-deposited autologous blood,[1101] or tranexamic acid in surgery (a medication that Professor Ian Roberts described as widely misunderstood and underused, notwithstanding a significant body of evidence and guidelines supporting it).[1102] Dr Thomas presented evidence of autologous transfusion's superior safety record in terms of TTIs.[1103] Only Dr Thomas spoke of this as routine in parts of his practice from 1989 onwards. But he described it as an "*uphill struggle to convince people*" of the innovation.[1104]

An emerging theme: clinical freedom over evidence

58. The areas of malpractice above are arguably united by a common overarching theme – the ignorance of evidence, and the reliance on "*what has always been done*" without oversight of practices by managers or hospitals. Patient interests were subsidiary to the rights of doctors to do what they thought was best, even if it did not actually reflect what was best, or even clinically appropriate.

[1099] Transcript 23/02/2022, pp94-95.
[1100] A paper by Professor Cash noted, "*our clinical colleagues have on occasion been somewhat reluctant to use this product*": PRSE0002637
[1101] Although it should be recognised that studies in autologous blood usage show that it was not widely taken up (link to the blood services evidence about this).
[1102] Transcript 10/11/2022. His evidence as a whole.
[1103] WITN6973006.
[1104] Transcript 02/03/2022, p93, l19.

59. There have also been systemic failings to educate doctors, to disseminate guidance and to impose proper systems to ensure that blood and blood products were not over or unnecessarily transfused/administered and that blood use was properly audited. These failings are attributable to other governmental, NHS (or professional bodies) and the NBTS and are discussed in other chapters.

60. However, even in the face of effective initiatives, almost all clinician witnesses discussed a reluctance on the part of their colleagues to change their practice and a resistance to better blood management. This cannot be solely attributed to a lack of education but is reflective of a more pernicious culture in the NHS; a resistance to change, even in the face of established scientific evidence that has been translated into digestible and accessible guidance. While it may be supportable to depart from guidelines where there is a valid clinical justification and it is in an individual patient's best interests (the use of tranexamic acid where clinically appropriate and outside the terms of its licence being one of them), it is not appropriate that a culture remains of doctors continuing to operate based on their own whims and biases (often passed down from doctor to doctor in entrenched hierarchies), even in the face of evidence to the contrary.

61. Former CMO and sickle cell expert, Professor Dame Sally Davies, described the problem as follows:

> *"But the big problem is not dissemination: you can email it, you can post it, you can put it on the wall, but* ***how do you change the hearts and minds so people do things differently****? And it is extraordinarily difficult."*[1105] (emphasis added)

Professor Dame Sally Davies therefore suggested that there should be proper research into how you initiate behavioural cultural change in organisations such as the NHS. She proposed a three-pronged approach: to enhance the effect of "good practice" standards with the weight of the law; to ensure adequate, high-quality training; and to incentivise practitioners with empirical evidence, demonstrating how changed practice benefits their patients.

[1105] Transcript 03/03/2022, p63, ll16-25.

Recommendation 1: Research regarding behavioural and cultural change in the NHS

a. The Inquiry should recommend research is conducted on how to initiate cultural change in the NHS with regards to compliance with guidelines.[1106]

Consent

62. Equal in significance to the issue of clinically unjustified blood transfusions is the apparent universal failure of medical practitioners, throughout the Relevant Period, to provide patients with adequate information about the risks of receiving blood.

63. Information is the cornerstone of consent; consent is the cornerstone of patient autonomy; and patient autonomy is the cornerstone of medical ethics. Its importance cannot be overstated.

64. Failure to provide information is not just a matter of form but has real life practical consequences. As many of our CPs state clearly in their evidence, if the known risks of BBVs had been explained to them before receiving blood (in accordance with the knowledge of risk and guidance set out above), they may well have refused a transfusion or decided not to proceed with the primary procedure. For those CPs for whom a transfusion was unavoidable or lifesaving, receiving information about TTIs would have allowed them to self-monitor for symptoms, make lifestyle changes (such as minimising alcohol intake), or seek medical assistance or attention at an earlier stage. It may also have helped patients whose symptoms were dismissed (on which see further below, particularly in relation to GPs), by arming them with the knowledge that transmission of viruses was a proven risk of transfusion, empowering them to self-advocate and ask for a specific test.

65. The "*open futures*" of our CPs were taken from them by choices wrongly made on their behalf by medical practitioners. A decision by a doctor that it would be better for a

[1106] There is significant overlap with this recommendation and our recommendation in the chapter on the Role of Other NHS Bodies on creating a national guidance repository, which we hope will in and of itself create cultural change. However, the Chair may consider that it is worth making a separate recommendation on research into cultural change, given the widespread non-compliance with critical evidence-based guidelines demonstrated by evidence to this Inquiry.

new mother to receive a transfusion so she could breast-feed her baby may have had devastating consequences for her future, when she could not be the energetic mother, or grandmother, that she wished to be because of the effects of her hepatitis. By not warning patients about the risks and symptoms of viruses to look out for, our CPs were denied the chance to mitigate that harm, or manage their illness more effectively, or with greater dignity.

66. The sad but incontrovertible truth is that the failure to give patients information peri-operatively on the risks of transfusion caused avoidable deaths and avoidable morbidity. The ripple effect of this suffering on everyone affected is explored in the chapter on Impact.

The ethical basis for consent and information-giving

67. CTI's presentations to the Inquiry on the development of guidance to clinicians on blood transfusion practice and medical ethics showed, undoubtedly, a progression throughout the second half of the 20th century in terms of how strongly and clearly medical ethical principles were articulated, particularly in relation to patient consent.

68. However, a requirement for "*mutual respect*" – that is a model based on shared decision-making rather than paternalism – has been a constant in medical ethics throughout the Relevant Period. While the articulation of this principle may have developed, it was set out in one form or another in ethical guidance from at least the 1970s onwards.[1107]

69. Moreover, the Medical Ethics Expert Group gave cogent evidence that there is a fundamental ethical imperative to explain materially significant risks, and that the discussion of risk, including viral infection, should have formed part of a consent discussion and process for a blood transfusion, wherever possible.

70. Linked to that fundamental ethical imperative to inform, the experts identified various principles and components of ethical behaviour, which the Inquiry should strongly endorse:

[1107] Transcript 28/05/2021, p49-50.

a. Provision of information to patients is intrinsic to autonomy, and therefore informed consent. This is because, without information a patient is denied a real choice.[1108]

b. Ethics requires doctors to be able to identify what principles and values a patient holds, to weigh them into decision making about what treatment is appropriate for that individual patient in a reasoned and rational way. Those values, for example whether a patient prioritises longevity over quality of life, are uniquely known to the patient so the doctor must explore what values are at play.[1109]

c. Patients should be told about "*common risks, even of minor events, and uncommon risks of major events, and thirdly, of things which would be of particular value to them that don't fall into one of those two categories*". In the same vein as above, ascertaining what is of value to patients, and thus what is a material risk for them subjectively, involves reasonable enquiry.[1110]

d. A risk of a blood borne infection, which may be life-limiting or fatal, we submit, falls into one or another of those categories above.

e. Informed consent also necessitates the provision of information about reasonable alternatives to the treatment recommended by the doctor. A "*meaningful choice*", however, also requires a doctor to make clear that an alternative to treatment is "*no treatment*", and that the patient has the freedom to decline any form of medical intervention.[1111]

f. By withholding information and denying the patient the chance to consent to treatment on an informed basis, namely make a meaningful choice, a doctor may be taking from the patient what is known as their "*open future*". This is linked to a failure to consider the patient's subjective values and desires, discussed above.[1112]

[1108] Transcript 26/01/2021, pp112-113.
[1109] Transcript 26/01/2021, pp17-18.
[1110] Transcript 26/01/2021, pp195-196.
[1111] Transcript 26/01/2021, p205, ll7-18. This has particular application for our CPs with mild and moderate bleeding disorders, discussed in further detail in the chapter on Haemophilia Doctors and the UKHCDO.
[1112] Discussed in particular by Professors Kerridge and Farsides: Transcript 26/01/2021, pp61-62, l11-21.

71. Although the position of the Medical Ethics Expert Group is that the principles set out above are objective, fundamental ethical principles, which govern how a doctor should behave, it is noted that guidance from as early as 1953[1113] also advised doctors to carefully explain the risks of treatment and *"what may ensue"* in non-technical language to obtain consent. CTI's presentation on ethical guidance is not repeated but is relied upon and sets out many other examples of relevant guidance on consent for practitioners.[1114]

CPs' experiences of blood transfusion and consent

72. The evidence shows overwhelmingly that the risks of BBV transmission, particularly viral hepatitis, were not clearly explained to patients – pre- or post-operatively – in the Relevant Period.

73. This is consistent with the Royal College of Physicians' "*National Audit of the Clinical Blood Transfusion Process*", dated January 1998 which found that *"no hospitals required informed consent for blood transfusion"*.[1115] Further analysis of our CPs' evidence demonstrates the following themes:[1116]

    a. Almost none of our CPs were given any explanation of the risks and benefits of transfusion, as well as any clinically appropriate alternatives.

    b. Where applicable, while some of our CPs consented, on the face of it, to a primary procedure, it is rare that information about blood transfusion as a distinct element of the treatment was explained to them and consent sought for it.

    c. Some CPs recall signing a consent form, but there is no suggestion in our CPs' evidence that signing such a form led to a greater or any understanding of the

[1113] MOJU0000001_013. Praised by the Medical Ethics Expert Group as broadly consist with the contemporary legal concept of informed consent and a *"pretty good"* reflection of what is required ethically: Transcript 26/01/2021, p126, ll8-24.
[1114] INQY0000249.
[1115] **NHBT0042247**.
[1116] Which, we note, were very consistent with the broader IAP evidence as set out in INQY0000327 - Presentation by Counsel to the Inquiry on blood transfusion on the perspectives of infected individuals and their families.

risks of transfusion. For example, one CP, W2701, believed that the consent form he signed may have been a "*waiver*".

d. As well as failure to obtain informed consent, there are some rarer but nonetheless significant examples of patients being proactively or negligently misled into treatment, by being told that blood was safe or infection-free. For example:

i. W1987 – recalls asking if blood was safe and being told that it had been treated with "*gamma rays*".

ii. W1934 – was given two units of blood on GRO-A 1985 at Staincliffe Hospital, Dewsbury, for a haemorrhage during labour. She expressly recalls trying to refuse a blood transfusion because she was afraid of contracting HIV, but that doctors "*badgered*" her into it and told her that her fears were "*groundless*". A junior doctor later misled her into believing that the blood may have been heat treated.[1117]

iii. W1885 - was told that the blood he received was 100% safe, there was *"no chance*" it could be contaminated, and that the doctor was so sure of this that he would have "*given it to his 7-year-old daughter.*"[1118]

iv. In terms of post-operative information, we cannot identify any CPs represented by Leigh Day who were given post-operative information about the risks of viral (particularly non-A non-B hepatitis/HCV) infection caused by transfusion, including signs and symptoms to watch out for. Indeed, many were unaware that they had been given a blood transfusion at all. This is the case particularly where blood transfusion was given when the patient was unconscious.

74. Clearly, therefore, the ethical principles identified by the Medical Ethics Expert Group, and in contemporary guidance, were widely contravened and ignored by medical

[1117] The Chair will recall that he raised this as a particularly egregious example on Transcript 21/02/2022, p60-61, ll25-5.
[1118] WS §6.

practitioners. This was indeed the overwhelming evidence of all clinicians who gave evidence on blood transfusion policy and practice.

75. Dr Bogod gave particularly instructive evidence, as an anaesthetist with the primary responsibility to transfuse, on the issues of consent around a transfusion. In summary, his evidence was:

    a. If there was a discussion pre-operatively, he did not normally mention a risk of transmission of disease (i) because "*the risk of transmission was very low*" and (ii) it would not be viable to get a patient to consent to every "*drug*" or treatment (blood) that they might receive under anaesthesia.[1119]

    b. In terms of the significance of HCV risk and the assessment he made, his evidence was that, "*Maybe because of the long-term nature of this complication, but it's not something that was forefront in my mind and, I suspect, in the minds of other anaesthetists either*"[1120], which demonstrates a paternalistic approach, and also one based on a clinically incorrect judgment of the risks of non-A non-B/HCV.

    c. In a conscious but "*urgent*" situation, a patient would be told, "'*you are losing a lot of blood and we are going to have to give you a blood transfusion*' *and I think that would be about it.*"[1121]

    d. He did not and does not know if another doctor followed up with them post-operatively and told them that they had had a transfusion; indeed (in our submission, worryingly) this had only occurred to him since participating in the Inquiry.[1122]

    e. Similarly, he does not know if a patient given a transfusion when unconscious under general anaesthetic would have been "*appropriately informed*".[1123]

76. Professor Steer's evidence was that a blood transfusion would not involve a discussion of risks, including viral hepatitis, unless perhaps a woman appeared nervous, worried,

[1119] Transcript 23/02/2022, pp141-142.
[1120] Transcript 23/02/2022, p142, ll4-7.
[1121] Transcript 23/02/2022, p138, ll18-23.
[1122] Transcript 23/02/2022, p139, ll5-14.
[1123] Transcript 23/02/2022, p140, ll19-24.

or raised an issue.[1124] Unsurprisingly, therefore, he does not recall ever specifically mentioning the risks of non-A non-B hepatitis/HCV (as distinct from viral hepatitis more generally) to patients.[1125] Nor could Dr Wallis.[1126] Dr Steer suggested that this may not have been "*particularly useful information for the women*".

77. For Professor Anthony Goldstone, in the context of malignant haematology (particularly leukaemia) where treatment typically involved significant platelet transfusion alongside chemotherapy, he frankly admitted that he formed a judgment on the patient's behalf as to what was best for them, and called the consent process "*ill-informed*":

> "*One might say the consent was ill-informed in that I'd made a judgment that when they wanted the treatment it was better to go ahead with it than go into too much statistical detail about that viral infection risk. And I will hold up my hands to that. But that was a kind of clinical judgment of, "How do I deal with you?" Which is not not giving information but trying to make life just about bearable at the lowest possible moment. Does that make sense?*"[1127]

78. Overall, therefore, clinicians' evidence demonstrated a woeful underappreciation of the significance – objectively and subjectively – of the risks of viral hepatitis, particularly non-A non-B hepatitis/HCV. Moreover, it showed a self-consciously paternalistic approach to information giving, that deprived patients of the opportunity to give informed consent to a transfusion based on knowledge of viral risk. It involved a doctor substituting his own judgment (and his own values) for that of the patient and deciding for them what would be in their best interests, particularly where they were *perceived* to be vulnerable or likely to be distressed by relevant information. Only the eloquent or well-informed patient, who pressed for information on viral hepatitis risks, appeared to have a chance of receiving it. However well-meaning, this approach is plainly unethical.

[1124] Transcript 23/02/2022, pp44-48.
[1125] Transcript 23/02/2022, pp76-77.
[1126] Transcript 24/02/2022, pp47-49.
[1127] Transcript 02/03/2022, p60, ll7-15.

Consent sub-issues

Testing without consent

79. The Medical Ethics Expert Group notes that "*in the past, clinicians made a paternalistic judgement about whether testing was appropriate but today the value of testing is established as a part of a broad discussion about the goals of care*".[1128] Consistent with this, some of our CPs' medical notes contain test results showing that they tested positive for a TTI months or years before they were told of their diagnosis.[1129] The only logical conclusion is that they were tested without their consent. The expert report makes very clear, however, that, "*the need to respect the patient's autonomy means it should be up to the patient to determine whether they will accept or reject [a] test [for a TTI]*".[1130] We strongly endorse this position and submit that such testing without consent was completely unethical and wrong.

Emergency treatment

80. There is a particular issue around blood transfusions being given to patients in an emergency setting and/or when they were unconscious and/or incapacitated. This was the case for some of our CPs and, as set out above, there is no evidence that the risks of transfusion were explained to them post-operatively, and many were unaware that they had even had a transfusion.[1131]

81. Professor Steer gave concerning evidence of what he accepted was a paternalistic attitude to post-operative information. He said that a "*very paternalistic approach with clinicians deciding for a new mother that she didn't need to worry herself about potentially distressing information about a transfusion*" was a "*common approach.*"[1132] His evidence was that, certainly up until the late 80s, it was a matter of

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[1128] Medical Ethics Expert Group Report, p61.

[1129] GRO-D, W1901 §11, 17, W3326 §12, W1889 [ANON] §8, W2642 §11, W1825 §11-12, W2643 [ANON] §8. W1832 §8, GRO-D.

[1130] Medical Ethics Expert Group Report, p60. See also transcript 27/01/2021, pp10-15 in particular, where experts discussed how, "*around the 1980s at the time of HIV, that expectation changed, and it no longer became reasonable to imply consent for certain kinds of tests* [including tests for hepatitis]".

[1131] Please see the chapter on Impact, in particular §4.

[1132] Transcript 23/02/2022, p74, ll17-23.

clinical judgment for the individual clinicians on a ward round (who may not have been in the treating team at the time of the transfusion) as to whether they would inform the woman that she had had a transfusion, and the significance of that. An attempt by Professor Steer to implement a form and procedure for post-operative information-sharing was discontinued following patient and staff complaints.[1133]

82. The Medical Ethics Expert Group's evidence was instructive on an ethical approach to consent in an emergency treatment situation:

a. As a preliminary point, even if treatment is required urgently, unless there is a genuine emergency, it is incumbent on a clinician to decide whether there is time (adequate for the situation) to nonetheless get informed consent from a patient for a transfusion or whether surgery could be put off, even for a period of hours, to allow a proper consent process to occur.[1134]

b. Where treatment is required in a genuine emergency, and consent cannot be taken, the least restrictive option of the patient's future choices (minimum blood) should be selected.[1135]

c. Where a blood transfusion has been given in a genuine emergency, the full informed consent process should still occur, just in a different way and after the event. A practitioner is under an ethical obligation to ensure that the patient is informed about the treatment they have received, what the risks of that treatment are, and what that might mean for them in the future, so the patient can make choices going forward at least.[1136]

d. The fact of the transfusion and the circumstances should be fully recorded in the usual way in a patient's medical records.[1137]

e. As an extra safeguard, where treatment is being given to a patient under emergency circumstances, a member of the treating team can talk with surrogate

[1133] Transcript 23/02/2022, pp71-74.
[1134] Transcript 27/01/2021, pp1-2 and p4, ll12-24
[1135] Transcript 27/01/2021, p4, ll3-12.
[1136] Transcript 27/01/2021, pp2-3 and pp4-5.
[1137] Transcript 27/01/2021, p6, ll6-16.

decision makers (such as family members, loved ones or carers) contemporaneously, so that they can also inform the patient when they regain consciousness.[1138]

83. As with consent more generally, these ethical principles appear to have been honoured in the breach. There is no evidence on a practitioner, departmental, Trust or systemic level of any functioning system in place to ensure that patients were made aware of the fact that they had received a blood transfusion in emergency circumstances, including when they temporarily lacked capacity, or the significance of this. To the contrary, Professor Steer's evidence was that his attempt to implement one was actively rejected by fellow clinicians.

84. We suggest a recommendation on post-operative consent below.

Medical practitioners' misunderstanding of consent

85. We note as a general theme the frequency with which the Chair had to put to clinicians that "*express consent*" did not equate to "*written consent*" (such as by way of a consent form), and to explore other misconceptions around consent.[1139] It was not clear that this was just a matter of semantics. We consider that there may have been confusion where a hospital did not require written consent as a matter of form for a blood transfusion, that this somehow diminished the ethical requirement for the patient to give informed consent. This confusion seems to be the most reasonable explanation for the very strange discussion[1140] in a note of the British Committee for Standards in Haematology, dated 13 July 1994, concerning "*Consent for Transfusion*". Its Task Force concluded that, "*The risks associated with blood transfusion were not of such magnitude that there should be a legal requirement for informed consent to transfusion*"[1141] – a conclusion that is on any view legally and ethically wrong.[1142] In any event, the evidence suggested an undue focus on formalistic, rather than substantive, conceptions of patient consent, even to the present day. Entirely on this

[1138] Transcript 27/01/2021, p6-7.
[1139] Dr Wallis for example.
[1140] Which perplexed the Chair in an oral hearing on 21/02/2022, pp143-147.
[1141] DHSC0004486_097.
[1142] See Medical Ethics Experts discussion in transcript 26/01/2021: pp 170-171.

point, we note the Chair's challenge to Professor Derek Manas on the subtle but important difference between the concepts of "*giving*" consent by and "*taking*" consent from a patient.[1143]

86. The evidence to the Inquiry has demonstrated that issues around blood transfusion and consent (for transfusion and more generally) are not historic but continue to the present day. Indeed, Dr Murphy's evidence was that, even in 2021, consent for blood transfusion was still not universal, and that 36% of patients received no verbal or written information about blood transfusion.[1144] Audit shows that the majority of patients are not being given the national resource leaflet drafted by NHSBT on blood transfusion.[1145]

87. We therefore suggest the following recommendations for the Chair's consideration.

Recommendation 2: Placing Montgomery on a statutory footing

a. The *Montgomery* duty in relation to patient consent should be placed on a statutory footing, which will encourage compliance and/or heighten awareness of the duty among both medical professionals and patients. This could be a similar mechanism to the statutory duty of candour, which is now seen as a crucial, underpinning aspect of a safe, open, and transparent culture in medicine. We suggest that there may be an added benefit in formalising the *Montgomery* duty in the same way.[1146]

Recommendation 3: Patient-focused consent campaign and questionnaires

a. There should be a consent campaign aimed at doctors and patients, similar to the "*choose wisely*" campaign, referred to by Dr Murphy, which encourages patients to

[1143] Transcript 10/11/2022, pp65-67.
[1144] Transcript 24/02/2022, p164, II17-23. This is also supported by the 2021 National Comparative Audit of the NICE quality standards that were published in February 2022 [WITN7001061], similarly referred to by Professor Ian Roberts.
[1145] Transcript 24/02/2022, p165, ll4-17.
[1146] Which was also the view of Dr Susan Hopkins: see Transcript 15/11/2022, p59.

ask their doctors five important questions, to avoid unnecessary medical intervention where not supported by evidence.[1147]

b. Patient surveys should ask questions to determine whether patients gave informed consent to treatment or procedures, for example by asking whether anyone spoke to them about giving consent, or whether the risks, side effects, and alternative treatments (including no treatment at all) were discussed with them. This information should be proactively audited to determine if there are issues with particular practitioners or departments.

Recommendation 4: Obstetric consent

a. Proactive discussions regarding transfusion should take place with all pregnant women and those with gynaecological conditions which may require surgery to ensure that they understand the risks associated with blood transfusion and that the clinical team understand their attitude to transfusion. Patients must be given written information setting out the risks discussed for consideration in their own time. The issues of obtaining effective and informed consent discussed above are particularly important for this group and should be emphasised throughout medical education and information literature in this area. As this is a time when ongoing conversations take place with midwives and obstetricians during ante natal care it would be possible to obtain informed written consent to transfusion (or not) well in advance of labour in the vast majority of cases following discussion and dialogue.

b. Practitioners should ensure that where a patient is of a minoritised ethnic group, biases are actively acknowledged, and full information is obtained from the patient (especially where this may be material to care and treatment choices) and provided by the practitioner in a bespoke and sensitive manner.

[1147] WITN7001029.

Recommendation 5: Post-operative consent under the Mental Capacity Act 2005 Code of Practice

a. The Mental Capacity Act Code of Practice[1148] stipulates that professionals should support individuals to plan ahead for the possibility that they might lack capacity in the future but does not discuss situations where decisions have been made on a best interests basis in the past.

b. We therefore recommend that, in addition to the existing guidance in the Mental Capacity Act Code of Practice, there should be a requirement for medical professionals who make best interests decisions for their patients, such as a blood transfusion while they are unconscious, to disclose those decisions in full and discuss the risks involved. Such guidance must stipulate which healthcare professional is responsible for having these conversations with patients. The Royal Colleges, NICE and other relevant bodies such as the GMC should be requested to amend their guidance in the same terms.

Failures to record transfusions in medical records

88. The Inquiry will be acutely aware of the systemic problem with recording blood transfusions in patient records. Among our CPs' cases, the majority demonstrate poor record keeping practices,[1149] including failures to record the fact of a transfusion at all. Other failures include:

    a. An absence of batch numbers, even where a transfusion may otherwise be recorded. Some examples among our CPs include:

        i. W1972–11 pints of blood and several units of plasma transfused on 18 August 1979 at Great Yarmouth Hospital during a thoracotomy following an assault by stabbing, but no batch numbers recorded.

1148 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/921428/Mental-capacity-act-code-of-practice.pdf

1149 We submit, entirely consistently with the evidence the Inquiry has heard as a whole and has presented on record keeping.

i. W2043 - records contain a note stating that she had a blood transfusion but there is no batch number.

ii. W2645– no records of batch numbers.

iii. W1888– given blood transfusion in June 1989 at Orsett Hospital in Essex as part of an operation for removal of spleen and gallbladder – her records refer to 4 or 8 units of blood transfused but no batch numbers are recorded.

b. "*Filleted*" records or missing pages or references to blood transfusions. Some examples among our clients include:

i. W1967.

ii. W1818 - note in extant records that "*notes missing*". Records requested in 1976 and 1980 are missing.

iii. W2644– six years missing from records.

iv. W1921– this client has obtained clinical notes for every day of admission apart from the day of the transfusion. There are no nursing notes at all and nothing in the records that confirms she had a transfusion. Her discharge letter states that she did not have anaemia and she has expressed concern that this was deliberate. The Trust has confirmed that no other records can be found.

c. Many of our clients' records have been confirmed destroyed by the extant NHS Trusts because of record retention policies.

89. The Inquiry will be aware of a significant consequence of the absence of records, which is that many clients missed out (for months, years or completely) in obtaining financial assistance, discussed in the chapter on Trusts and Schemes.

90. Blood transfusion record keeping failures are discussed in further detail in the chapter on the Role of Other NHS Bodies, given the systemic nature of this issue.

91. However, failure at a systems level does not exculpate individual clinicians entirely. As set out above, there is a clear ethical imperative to record a blood transfusion in a

patient's records, particularly where it was not possible to gain pre-operative patient consent.

92. Moreover, like guidance on the clinical appropriateness of transfusion itself, the need and rationale for good record keeping of blood transfusions was communicated to clinicians from as early as the late 1940s. The 1949 edition of Notes on Transfusion set out unequivocally the requirement to record not just the fact of a transfusion, but serial numbers of bottles of blood and plasma, in a patient's records.[1150] The 1958 updated edition clarified that it was *"not always appreciated that the main reason for accurate recording is protection of the patient"*.[1151] The evidence is not repeated here, but CTI's presentation to the Inquiry set out how that guidance was strengthened into the 1970s and 80s.

93. Medical practitioners played a role in recording blood transfusions not merely on the treating side, but on the supply side within a hospital too. Individual haematologists were ethically and professionally responsible for blood banks and good blood management. Evidence suggests that many did not carry out these functions properly. For example, a Report of the CMS in 1982 found that:

> "*127. The haematologists in charge of the blood banks were considered to be responsible for the services offered. Some were actively concerned with good management practice, most were not. They are best placed to influence usage of blood and blood products and should be encouraged to pay more attention to the economical management of the stock.*
>
> *128. It is recommended that haematologists are reminded of their full responsibilities in the management of blood.*" [1152]

[1150] DHSC0200152 and see §4 of INQY0000328 - Presentation by CTI about the guidance available to clinicians regarding the use of blood transfusions.
[1151] WCAS0000008 and see §13 of INQY0000328 - Presentation by CTI about the guidance available to clinicians regarding the use of blood transfusions.
[1152] DHSC0002221_011.

Diagnosis

94. After our CPs were infected, they faced new forms of malpractice on the part of medical practitioners, starting with the failure of medical practitioners to diagnose them. Of course, this failure is inextricably linked to the issue of consent, discussed above; if practitioners had systematically warned patients of the signs and symptoms to look out for, they would have been more empowered to seek their own diagnoses.

95. Instead, our CPs were faced with near universal lack of knowledge of the risk that transfusions could transmit BBVs, particularly HBV and HCV, and the signs and symptoms. Similarly, some of our CPs were faced with bias, based on their gender or race.

96. Not only did this contribute to the delay many of our CPs encountered before being diagnosed, but also to the poor experience they experienced at the point of diagnosis. Those failures are explored below.

Delay to diagnose

97. It is striking how many of our CPs' infections went undiagnosed for many years and sometimes for decades. Where it was possible to ascertain the gap between infection by transfusion and diagnosis,[1153] we have set out broad trends in the table below:

Number of years between transfusion and diagnosis	**Number of clients**
0-5	20
6-10	12
11-15	15
16-20	17

[1153] This does not include most patients with thalassemia/sickle cell disease, who received transfusions sometimes over decades, and also excludes some other complex cases characterised by multiple transfusion.

21-25	15
26-30	16
31-35	12
36-40	9
More than 40	2

98. The Inquiry will be aware of the serious and potentially fatal consequences for persons whose HBV or HCV remains undiagnosed and untreated. The psychological consequences of this delay in diagnosis also cannot be underestimated.[1154]

99. These delays are exacerbated by the fact that many of our CPs were treated at a point where the risks of non-A non-B hepatitis were clearly known and, in some cases, even after HCV was identified although not routinely tested for by the NBTS.

100. It took until the 2000s or 2010s before many of our CPs were finally diagnosed. It can be inferred, therefore, that the national lookback programme, which took place in 1995, was largely unsuccessful in identifying potential infected blood cases.[1155] We consider that the only reasonable conclusion is that there are likely to be members of the general public who are infected yet still unaware. This was indeed confirmed by Dr Ben Hudson, Advanced Liver Disease ("**ALD**") expert, who said that this was "*not a historical thing; this is seeing patients within the last few weeks of my practice who have been -- who are presenting with advanced liver disease from blood transfusions years ago. It's still an active issue, and these issues are still very live*".[1156]

101. Our CP, Samantha May (on behalf of the Hepatitis C Trust) also confirmed in her oral evidence that Between January 2018 and June 2021, the Trust had been contacted by

[1154] These are explored in the Chapter on Impact.
[1155] The reasons for this failure are explored in the Chapter on the Role of the Blood Services.
[1156] Transcript 04/03/2022, p12, ll5-10.

46 people who had only just been diagnosed with HCV where the only identifiable risk factor was blood transfusion.[1157]

Other failings around the diagnosis of TTIs

102. We have identified the following themes and issues around the diagnosis of our CPs. As the Inquiry is aware, these failings are most prevalent among GPs, who would have been the first point of contact and "*gatekeeper*" of the diagnosis of a TTI for most of our clients:

a. As stated above, our CPs were faced with a near universal ignorance on the part of practitioners of the risk that transfusions could transmit BBVs, particularly HBV and HCV, and the signs and symptoms of those diseases. This led to a reticence (or complete refusal) on the part of many GPs to refer a patient for viral hepatitis testing and missed opportunities for diagnosis. This was sometimes in spite of a patient's request for a test. That lack of knowledge is, we submit, the lynchpin of all the failings set out below.

b. Notwithstanding the raised Liver Function Tests ("**LFT**") results of many of our CPs, GPs failed to refer them for tests for viral hepatitis. Moreover, many CPs were accused of alcoholism or drug use as an explanation for their LFTs. This was plainly wrong. Professor Dillon was clear in his oral evidence that "*an abnormal liver test should have an explanation, and that should trigger a series of investigations of which hepatitis screening is one of them, to see if that's the cause of it.*"[1158] Dr Jamieson also made clear that an abnormal LFT should be accompanied by a sensitive discussion around BBVs and routes of transmission, which should always be accompanied by asking about a blood transfusion.[1159] This did not occur in our CPs' experience.

[1157] Transcript 04/03/2022, p142, ll12-20.
[1158] Transcript 26/02/2020, p218, ll1-5.
[1159] Transcript 26/02/2020, pp203-204.

c. Consistent with other inquiries such as the IMMDSR, there is a clear trend for our female CPs to have been ignored or "*fobbed off*" by GPs in particular. This was also confirmed by Samantha May.[1160]

d. There is evidence that some GPs failed or delayed communicating a viral hepatitis test result, including in cases where a patient was identified by a lookback exercise, because they did not feel sufficiently competent or able to accept responsibility for counselling a patient.

e. At the point where our CPs were finally diagnosed (and indeed into the future), many experienced examples of extremely poor and insensitive communication around their viral hepatitis diagnosis. In particular:

   i. Samantha May described information being supplied to those who had engaged with the Hepatitis C Trust in a "*heavy-handed, judgmental and frightening manner*"[1161] and in oral evidence described infected people being given "*very little information or support*" with "*devastating*" effects.[1162]

   ii. There appears to have been a complete failure by GPs to understand the sociological and/or cultural sensitivities that surround viral diseases such as Hepatitis, as a heavily stigmatised disease – something that Professor Farsides suggested was required as a matter of ethics.[1163] Instead, many of our CPs report that their diagnosis was communicated to them in a "*flippant*" or "*matter of fact*" way, sometimes by way of a letter or phone call, with no consideration of the shock or distress this may cause a patient (who was not necessarily aware that they had any risk factors for hepatitis).

   iii. The precise circumstances of the cohort of patients contracting infections through NHS blood or blood products meant that the usual manner of diagnosis by way of a letter or phone call caused distress and trauma for many of our CPs.

[1160] Transcript 04/03/2022.
[1161] WITN0912001, §45.
[1162] Transcript 04/03/2022, p. 141, 159.
[1163] Transcript 27/01/2021, p34, ll7-15.

iv. Moreover, there is evidence that this casual manner of diagnosis (coupled with insufficient information given by other means) led to a misunderstanding among some of our CPs as to the severity of viral hepatitis.

v. Contrary to the ethical principle discussed by Professor Farsides, some IAPs were actively advised by their GP to hide their infection status.

vi. Many of our CPs were told that they had viral hepatitis but without a corresponding explanation of the route of transmission. This left patients confused, distressed, and in some cases led to significant consequences for the family dynamic. All Medical Ethics Experts agreed that where medical treatment is the cause of a patient's infection, there is an ethical duty on the part of the practitioner to make this clear to the patient.[1164]

f. Similarly, there is a near universal theme among our CPs of being given insufficient information to understand and manage their condition (including prognosis and treatment options) and to understand the risks to their close contacts and family members. Almost none of our CPs were signposted to any helpful information or patient groups, such as the Hepatitis C Trust.

g. There is a particular issue around the sexual and other general transmission risk (for example on household objects) being poorly communicated to patients, such that a number of our CPs became celibate, with obvious impacts on their relationship, and lived in permanent fear they would infect their partner, child, or another close contact.[1165]

h. There is evidence of widespread failure to signpost patients to the relevant financial support schemes for infected blood, by GPs but also by hepatologists and gastroenterologists.[1166]

[1164] Transcript 27/07/2021, p38, ll7-18.
[1165] Avoidably, since the Hepatitis Experts confirmed that "*Sexual transmission of HCV between heterosexual couples is rare, estimated at 0.07% per year or one in 190,000 occurrences of intercourse.*": LL8-11, p47.
[1166] Trust and Schemes chapter.

Treatment and care post diagnosis

103. Our CPs have experienced a litany of failings in terms of the care and treatment for their hepatitis, once diagnosed. At the outset, however, we emphasise that there is a worrying number of clients who have still not been offered treatment for their HCV.

Early treatments for HCV: interferon, pegylated interferon and ribavirin

104. There were significant issues for our CPs around the early treatments for HCV - interferon, pegylated interferon and ribavirin - and whether these treatments were appropriately administered; whether appropriate advice was given about the risks and side effects; and whether adequate psychological care and treatment was offered to alleviate the side effects.

105. The Inquiry has been provided with overwhelming evidence of the dreadful side effects and secondary conditions caused by these treatments, from many IAPs as well as the Hepatitis Expert Group. Nurse Emma Prescott event went so far as to describe interferon as the "*worst drug I have ever had to use on patients*", adding, "*it can turn a very mild mannered person into the most -- into -- spontaneous bouts of aggression, through no control of their own. It causes severe depression. It makes you extremely tired, very, very fatigued.*"[1167] This description is entirely consistent with the experience of our CPs.[1168]

106. Moreover, the irreversibility of some side effects of interferon, particularly nervous system disorders, was discussed by the Hepatitis experts in their oral evidence.[1169] Our CPs have found that many of the side effects of these early treatments did not, or did not fully, subside. Some described the treatment as worse than the HCV itself[1170].

107. Crucially, Professor Dillon made clear in his oral evidence that interferon was not a new drug by the time it was being used for HCV treatment – it had been used as a chemotherapy drug for a decade – and so the psychiatric side effects (and their

[1167] Emma Prescott, Transcript 03/03/2022, p116, ll6-16.
[1168] See also the Hepatitis Expert Group Report, Side effects of interferon treatment: psychiatric side effects, table 15.13, pp42-44.
[1169] Transcript 26/02/2020, p142, ll13-24.
[1170] See sub-paragraphs of the Impact chapter entitled efficacy of treatment and side effects of treatment.

prevalence) were well known and should have been part of the conversation with patients. Moreover, as demonstrated by the chart showing SVR12 (sustained virological response (cure) rate at 12 weeks) in the Hepatitis Expert Report,[1171] early interferon-treatment for HCV offered such low cure rates that there ought to have been "*a really difficult discussion/decision, about whether it was even worth having treatment given the prolonged nature of treatment and the success rates.*"[1172]

108. He admitted, however, that he could not guarantee that these "*difficult*" conversations were always being had.[1173]

109. In our submission, it is clear that many of our CPs would not have consented to these early treatments had they been given proper advice as to the cost-benefit ratio of poor cure rates, side effects and potential irreversibility. Moreover, once on these treatments, they were given inadequate psychological and psychosocial support.

Modern directly-acting antiviral ("**DAA**") treatments

110. While the more modern DAAs undoubtedly changed the landscape of treatment for HCV, many of our CPs experienced delays in obtaining access to these treatments. There was an acknowledgement by one of the Hepatitis Experts, Professor Cooke, that there was a "*very big issue*" around the cost of the drugs and the rationing of them.[1174] His evidence was that there were patient access issues up to 2017.[1175]

111. In our submission, these drugs should have been made available for victims of infected blood, whose infections by this stage had gone untreated (or untreated successfully) for decades.[1176] In the absence of availability, we consider that there were serious miscommunication problems, given the implicit rationing role undertaken by practitioners, with many of our CPs made to feel they were not worthy of receiving the drugs, or not given a sufficient understanding as to why they were not eligible. Moreover, where these drugs were not available on the NHS, practitioners should

[1171] Report p41, Figure 15.13b.
[1172] Transcript 26/02/2020, p126, ll4-16.
[1173] Transcript 26/02/2020, pp140-141.
[1174] Explored further in the Chapter on the Role of Other NHS Bodies.
[1175] Transcript 26/02/2020, pp130-132.
[1176] The commissioning and guidance failures are discussed in the chapter on the Role of Other NHS Bodies.

have had a more nuanced discussion with patients about alternative access routes (for example private access). There is no evidence that this occurred at a systemic level.[1177]

112. We note in general that, given these drugs have only been in widespread use for less than ten years, there will still be a developing knowledge base about their side effects, both physical and psychological. We invite the Inquiry to be mindful of this, particularly in view of the historic issues around interferon and ribavirin and the burden experienced by IAP. It may wish to make a recommendation to ensure side effects are being appropriately monitored and reported.

Follow up and monitoring

113. One of the most important issues for our CPs in terms of their treatment is their ability to access monitoring and follow up care for their HCV (and related symptoms and conditions) after they achieve Sustained Virological Response ("**SVR**"). This is a matter of utmost importance to them, given their very reasonable anxieties about the harm long-untreated HCV may have done to their bodies and their increased risk of developing end-stage liver disease or HCC.

114. The Hepatitis Experts accurately described these services as "*patchy*"[1178] across the UK, which entirely reflects the experiences of our CPs, many of whom have simply been discharged from any ongoing care or monitoring following achievement of SVR. Currently there is no consistent clinical practice, and some patients receive no clinical surveillance.[1179]

115. The evidence available to the Inquiry, however, provides a clear and compelling case for why ongoing and life-long monitoring should be available across the UK (on a consistent basis) for all those who contracted HCV from NHS treatment:

[1177] See evidence of Professor Kerridge on the ethical importance of these discussions: transcript 26/01/2021, pp87-88, ll13-7.
[1178] Transcript 26/02/2020, p241, l5.
[1179] See Claire Foreman's evidence at WITN3953053, §§29-37, John Dillon's evidence at WITN4062001_03 and Chris Jones' evidence at WITN4065001_0003.

a. First, the Hepatitis Experts confirmed that the natural progression of HCV is such that a patient has a high chance of developing a chronic condition that progresses to cirrhosis and HCC, particularly over time.[1180]

b. The prognosis and progression to cirrhosis and HCC is highly variable between patients,[1181] which we submit has treatment and monitoring implications.

c. Although there is developing evidence that treatment intervention, even at the late stages of fibrosis, will change the natural history of HCV, even successfully treated patients will still carry risks of progressing to cirrhosis.[1182]

d. Moreover, evidence from Scotland showed that after successful treatment, the risk of cancer fell but did not return to normal after a 3-year period.[1183]

e. The extent to which SVR is associated with a reduction (not eradication) in risk of HCV-related damage depends on the time HCV was left to progress untreated and to what extent fibrosis or cirrhosis had already occurred. There is therefore a long-term risk of developing HCC in the group infected by NHS treatment (the vast majority of whom were left untreated for years or decades), even for those who have not reached liver failure.[1184]

f. The nature of HCC is such that surveillance is crucial for identifying it at an early stage, but it is a "*very variable tumour and some patients despite screening may be diagnosed at a late stage, even though they've been undergoing tests*".[1185]

g. Professor Richard Tedder confirmed in his oral evidence that it was possible in theory for HCV to "*reactivate*" following immunosuppression, for example associated with cancer treatment, if the assumed SVR did not equate in actual fact to full clearance of the virus: "*You can think you have got rid of a virus*

[1180] Transcript 26/02/2020, pp61-65.
[1181] Transcript 26/02/2020,p66, ll13-21.
[1182] Transcript 26/02/2020, pp96-97, ll24-19.
[1183] Ibid.
[1184] Hepatitis Expert Report, p56 – this was also confirmed by Professor Dillon in oral evidence to be a reflection of available evidence at that point in time.
[1185] Transcript 26/02/2020, p119, ll12-19.

infection in a human host and then you do something to them and if there's any residual virus it may reactivate."[1186]

116. All of the above, and the state of scientific uncertainty described, causes understandable distress and anxiety to our CPs about the progression of their HCV, even when they have "*cleared*" the virus. We submit, therefore, that they should receive regular (as frequent as possible) monitoring and screening, to mitigate their continued risks of developing cirrhosis and HCC. To the extent required, a bespoke policy should be in place that reflects the historic wrongdoing and failures to diagnose victims of infected blood over decades, and the heightened risks and anxiety they therefore face. We consider that the recommendation we suggest below is based on what the Hepatitis Experts said all patients were entitled to expect as best practice.[1187] Moreover, it would be likely to save costs overall.

Recommendation 6: HCV monitoring

a. All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

b. Those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with specialist interest in hepatitis.

c. Those who have fibrosis should receive the same care.

d. Where there is any uncertainty about whether a patient has fibrosis, they should receive the same care.

e. Fibroscan technology should be used for liver imaging, rather than inferior ultrasound technology, or other alternative tests such as advanced LFTs.

[1186] Transcript 14/10/2022, p75, ll3-17. The possibility of HCV "reactivating" has also been confirmed as a theoretical possibility in the Expert Report to the Infected Blood Inquiry Virology (Hepatitis Supplementary), pp8-9. It also confirms that there "*is no perfect test to establish* [complete eradication]" of HCV.
[1187] Transcript 26/02/2020, p173. See also pp212-214.

f. This care should be delivered throughout the United Kingdom on a consistent basis as geographically close to the patient as possible.

g. There should be the possibility of additional ad hoc appointments, just as with other areas where there is an elevated risk of cancer. This group should not be in a different position to other groups at higher risk of serious disease.

h. In Ireland dedicated times / days have been set aside for treatment, follow up and appointments of those who fell ill as a result of receiving infected blood. This has the advantage of facilitating more effective, informed care. We invite the Inquiry to consider the viability of such a recommendation.

117. The above recommendation of course only captures those patients who remain "*in the system*". There is evidence among our CPs of patients falling outside of the system after successful or failed treatment, particularly with early interferon treatment, when they might still be clinically entitled to monitoring, or indeed other services such as palliative care.

Recommendation 7: Patients lost to the system

a. There should be conscious efforts (the most effective means for which we invite the Inquiry to consider and/or recommend further study into) to recall patients who were "*lost to the system*" and thus have not benefited from any monitoring (who may still have cirrhosis or be at risk of HCC) or other treatment services they may be entitled to. There should be a particular focus on those who received early interferon and/or ribavirin treatment.

Inappropriate management of HCV as a multi-systemic disorder

118. Another overriding theme from our CPs' evidence is the failure of their treating medical practitioners to provide care and treatment for <u>all</u> the manifestations of their HCV in a joined up and integrated way. To the contrary, the experience of most of our

CPs was that clinicians were not even aware of basic information about HCV, nor the latest research around its various extra hepatic manifestations and its nature as a multi-systemic disorder. Some of our CPs have reported better experiences when being treated by a doctor or nurse that specialises in HCV (rather than, for example, gastroenterology or hepatology more generally).

119. The Hepatitis Expert Report sets out a vast number of hepatic and extra hepatic manifestations of HCV. Moreover, the evidence of Professor Dillon was that the evidence base is still developing and thus the anecdotal evidence of our clients is very significant in contributing to that evidence basis - particularly constellations of symptoms that are less cohesive and less tied together.[11881189] Of particular significance to our CPs, Professor Dillon gave the scientific basis for why HCV can lead to brain inflammation, which may be a cause of the ongoing cognitive symptoms ("*brain fog*") experienced by the vast majority of our CPs with HCV.[1190]

120. In the same vein as the above section, there are particular issues in terms of the management of HCV as a multi-systemic disorder given the likelihood of patients being discharged following achievement of SVR (what appears to be treated as a surrogate end point for treatment for HCV). The Hepatitis C Post Treatment Survey conducted by the Hepatitis C Trust demonstrates exactly why there is a need for ongoing care and treatment following SVR.[1191]

121. We consider that the overwhelming evidence before the Inquiry is that the best way our CPs can receive this care is through multi-disciplinary team working, a manner of delivering care that was praised by multiple expert clinicians:

[1188] Transcript 26/02/2020, pp153-15.

[1189] Please see Annex 2, where we set out the vast number of conditions suffered by our CPs, which overlaps significantly with the Hepatitis Expert Group.

[1190] Transcript 26/02/2020, p80, ll5-15.

[1191] **WITN0912002**

1. 90% reported ongoing symptoms/side effects for longer than 12 months
2. Five most commonly reported symptoms were fatigue, joint aches or pains, brain fog, depression and mood swings
3. Regardless of SVR, 40% of people felt worse after treatment than before and 31% felt better
4. For those who had attained SVR 37% felt better and 36% felt worse
5. For those who had not attained SVR 18% felt better and 50% felt worse
6. Survey noted that it was retrospective and that there was a potential for bias but that the results indicated a requirement for more research

a. Professor Steer said, "*we should have teams working together who have a common ethos who work together to look at the guidelines and advise one another and cross-check one another's ability.*"[1192]

b. Dr Bogod also extolled the virtues of multi-disciplinary working between specialities, describing it as "*extraordinarily helpful*".[1193]

c. The ALD/Palliative Care Experts referred to the "*immeasurable value*" of a patient being present in a multi-disciplinary team ("**MDT**") meeting (crucially, should they so wish) to reach "*co-authored decisions*".[1194]

d. Professor Kerridge raised the important caveat to the issue of MDT working, which is that there is a need for a "*care coordinator*" to ensure teamwork is effective.[1195]

e. Many expert witnesses described the benefits of MDT being nurse-led or coordinated. Emma Prescott, who thought the model in general had "*tremendous benefits*"[1196] described the significance of the nurse as a "*point of access. I'm always there, if you like.*"[1197]

f. The ALD/Palliative Care Experts also extolled the benefits of MDT working, with specialist nurses taking a leading/coordinating role, acting as a point of access for the patient, and also between primary and secondary care.[1198]

122. We consider that a model of care specifically for people with HCV is necessary, which ensures joined-up care and continuity of support. This should be managed on a multi-disciplinary basis which embraces the patient's entire physical and psychosocial needs. This MDT model would benefit both patients and doctors, in the sense that it would allow medical professionals to make more collaborative, patient-driven, supported and evidence-based decisions. It would also allow for cross-fertilisation of knowledge,

[1192] Transcript 23/02/2022, p99, ll13-16.
[1193] Transcript 23/02/2022, p144, l9.
[1194] Transcript 04/03/2022,p112.
[1195] Transcript 26/01/21, pp53-54.
[1196] Transcript 03/03/2022, p132, l11.
[1197] Transcript 03/03/2022, p123-124, ll20-5.
[1198] EXPG0000043, pp15-16.

including between specialities. While we submit this is good practice in medicine generally, it is all the more vital for our clients, because of the multi-systemic nature of their conditions and the tendency for them to "*fall through the cracks*" of the system or have their multiple conditions and treatment for them mismanaged and inappropriately coordinated.

Recommendation 8: MDT care for HCV as a multi-systemic disorder

The Inquiry should recommend:

a. Regional HCV "hubs" for commissioning care and ensuring joined-up working between practitioners; at present, the elimination programme operated by NHS England has led to the creation of these "*hubs*" (or Operational Delivery Networks "**ODN**"), and these systems should continue after the elimination programme has ended (in 2030).

b. Integrated care by an MDT model with effective communication between practitioners.

c. Oversight and management of each individual's care by a specialist HCV nurse.

d. Opportunities for patient involvement in decisions relating to their care and treatment, for example at MDT meetings or by some other bespoke means.

e. Psychosocial support as described below.

f. Regular and consistent follow-up for those not currently under active clinical care as described above.

g. Involvement of specialist HCV nurses to bridge the gap between hepatology and palliative care, and between primary and secondary care.[1199]

Inadequate psychological care and treatment

123. As explored in the Chapter on Trusts and Schemes (because of the English schemes' (limited) involvement in funding counselling), our CPs have struggled, and in most

[1199] EXPG0000043, pp15-16, 18-19.

cases, failed to obtain psychological care and treatment, or counselling of any sort, to address their HCV and its consequences, including the trauma occasioned by their route of transmission. There has not been across the UK a dedicated service for blood transfusion victims (as distinct from routine Improving Access to Psychological Therapies ("**IAPT**") services, which are known to be seriously under-resourced). By contrast the Inquiry has heard and received evidence of HIV and haemophilia-specific services. The limited services some of our CPs received through the Trusts and Schemes were inappropriate, inadequate in the length of treatment, and not tailored to infected blood.

124. Samantha May of the Hepatitis C Trust explained in her oral evidence that the cost of counselling for infected people is often between £50 and £120 per session[1200] and so it is unrealistic to expect this to be covered privately or for this to be met by the current £900.00 grant provision through EIBSS, recently made available (by application) to those for whom the general NHS IAPT programme is not appropriate or who choose not to go through that route.

125. The justification for such a service has emerged from a vast range of evidence to the Inquiry:

    a. The evidence and recommendations of the Psychosocial Expert Group.[1201]

    b. Diagnosis of, and living with, a chronic disease can have severe psychological effects.[1202] Our chapter on Impact explores the massive extent of psychological consequences for our CPs.

    c. Mental health disorders and other cognitive disorders, including depression are recognised symptoms of HCV in and of themselves.[1203]

[1200] Transcript 04/03/2022, p180.
[1201] In particular we note their supplementary report, p35.
[1202] The expert report on psychosocial issues sets out the serious psychological impact on living with medical conditions and long-term treatment.
[1203] Hepatitis Expert Group Report, p25.

d. The ALD/Palliative Care experts confirmed that ALD is also associated with high rates of depression and high rates of anxiety. This extends to caregivers.[1204]

e. They also suggested that patients infected from NHS infected blood "*may struggle more with associated stigma, because of general perceptions around liver disease globally*" and assumptions made around alcohol or drug abuse, which are untrue.[1205] They also suggested that there might be an extra psychological burden because of the injustice of the way that a patient their disease.[1206]

f. Dr Finlay expanded moreover on why psychological and spiritual needs were such an important part of ensuring the success of physical treatment and health in a more holistic sense.[1207]

126. We therefore invite the chair to consider the following recommendation on psychological care and treatment.

Recommendation 9: Psychological care and treatment

a. Specialist psychological input should be offered as routine upon diagnosis with HBV and HCV (and available after diagnosis as well) as a result of receiving infected blood or blood products. This should be funded and not limited to the usual NHS offer of 12 sessions of CBT in the first instance. It could also include support groups or where appropriate family therapy, considered on a case-by-case basis. Family members of those infected should be offered psychological support, as has been done successfully in Ireland.

b. As Samantha May and many of our CPs have explained in their evidence to the Inquiry,[1208] psychological support and/or counselling for those infected with viral hepatitis from infected blood should be targeted towards the needs of this group. It is essential that professionals providing psychological support and/or counselling for this

[1204] Transcript 04/03/2022,pp7-8.
[1205] Transcript 04/03/2022, p11, ll19-25.
[1206] Transcript 04/03/2022, p12, ll2-5.
[1207] Transcript 04/03/2022,p28.
[1208] See WITN0912001, §209. The psychosocial expert report also identified this need, as above.

group understand the history of NHS infected blood and therefore the nature of the trauma, sense of injustice, or lack of trust in the NHS and medical professionals that may be experienced by those infected by this route.[1209] We understand that there is specialist counselling available in Wales, Scotland, and Northern Ireland, but not in England. We recommend centralised commissioning through NHS England and delivery via the regional HCV/ODN hubs in England.

c. Treatment should not be viewed as the end-point of psycho-social difficulties for those suffering with HCV. Access to HCV support should not be time-limited and should be provided on the basis of need, without unnecessary access hurdles.

d. Alongside psychological support, there is a need for day-to-day support via support groups, help and information lines to assist people manage the impact of living with infection. This should be commissioned in addition to any psychosocial service – there is a great need to help people access relevant clinical care, and psychosocial care – particularly given the lack of trust that the infection has engendered in NHS services. The Hepatitis C Trust identifies that they provide a great deal of support through their information lines without any form of government support at present, something which may not be sustainable in the long term. The Inquiry may wish to consider if such services should be funded through an NHS grant.

e. Patients from minoritised ethnic groups, who have sickle cell disease and thalassaemia, have faced stigma, inequality in care, and discrimination on grounds of their race and ethnicity.[1210] They therefore should be provided with specialist psychosocial support that acknowledges and is informed by the unique obstacles they have faced.

f. Where appropriate, this support should be provided as part of properly commissioned palliative care pathway (see below).

[1209] This was referred to by Dr Ben Hudson and Dr Fiona Finlay (of the Palliative Care in Advanced Liver Disease Expert Group) in their evidence to the Inquiry on 4 March 2022: Transcript 04/03/2022, pp128-129.
[1210] See evidence of Professor Dame Sally Davies.

Failure to provide adequate palliative care

127. It is clear from expert and IAP evidence that good palliative care has a role in empowering and providing greater autonomy and dignity to patients and their families. In our CPs' experience, very few of them received or are receiving any palliative care at all – a phenomenon that the ALD/Palliative Care Experts implied was common given its low prioritisation in the NHS. We therefore endorse the analysis and conclusions of the Palliative Care Expert Group and do not intend to repeat them here.[1211] We consider the key recommendations to be as follows.

Recommendation 10: Palliative care

Palliative care for those infected by NHS blood and blood products should:

a. Be provided at an earlier stage (Dr Hudson said at the point of diagnosis and/or at the pre-cirrhotic stage) and as part of a MDT.

b. Be expressly commissioned as part of HCV/hepatitis pathway (Dr Hudson).

c. Be included within speciality-specific training curricula and treatment guidelines; this should promote care planning and improve the standard and consistency of care.

d. These guidelines must be properly disseminated and emphasised as part of continuing professional development. This should be done by mandating that hepatologists gain accreditation under the Royal College of Physicians' IQILS (Improving Quality in Liver Services) programme and are funded to do so.[1212] There are currently only four accredited services in the UK.

e. Use the CQUIN (Commissioning for Quality and Innovation) payment framework to incentivise multi-disciplinary working and integration of palliative care.

f. Include funding of high-quality, large-scale research studies into best practice in palliative care.

[1211] EXPG0000043_0019. The experts' recommendations pp14-20.
[1212] https://www.iqils.org/

g. Involve specialist hepatitis nurses to support palliative care, as part of the HCV hub model we recommend above and ensure integrated working with palliative care best practice.

h. Facilitate patient-led advocacy by:

   i. Using a diversity of information sources and media to convey information about patients' health, prognosis and treatment/care options;

   ii. Incorporating healthcare advocates into care planning, both by including carers where patients ask for this and employing independent advocates to support patients who struggle to advocate for themselves.

Stigma, dignity and confidentiality

128. It goes without saying that it is unethical for a doctor to attach stigma to their own patient (particularly where that condition is already societally stigmatised, such as HIV or viral hepatitis), breach their patient's confidentiality, or to refuse to treat a patient (or someone associated with them) because they suffer from a medical condition. Unfortunately, there are multiple examples of this occurring to our CPs:

   a. Many of our CPs suffered a general lack of compassion and dignity, with their viral status being announced or disclosed, inadvertently or not, in a non-private setting such as a ward or waiting room.

   b. Many of our CPs report their confidentiality and dignity being compromised by visible skull and crossbones stickers on their medical notes, or other non-discrete means of identifying that they were an "*infection risk*".

   c. Similarly, many report being deprioritised for treatment, often put to the end of a waiting list, or being refused treatment altogether, because of their viral status. This appears to have been particularly common among dentists. This was wrong – Hepatitis Expert, Dr Jeffrey confirmed that standard precautions for hygiene and

safety in hospitals should apply for those with hepatitis and HIV, apart from rare and specific scenarios, such as in a renal dialysis setting.[1213]

d. Some of our CPs state in evidence that they were told that they were "*lucky*" to receive treatment for viral hepatitis. Not only does this suggest a stigmatising approach to treatment, singling out a patient group as somehow "*unworthy*" of treatment that has been properly allocated to them, but also constitutes rationing "*at the bedside*", something Professor Savulescu warned was not appropriate in circumstances where a doctor should be concerned instead with simply promoting the best interests of their patient.[1214]

129. In many cases, we submit that a sort of inverse stigma operated which contributed to the failure to diagnose our CPs, who were not perceived as "*at risk*" patients, notwithstanding their history of blood transfusion.

Research

130. The biggest issue regarding research among our CPs relates to the HCV Register. This Register appears to have been established in conjunction with the 1995 lookback programme. Some of our CPs have discovered from their medical records that their data was entered onto this register anonymously, but without their knowledge or consent.[1215] For some an update was provided to the HCV register by their GP several years later, again without their knowledge or consent.

131. While we do not raise an issue as to the lawfulness of this research, we submit that this approach was nonetheless unethical. Professor Farsides discussed the requirement for similar database or research projects, such as biobanks, to have "*good ethical values at their outset*" that allow research "*subjects*"[1216] to become

[1213] Transcript 26/01/21, p193, ll5-14. Report pp78-80.
[1214] Transcript 26/01/21, p48, L6-15.
[1215] W2692 - identified through lookback. Entered onto HCV register without his knowledge and/or consent; W2043– entered onto the HCV Register; W2702– Entered onto HCV register without her knowledge and/or consent; W0065 - entered onto HCV register without her knowledge and/or consent; W1966 (affected daughter) – entered onto HCV Register but unclear whether this was done with her knowledge and/or consent.
[1216] In this case the term "*subjects*" is more factually accurate than the preferred term, "*participant*".

"*part of that enterprise*".[1217] In the case of victims of infected blood, we submit that the HCV Register and the failure to obtain consent from, or even inform, research subjects was especially unethical given the failure to obtain consent in the first place for the treatment that caused the infection, delays to diagnose, and the issues of cover-up and lack of candour that permeate the entire infected blood scandal.

132. Crucially, however, there was also a missed opportunity to engage research subjects to increase the effectiveness of the research project. For example, it would have been a useful opportunity to develop a database of extra hepatic manifestations of HCV and the "*constellations of symptoms*" referred to by Professor Dillon (discussed above).

People with blood disorders and health inequalities

133. Finally, we have a number of CPs who were infected via their treatment for blood disorders, particularly thalassemia, sickle cell anaemia, aplastic anaemia, other platelet disorders and leukaemia. In general, these conditions are likely to require frequent transfusions with blood components of various kinds (for many throughout their lives).

134. The Expert Report on Bleeding and Blood Disorders[1218] referred to the National Haemoglobinopathy Registry which has been in place since 2009 and which collects data on the numbers, geographical prevalence and treatments of such disorders. As of September 2019, it is estimated that there were 1,921 patients with thalassaemia in England, and 13,675 with sickle cell anaemia.[1219] The NHS estimates that sickle cell anaemia is one of the most common genetic conditions in England. The expert report identifies that those with sickle cell anaemia have a reduced life expectancy, living 20 years less than non-sickle individuals, with a mean age of 42 in a 2016 cohort study.[1220]

135. For those with beta thalassaemia, a significant majority require transfusions every 3-6 weeks in order to survive during childhood and into adulthood, and this is the

[1217] Transcript 27/07/2021, pp54-54.
[1218] EXPG0000002_0039.
[1219] EXPG0000002_0039.
[1220] EXPG0000002_0049

"*mainstay of treatment*".[1221] For those with sickle cell anaemia, prior to the development of drugs in the mid-1990s, blood transfusions were used to correct anaemia or to reduce the proportion of circulating sickle cells, and were also used in cases of acute anaemia, acute chest syndrome or to prevent stroke and other complications of sickle cell disease.[1222] Professor Dame Sally Davies indicated that a transfusion would only be given to a sickle cell patient in her clinic if it was "*lifesaving*" because of the risks of raised blood viscosity through such transfusions, but that those severely affected would or could have regular transfusions by way of exchange transfusions as lifesaving treatment.[1223]

136. Given the frequency with which people with thalassaemia require transfusions, it is striking that CPs with thalassemia appear to have been no more aware than our CP cohort generally of the viral risks occasioned by blood transfusions. This suggests, in our view, a particular failing on the part of clinicians to obtain consent and provide information, and a paternalistic culture of making a cost-benefit analysis on patients' behalf on the basis that the transfusions were life-preserving (entirely consistent with the approach described generally above).

137. Similarly, Professor Davies remembers having discussions with patients about the risk/benefit analysis of transfusion, but it does not appear from her evidence that the risks of HIV or HCV were specifically mentioned. [1224]

138. This failure to obtain consent and provide information, however, deprived these patients of the knowledge that they may be infected, and the chance to make consequential lifestyle amendments to mitigate their risk, or to be tested and treated at the earliest opportunity. Emma Prescott, thalassaemia and HCV nurse, described the impact of HCV on the livers of people with thalassaemia as a "*double whammy*".[1225]

[1221] EXPG0000002_0042.
[1222] EXPG0000002_0048.
[1223] Transcript 03/03/2022, pp19-21.
[1224] Transcript 03/03/2022, pp32-39
[1225] Transcript 03/03/2022, p117, l15.

139. Once testing technologies came into existence in the late 1980s, there does not appear to have been any systematic approach to testing patients with blood disorders. For example, Professor Goldstone's evidence about the interaction of the NBTS 1995 Lookback programme with University College London Hospital efforts to ascertain which of its patients had been infected with BBVs because of their treatment for leukaemia, suggests that there was no proper system in place to test every single patient who had received blood components on a regular basis. Rather, there was reliance on initial information from the NBTS as to who may have received infected products, and even then the patients who were tested for HCV were those with abnormal liver function tests. It is not clear whether there was a systematic testing programme for every single patient. Professor Goldstone's own evidence was that "*it was not systematic enough*".[1226]

140. Similarly, in the sickle cell field, Professor Dame Sally Davies said she did not, and was not aware of any clinician who "*set out to test their whole clinic [for HCV]*", because "*we had a group think that the blood was tested and therefore the risk was low*" and because "*with the look-backs that were going on, if any were, at particular risk, that we would pick them up*".[1227] It can be inferred, therefore, that no systematic testing was conducted or advised on a national basis between 1989-1995 – a crucial missed opportunity.

141. This failure to test similarly deprived patients of the knowledge that they may have been suffering from a viral infection on top of their sickle cell anaemia. There is also lack of epidemiological knowledge about the numbers of those with sickle cell anaemia who were infected. Professor Dame Sally Davies was unaware of any of her sickle cell patients who acquired HIV or HCV.[1228]

142. Given the significant number of individuals in the UK with sickle cell anaemia or thalassaemia, it is likely that a number of these patients would have been infected with HCV and HIV. The Statistics Expert Group was unable to break down the medical

[1226] Transcript 02/03/2022, pp52-53, ll9-2.
[1227] Transcript 03/03/2022, p38, ll5-19.
[1228] Transcript 03/03/2022, p36, l15-16.

reasons for blood transfusions in those who were infected with HCV or HIV, other than to identify that more women than men aged 20 – 50 required transfusions because of the use of this treatment during maternity care.

143. The Statistics Expert Group's failure to assess the number of people with blood disorders infected by NHS treatment, and the extent to which viral infection interacted with the already high mortality rate in this group, is, we consider, a missed opportunity by the Inquiry.

144. In response to a comment put to Professor Dame Sally Davies by CTI that "*blood-borne viruses were not really on the radar for this group of patients*", she referred to the context of health inequalities suffered by her group of patients and the patchy services they received. We submit that the fact that this condition is disproportionality suffered by those from a sub-Saharan African or Afro-Caribbean ethnic heritage contributed to and compounded these inequalities, and therefore contributed to the lack of spotlight or understanding of the secondary issue of blood-borne viruses, which, statistically it can be inferred would have affected this group disproportionately.

145. Professor Davies indicated that during her time at the Middlesex Hospital there was less research being undertaken into sickle cell anaemia than other forms of blood cancers/disorders and she expressed her concern that this may well have been because of what she termed "*institutional racism*".[1229] She also identified that the funding for sickle cell patients may have been influenced by their ethnic background saying:

> "*I feared it might be, because if you looked at the money spent on haemophilia patients and the numbers, the discrepancy was unfair. … I was concerned about the fairness of it*". [1230]

146. Her concerns were reinforced by the Standing Advisory Committee on Sickle Cell, Thalassaemia and other Haemoglobinopathies, which produced a report in 1993[1231]

[1229] Transcript 03/03/2022, p40.
[1230] Transcript 03/03/2022, p41.
[1231] SCGV0000267_152.

identifying that for patients with such disorders, the care was "*not of the highest quality*". Professor Davies said that many of the patients she saw who came from other centres knew substantially more about their condition than any doctor who had ever treated them previously.[1232] The fact that clinicians such as Professor Dame Sally Davies were focusing on the "*priority [of getting] decent services in place*" as a "*starting base for these patients*"[1233] meant the issue of BBVs was (perhaps understandably if not justifiably) overlooked.

147. We consider that a similar inference can be drawn for patients with thalassaemia, who are disproportionately people of Mediterranean, south Asian, southeast Asian and Middle Eastern origin.

148. We invite the Inquiry to conclude that, much like our female CP cohort, existing heath inequalities (in this case arising from ethnic and sociocultural determinants of health) intersected with the general failings outlined above, leading to disproportionately worse outcomes for CPs with blood disorders. We suggest recommendations on health inequalities regarding race and gender in our chapter on the Role of Government.[1234]

[1232] Transcript 03/03/2022, p45, ll1-20
[1233] Transcript 03/03/2022, p45, ll14-20.
[1234] See Recommendation 7 of the Government chapter regarding gender inequalities and Recommendation 8 of the Government chapter regarding race inequalities.

CHAPTER 4: HAEMOPHILIA CENTRES, CLINICIANS, THE UKHCDO, AND HAEMOPHILIA SOCIETY

"My trust in the medical treatment for Haemophilia has disappeared completely. I have pulled some of my own teeth out to avoid having Haemophilia treatment and I would rather rest swollen knees or other joints for extended periods than have clotting agents."[1235]

Introduction

1. This chapter first focusses on treatment for those with bleeding disorders including at haemophilia centres, the actions of haemophilia doctors and of the UKHCDO.[1236] We then consider the distinct but interrelated topic of the Haemophilia Society. This chapter repeats themes seen throughout our final submissions.

2. There were three key failings in the treatment of haemophiliacs during the period under consideration by the Inquiry:

    a. Patients were not informed about the risks associated with treatment, depriving them of the opportunity to give informed consent, choose alternative treatments or refuse treatment, especially mild and moderate haemophiliacs who had a greater range of alternative treatment options;

    b. The risks of treatment, in particular factor concentrates, were not adequately recognised. When, belatedly, risks were recognised, they were not properly or timeously reflected in guidance or communicated to patients; and

    c. Appropriate risk reduction measures were not used, or not uniformly used.

3. These failings amounted to a breach of trust, leaving many of our clients feeling betrayed by the professionals whom they depended on for ongoing treatment and support.

[1235] WITN2053001, §19

[1236] Most of our CPs who have bleeding disorders are haemophiliacs but this chapter concerns patients with all bleeding disorders such as Von Willebrand's disease, who were also treated in haemophilia centres. References to haemophilia centres and their work are intended to refer to all bleeding disorders.

4. The UKHCDO improperly delegated advisory duties to the Haemophilia Society, which was not equipped to question the clinical consensus on the use of blood products. The information provided to the Haemophilia Society by the UKHCDO, and Professor Bloom in particular, was inaccurate and misleading, with the result that the Society advised its members to pursue unsafe treatment options.

Haemophilia centres and clinicians

5. Many haemophilia doctors, and the centres at which they worked, failed their patients by exposing them to known or knowable risks of infection without proper information on the risks being provided. This was an unacceptable failure to comply with professional standards and led directly to many of the infections and deaths considered by this Inquiry.

Failure to inform patients about risk

6. None of our CPs were informed of the risks associated with blood products. It was presented to many of them as a *'miracle cure'* which would make their lives much better, without any downsides. Decisions about treatment were generally made by clinicians without patients being given any choice. This failure to inform patients of risk was a consistent feature of haemophilia treatment at the time and stemmed both from a failure to recognise the risks associated with such products, particularly imported and large pool products, and a preference for such products even when the risks were acknowledged.

7. Clinicians were ethically obliged to obtain informed consent and to inform patients about the risks of treatment. The ethical basis for consent and information-giving is set out in detail in the Role of Medical Practitioners chapter. Dr Shirley accepted in her evidence that information about risks should have been given as a standard part of medical care at the time she was working in the early 1980s.[1237] However, her confusion as to which professionals were responsible for informing patients about

[1237] Transcript, 14/01/2021, p22, ll10-12.

risks and her assertion that most haemophiliacs would have been aware of the problems associated with hepatitis reflect the fact that proper information about risks was not given in practice. Patients required and were entitled to clear, up-to-date and evidence-based information on the likelihood of infection from blood products as well as the likely harm posed by hepatitis. Most of our CPs simply received no information at all.

8. Haemophilia clinicians, in particular Haemophilia Centre Directors, were well aware that blood products posed health risks of both known viruses and emerging novel infections. In 1971, the UKHCDO noted the existence of jaundice and Factor VIII antibodies as "*two most alarming complications*" of treatment.[1238] In 1972, Dr Maycock at Blood Products Laboratory ("**BPL**") expressed the view that viral hepatitis was "*the most serious complication of the use of blood and blood products*".[1239] By January 1975, Dr Maycock was being informed about the high rates of non-A non-B hepatitis in blood products, especially commercial products.[1240] Professor Cash wrote in the British Medical Journal in January 1976, expressing his view that "*there's no doubt that the import into the UK of Factor VIII concentrates derived from external sources, however well-screened for hepatitis viruses, represents an unequivocal pathway by which the level of a potentially lethal virus into the whole community is being deliberately increased*".[1241] By 1979, the evidence suggested that 40% of non-A non-B hepatitis sufferers progressed to chronic liver disease.[1242]

9. The haemophilia clinical profession was therefore aware that blood products, especially imported concentrates, posed a real risk of life-threatening illness, but failed to act. Dr Colvin described this as an "*unjustified but justifiable…feeling that it would be all right*" and agreed that this was "*more of a hope than based in evidence*".[1243] Dr Franklin described this as "*an atmosphere of denial in the UK over the risks of non-A, non-B hepatitis*".[1244] His view, which we invite the Inquiry to

[1238] DHSC0002173_048.
[1239] RLIT0000169.
[1240] CBLA0000249.
[1241] PRSE0004064.
[1242] PRSE0001960.
[1243] Transcript 6/10/2020, p42, ll22-24; p43, ll1-2.
[1244] Transcript 27/10/2020, p17, ll24-25.

endorse, is that "*there wasn't enough effort made to introduce heat-treated safe products because there was a feeling that hepatitis was … viewed as an acceptable risk*".[1245] Dr Al-Ismail explained that Professor Bloom's attitude, shared by many in the profession at the time, was that "*for the vast majority of patients non-A, non-B hepatitis is probably not going to be a big issue*".[1246] It was unacceptable that – long before the emergence of HIV/AIDS – a more precautionary approach was not taken, and patients were not warned adequately, or at all, about risks.

10. A similarly dilatory response was seen in clinicians' responses to the outbreak of HIV/AIDS. The Department of Health and Social Security ("**DHSS**") was aware, by at least July 1982, that imported US commercial blood products may pose a risk of the virus.[1247] The September 1982 UKHCDO meeting considered AIDS but concluded that there was only "*a remote possibility that commercial blood products had been involved*"[1248] in infections in the US. We invite the Inquiry to find that this was an unacceptable response which suggested an inappropriately lax attitude to emerging viral threats, especially given the data reported that month was that the mortality rate for AIDS could vastly exceed 41%.[1249] In practice, clinicians working with haemophiliacs were aware of a real risk of infection associated with commercial blood products by late 1982/early 1983,[1250] but did not share that information with patients.

11. The role of the UKHCDO, and Professor Bloom in particular, in failing to warn patients about risks and misrepresenting the evidence of risk is discussed further below. In our chapter on Self-Sufficiency, Fractionation and Pharmaceutical Companies we explore the impact which the lack of information given to patients had on demand and the UK's ability to become self-sufficient.

[1245] Ibid, pp. 158-159, ll. 25-8.
[1246] Transcript, 17/11/2020, p72, ll5 – 23.
[1247] DHSC0002219_009.
[1248] CBLA0001619.
[1249] OXUH0002848.
[1250] WITN0047004. See further discussion below.

Failure to consider alternative treatment options

12. These submissions have repeatedly endorsed the principle that "*the safest blood is the blood not given*".[1251] That is equally true in the context of blood products, even though they may be life-saving for some patients. The precautionary principle should have required that blood products (especially those imported from the US) were only used where strictly necessary and where alternative treatments would not be an adequate clinical alternative. We invite the Inquiry to find that the precautionary principle was not followed during the Relevant Period. There were alternative treatments available to clinicians at the time, which were suitable as an alternative for many patients, including:

    a. Bed rest;

    b. Cancellation or postponement of elective surgery;[1252]

    c. Tranexamic Acid;

    d. Topical haemostatic agents;

    e. DDAVP;

    f. Fresh frozen plasma;

    g. Cryoprecipitate (especially that made from single blood donations);

    h. NHS factor concentrate (again, ideally from small pools); and/or

    i. Heat treated products, as they became available.

13. We recognise that this range of treatment options may not have been appropriate for all those with bleeding disorders, especially severe bleeding disorders. Mild and moderate haemophiliacs could have been effectively treated with most of the above alternative treatments. Even severe haemophiliacs, for whom alternatives such as bed

[1251] Dr Galea, Transcript 03/12/2021, p25,ll11-12.

[1252] This was a particularly significant option as heat-treatment developed and it became clear that safer products would be available in the medium to short-term. In retrospect, Dr Colvin agrees this should have been done: WITN3343007, p17.

rest may not have been safe, should have been offered advice and information about the risks of their treatment and offered the possibility of reverting to cryoprecipitate.

14. We invite the Inquiry to find that most centres, from whom we have heard evidence, did not use or recommend these alternatives. Professor Parapia correctly explained that "*…there is no doubt with hindsight that there would have been less transmission of infections using cryoprecipitate and locally made NHS products.*"[1253] However, hindsight was not a prerequisite to the identification of imported US concentrate as the least safe option, or to ensure that patients were supported to make informed decisions about the risks involved with their treatment. We invite the Inquiry to conclude that the evidence it has heard shows that most centres were unnecessarily overdependent upon concentrates, often commercial concentrates. Directors such as Professor Parapia and Dr Mitchell were an exception to the rule seen elsewhere. Professor Parapia's approach was that "*commercial products were avoided as much as possible. The safest blood products and alternatives were already considered first … Alternative treatments in order to avoid plasma derived concentrates were always given priority.*"[1254] Our CPs' experience, like that of many CPs, was that they were treated with imported commercial products as a first port of call. Alternative treatment options were not discussed or explored. This made Professor Parapia's centre, the Bradford Haemophilia Centre, a notable exception, proving it was possible to successfully offer alternatives, and avoid imported concentrate.

15. We endorse Professor Savidge's analysis contained in the reports he prepared during the course of the HIV litigation. As seen across our CP group, his reports considered haemophiliacs who had been treated with US commercial factor VIII concentrates. There was no evidence that they had been informed about alternative treatment or that this had been considered by their treating clinicians. He concluded that:

> "*The lack of consideration and disregard of the then current therapeutic recommendations for the treatment of children under the age of four years regarding the use of cryoprecipitate… was negligent. Any argument that*

[1253] WITN0785003, §13.
[1254] Ibid, §17.

cryoprecipitate was in poor supply at the time is untenable since the material was being used in significant amounts for home therapy. … The overwhelming use of commercial US concentrates in preference to cryoprecipitate or NHS factor VIII is remarkable."[1255]

16. This analysis refers to the individual case Dr Savidge was analysing, and we also endorse his criticism of the wider policy framework for that decision-making:

"The lack of a well-defined therapeutic policy regarding preferential use of domestic plasma derivatives in children at this time was negligent."[1256]

17. The Inquiry has heard evidence which demonstrated that alternative treatments could and should have been offered to patients. There are examples of good practice at some haemophilia centres, but the general national practice pointed to the use of commercial factor concentres to the exclusion of alternative treatments, and failed to discuss such alternatives with patients, despite this forming an essential part of proper clinical care.

Unnecessary use of blood products

18. Much treatment for haemophilia and other bleeding disorders involved the administration of blood products, including where such products were not clinically necessary.

19. Some examples amongst our CPs include:

a. One of our CPs was treated with blood products despite the fact that he was able to successfully manage his haemophilia with only one admission to hospital;[1257]

b. Being given blood products on a purely precautionary basis before a routine procedure;[1258]

c. A mild haemophiliac who did not require blood products for injuries as a child but in adulthood started to be given blood products for bruising. He expressly explains

[1255] DHSC0043164_068, pp. 5 – 6.
[1256] Ibid, p. 6.
[1257] WITN2004001
[1258] WITN1996001.

that "*I did not even need any blood products [on the day I was given Factor VIII]. I could have been given DDAVP tablets or Tranexamic Acid tablets. These methods do not stop the bleed as quickly as if you have Factor VIII or cryoprecipitate but they can be used instead. My condition that day was not life-threatening*";[1259]

d. GRO-D

e. Yet another mild haemophiliac was treated on a precautionary basis before minor surgery and in the case of nosebleeds.[1261]

20. All patients should have been given information about alternative treatments. Those patients who did not necessarily need any treatment, for example, mild and moderate haemophiliacs, should have been advised of alternatives, including the option of no treatment. As Professor Franklin put it, "*the regular use of Factor VIII as a home therapy was a quality of life, rather than a life-saving, approach. Most home therapy was for incipient joint or soft tissue bleeds. These are not trivial, they are very unpleasant, but in the main they are not life-threatening*".[1262] Many patients could have 'managed' with alternative therapies until the advent of effective heat treatment, or while other safer domestic products were supplied. The UKHCDO, Professor Bloom, and many haemophilia clinicians, articulated a false paradigm whereby any move away from factor concentrates would lead to loss of life.[1263] That advice led to patients being treated unnecessarily and was highly influential on government policy.

21. Robust clinical guidance was not only needed in haemophilia centres but also in A&E and other sites where those with bleeding disorders might present. We are not aware of any such guidance being issued in the 1970s and 1980s.

[1259] WITN1938001, §8.

[1260] GRO-D

[1261] WITN1111001.

[1262] ARCH0000443.

[1263] This attitude is still prevalent amongst some clinicians, e.g. Professor Hay who viewed reversion to cryoprecipitate as being "*a matter of life or death*" for at least some patients: Transcript 4/11/2020, p.69, ll.12-13.

Feelings of betrayal

22. Our CPs, like all haemophilia centre patients, were dependent on their treating clinicians for guidance, information and treatment. As bleeding disorders are generally life-long, relationships developed between patients and their families and the haemophilia centre clinicians and staff. Very few of our clients had any independent medical knowledge. They therefore had a double vulnerability, both by reason of their health and by reason of their dependence on their clinicians' greater knowledge. The widespread clinical practice of giving patients no information about their treatment, exposing patients to life-threatening risks, and failing to apologise or give proper information, contributed to the feelings of betrayal felt by our CPs.

23. One CP had a "*very close doctor-patient relationship*" with his treating clinicians and the staff at the local haemophilia centre. His widow explains that she feels "*betrayed …. Because* [we] *had always regarded the Centre as a very important place in our lives*".[1264] Another CP explains: "*[w]e are meant to trust our doctors and our government but they messed up royally without giving anyone a choice in the matter*".[1265] Other CPs described feeling lied to and knowingly harmed.

24. It has taken time to rebuild the trust that was lost. Aileen Gibson explained that "*it took some time to get the trust of … families*" who she had previously treated and who had been infected.[1266] We consider that the moral damage to IAP was compounded by their dependence on the very institution which had injured them for lifelong treatment and care.

25. This sense of betrayal was compounded by the wider failures in treatment, care, information-sharing, timely diagnosis, and financial support, which are explored in the impact and trusts and schemes chapters.

[1264] WITN2004001, §19.
[1265] WITN1928001.
[1266] WITN4046001.

UKHCDO

26. The UKHCDO was formed in the late 1960s to collect and coordinate data on haemophilia patients and their treatment. Its first meeting was in 1968 and organised by Dr Biggs.[1267] It proved to be significant that this de facto leadership organisation was a voluntary and unincorporated association, essentially dominated by the largest and most influential haemophilia centres. Its role was to share and disseminate best clinical practice.

27. The UKHCDO made serious failings in its response to the outbreak of HIV/AIDS. By late 1982 to early 1983, the UKHCDO was aware that AIDS was a real risk. At the Directors' meeting on 14 February 1983 there was agreement that it was necessary to report on cases emerging amongst patients but there was no discussion about taking steps to inform patients of risk.[1268] This was in stark contrast to the approach taken by the National Haemophilia Foundation in the US at that time, which concluded in December 1982 that previously untreated patients should not be started on concentrates and that patients and parents should be made aware of potential risks.[1269] We invite the Inquiry to find that this is the approach which the UKHCDO and DHSS should have taken in late 1982/early 1983.

28. Instead, in an unacceptable act of risk-taking, the approach spearheaded by the chair of UKHCDO (Professor Bloom) was that previously-untreated patients should be treated with new imported factor concentrates to see whether this reduced the rates of non-A non-B hepatitis.[1270] At this time, the UKHCDO, under Professor Bloom's leadership, was aware of increasing rates of AIDS in haemophilia patients, and noted the analysis in the New England Journal of Medicine from Janet Desforges that there should be reversion to cryoprecipitate.[1271] Leading haemophilia clinicians were clearly aware of this recommendation but did not follow it.

[1267] RLIT0000022, p. 64.
[1268] HCDO0000411.
[1269] PRSE0002436.
[1270] HCDO0000252_042.
[1271] HCDO0000558

29. The subsequent (in)action of the UKHCDO in March 1983 was to ramp up monitoring efforts in the hope of reporting symptoms and cases of AIDS. The UKHCDO's approach was explained on the basis that: "*…it is most important that the extent of the problem is quickly identified so that preventative measures can be instituted as soon as possible to minimise numbers of cases occurring in the UK*".[1272] That approach was clearly fallacious; preventative measures were needed in advance of an outbreak in order to minimise the number of cases in the UK. It was wholly unacceptable that there was no change – or apparently any discussion of a change – to clinical practice in any respect, nor was information disseminated to patients. We invite the Inquiry to find this failure to advocate any change in approach to treatment on behalf of UKHCDO was unacceptable and caused preventable infections.

30. The UKHCDO did not change tack meaningfully even in May 1983,[1273] when its recommendation was essentially to preserve the status quo. The UKHCDO encouraged using domestic blood products for mild haemophiliacs and children, but did not mandate it, which we invite the Inquiry to find was an error. It was only by June 1983 that the UKHCDO accepted that AIDS appeared to be transmitted through blood and blood products.[1274] It subsequently issued guidelines in late June 1983 that mild haemophiliacs and those with von Willebrand's disease should be treated with DDAVP, and that for children and mildly affected patients or patients who had not previously received imported concentrates, it would be appropriate to use NHS concentrates.[1275] These recommendations still failed to raise the alarm about the use of imported concentrates, in fact expressly noting, "*there is as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy*".[1276] Nor did it address the possibility of other alternative treatments. Finally, it was merely a set of non-binding recommendations, with no mention of informing patients of any of the risks or discussing alternative treatments.

[1272] HCDO0000517_001
[1273] DHSC0001177.
[1274] PRSE0002741.
[1275] HCDO0000270_004.
[1276] Ibid.

31. It is significant to consider the UKHCDO's actions in June 1983 in light of the Council of Europe's recommendation of the same month. It recommended that Member States:

> "*Take all necessary steps and measures with respect to AIDS and in particular to avoid, wherever possible, the use of coagulation factor products prepared from large plasma pools; especially important for those countries where self-sufficiency has not yet been achieved.*
>
> *To inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks*".[1277]

32. This is the approach which we consider the UKHCDO should have been taking. It appears that the body was not aware of the recommendation,[1278] which reflects a serious failure by the DHSS and its representative who attended UKHCDO meetings. It is inexcusable that a major announcement such as this was apparently overlooked by both the DHSS and the UKHCDO, and we invite the Inquiry to find accordingly. Had it been formally considered it may have materially altered the UKHCDO's approach, as Professor Ludlam acknowledged.[1279]

33. We do not suggest that the UKHCDO could have granted itself a power to make binding clinical recommendations, but it could and should have (i) issued its recommendations in more forceful terms, and (ii) petitioned the DHSS to place the UKHCDO on a statutory footing to allow it to issue such guidance or for the Department to issue such guidance itself. As a result of the non-binding nature of these recommendations, most haemophilia centres failed to change their practice as the pandemic unfolded. While most centres continued to treat patients with imported blood products, it is significant that some haemophilia centres took diverging approaches to treatment; for instance, the Birmingham Centre continued to use

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[1277] PRSE0000372.
[1278] See evidence of Professor Ludlam, transcript 3/12/2020, p73, ll4-15.
[1279] Ibid.

commercial concentrates on children into 1985. However, the majority followed the approach of the UKHCDO.

34. The UKHCDO, and particularly Professor Bloom, were uniquely placed to provide specialist advice to the government about the appropriate response to the AIDS crisis. Instead, the information received in July 1983 from Professor Bloom led to the following conclusions by the Subcommittee on Biological Products of the Committee on the Safety of Medicines:

    a. The cause of AIDS was unknown but likely to be infectious;

    b. The benefits of concentrates were justified even when balanced against the risks of AIDS;

    c. It was not feasible to replace concentrates with cryoprecipitate on grounds of supply;[1280]

    d. It was not feasible to stop using US concentrates on grounds of supply or risk.[1281]

35. Even in December 1983 the UKHCDO's view was that "*the aetiology of AIDS is yet to be established, but current knowledge points to it being caused by a transmissible agent*".[1282] In early 1984 its view was that "*facts are in very short supply… there is no reliable evidence that the disease is transmitted through blood products*".[1283] This was not justified in light of the evidence before that body, including the Cardiff patient under Professor Bloom's care who clearly acquired AIDS through blood products. The approach of the UKHCDO appeared to be that urgent action was not justified unless it was certain. It was not clinically or ethically justified to impose what was in practice a criminal standard of proof before taking any action at all to protect patients. As Professor Franklin expressed it, this was the opposite of the precautionary

[1280] This is not reflected in other evidence (see e.g. PRSE0004440, §9 where in fact the opposite is described by Dr Chisholm when she makes reference to 'problems in getting large amounts of commercial concentrates whereas she could get unlimited supplies of cryoprecipitate') and is addressed further in our self-sufficiency chapter.
[1281] ARCH0001710.
[1282] BSHA0000023_081.
[1283] BPLL0001351_093.

principle.[1284] As Dr Bevan put it "*they held the line to the point where it almost became like denial*".[1285]

36. The UKHCDO finally began to recognise the depth of the crisis and address the need for guidance in December 1984. It issued the AIDS Advisory Document,[1286] which acknowledged the need to explore alternative treatments. It did not recommend that patients should be informed if found to be infected. This was a serious ethical failing, both as regards an individual patient's right to know about their own health and because of the risk of infected individuals unintentionally spreading the disease. These guidelines were an unacceptably late response to the unfolding pandemic. Such hesitancy was not necessary, especially given the non-binding nature of the recommendations.

37. Dr Tuddenham rightly criticised the UKHCDO's guidelines as "*very gradual and cautious*"[1287] and "*vague*".[1288] The UKHCDO's gradual and vague approach directly led to individual centres and clinicians taking an equally dilatory response: Professor Ludlam confirmed that he did not take any proactive steps in 1983-1984 to advise his patients about the possible risks of AIDS from factor concentrates, nor did he explore alternatives with them;[1289] Dr Pettigrew of Yorkhill mainly used commercial blood products;[1290] Dr Jones of Newcastle was reluctant to abandon factor concentrates and "*go back ten years*".[1291]

38. The UKHCDO could and should have done more than it did. It is no adequate defence to characterise the UKHCDO as Professor Ludlam did, calling it "*an informal mechanism, part of developing people's knowledge*".[1292] The UKHCDO was the leading clinical body on haemophilia and blood disorders at the time. The UKHCDO should have been aware that it was setting policy – both by issuing guidance and failing to do

[1284] Transcript 28/10/2020, p65, l20.
[1285] Transcript, 12/01/2021, p98, ll13-14.
[1286] HCDO0000270_007.
[1287] Transcript 22/10/2020, p112, l14.
[1288] Ibid, p113, l6.
[1289] Transcript 2/12/2020, p59, ll8 - 15
[1290] Transcript 7/12/2020, p4, ll20-25.
[1291] Transcript 03/02/2022, p120, ll13-14.
[1292] Transcript 3/12/2020, p62, ll8-9.

so – for many haemophilia centres across the UK.[1293] Dr Bevan explained that, in light of the *Bolam* test,[1294] "*if you'd gone off, away from their advice, you would have become vulnerable to claims of negligence*".[1295] The UKHCDO should have taken on its leadership role more proactively. This would have involved issuing firm, precautionary and clear guidance. Instead, its failure to act allowed unsafe practices to continue across the UK.

39. The UKHCDO's inappropriately sanguine attitude to risks associated with blood products must be seen in the context of the close relationship between pharmaceutical companies and haemophilia clinicians at this time, with lavish hospitality being provided by the industry to leading clinicians. This is explored in greater detail in our self-sufficiency and pharmaceutical companies chapter.

Professor Bloom

40. Professor Bloom took a leading role in disseminating advice about the risks posed by blood products. It is clear from the evidence before this Inquiry that he played an enormously influential role in the UKHCDO in shaping government policy, and was also seen as an influential figure internationally. In response to a request from the Haemophilia Society regarding the risks posed by HIV/AIDS, he advised in January 1983 that "*…at the present time the cause is quite unknown and neither has it been proven that it is transmitted through contaminated blood products*".[1296] Professor Bloom expressed unjustified confidence about the safety of blood products, suggesting that he would have expected to see cases identified in the UK already if the risks were as feared.[1297] He simply did not have sufficient data at the time to draft that conclusion. He must be criticised for incorrectly asserting in this response that "*there is no evidence yet*" to implicate blood products and that "*…there is certainly no need for the haemophiliac community to be unduly concerned about this new syndrome…there is no doubt whatsoever that their advantages [i.e. of blood products]*

[1293] See Dr Bevan's evidence; Transcript 12/01/2021, p67, ll16-24.
[1294] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583, which required consideration of whether a doctor's practice was supported by a body of professional opinion.
[1295] Ibid, p. 68, ll. 8-9.
[1296] HCDO0000003_066.
[1297] Ibid.

far outweigh this disadvantage which, at the moment, seems to be potential rather than real in the UK".[1298] This is an unjustified and misleading claim which provided false reassurance and demonstrates not only the UKHCDO's failure to advise patients about risk, but its role in misrepresenting evidence on risk when information was sought on behalf of patients.

41. Professor Bloom and Dr Moffatt also gave false hope to patients in the template letter circulated in mid-February 1983, which stated that "*there is no cause for alarm … the occurrence of these illnesses has been extremely uncommon …*" whilst asking patients to engage in testing.[1299] This is out of step with what many practitioners, including Dr Craske, were saying at this time.[1300] It again gave false reassurance to a vulnerable population. Professor Bloom was aware of the risks of imported factor concentrates in particular, for instance he was informed in March 1983 about the "*major impact*" which AIDS was having on the treatment of haemophiliacs in the US, where it was growing at a "*frightening pace*".[1301] Given his knowledge that the US was the major source of blood products for the UK, this should have spurred him into immediate action.

42. Professor Bloom did not take the outbreak of HIV/AIDS sufficiently seriously, in the face of growing and alarming evidence about its virulence, transmission, and mortality. In late March 1983 he described the US response as an "*overreaction*".[1302] In April of the same year he was either concealing or, at a minimum, underselling the AIDS case in his care at a talk given at the Haemophilia Society's Annual General Meeting, where he claimed not to be aware of any AIDS cases in the UK.[1303] He also estimated in the same speech that there was likely only to be a single case in the UK, which was not justified on the evidence before him. He provided a misleadingly

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[1298] Ibid.
[1299] CVHB0000002_003.
[1300] See Dr Craske's research at HCDO0000557; HCDO0000273_079.
[1301] BPLL0001351_021.
[1302] CBLA0001691. It is not certain that this word is Professor Bloom's own, but we consider it is a reasonable inference to draw from the document.
[1303] PRSE0000411. Professor Bloom carefully referred to being unaware of any "*definite*" cases of AIDS in British haemophiliacs but in the subsequent question and answer session said that one of his patients *'may have a mild form of it*". He later reported in early May 1983 that his patient did have AIDS: PRSE0000353.

optimistic picture to the Haemophilia Society in early May 1983 despite being aware that he had a patient suffering from AIDS. In October 1983 he was advising that there was no need for patients to stop using commercial concentrates because of a lack of proof that they caused AIDS.[1304] In June 1984 he was writing that "*the role of American concentrates in the causation of AIDS in European haemophiliacs must be regarded as unproven*", emphasising that AIDS only posed "*hypothetical dangers*".[1305]

43. It is not unreasonable to speculate that Professor Bloom's close relationship with US pharmaceutical companies, and the false reassurances they gave him,[1306] influenced his inappropriately sanguine attitude. His comments were echoed by pharmaceutical companies seeking to persuade the Department of Health that their blood products were still safe for use.[1307]

44. Professor Bloom also appears to be responsible for the mass testing of UK haemophiliacs for antibodies associated with AIDS in 1983/84 without their knowledge or consent.[1308] This was a serious ethical breach, which was compounded by the extreme delays in informing many patients of their diagnosis.

45. Professor Bloom's scepticism about the aetiology of AIDS continued well into the pandemic. In 1985 he expressed the view that a patient who had been exposed to HTLV-III was "*extremely unlikely*"[1309] to develop AIDS. While we cannot speculate about Professor Bloom's understanding and actions in that case, placed against the background of previous actions this suggests that he was probably giving his individual patients unsafe and misleading medical advice.

46. Professor Bloom should also be criticised for his attitude towards hepatitis. While under his leadership the UKHCDO did take steps to study and avoid hepatitis, he failed to ensure that patients were given appropriate information about its risks or to advise that alternative treatments be explored, despite his awareness of "*increasing*

[1304] CBLA0000060_050.
[1305] PRSE0003037.
[1306] E.g. CBLA0000060_067; BAYP0000028_076; DHSC0001291.
[1307] BAYP0000002_183.
[1308] HSOC0002735.
[1309] WITN1275005.

evidence that more insidious signs of chronic inflammation of the liver are much more common".[1310] He was in a key leadership role to promote clinical guidance and treatment alternatives which minimise the risk of hepatitis, but did not take them.

47. We invite the Inquiry to find that the UKHCDO, in large part due to Professor Bloom's leadership, failed in its role to protect haemophiliacs and instead knowingly exposed them to risks of HIV/AIDS as well as other blood-borne infections. The body, and Professor Bloom in particular, spread false reassurance which it knew to be unjustified in light of the evidence of risk before it. The UKHCDO was uniquely placed to set best practice in haemophilia care and instead undermined it, resulting in a large number of infections and deaths.

Relationship with government

48. The failures of the UKHCDO became a governmental failure, with the DHSS depending on the expert advice it received from Professor Bloom and the UKHCDO more generally, who were recognised as the leading experts amongst the UK's haemophilia clinicians.

49. The UKHCDO failed to advise the government sufficiently or at all regarding the risks of hepatitis, and particularly about the severe risks posed by HIV/AIDS. In particular, it did not inform the government about the different treatment options available, including no treatment (for example, in the case of mild/moderate haemophiliacs) and the implications that this could have on assisting the UK's efforts to achieve self-sufficiency, as set out in our chapter on that topic. Dr Goff rightly acknowledged that the haematology community could have pushed harder than it did;[1311] though the government retained final responsibility.

50. This was a two-way failure; the UKHCDO did not give sufficient warnings about the unfolding AIDS crisis, but at the same time the government did not show leadership in achieving self-sufficiency which would have mitigated that crisis. David Watters explained that self-sufficiency "*simply dropped way down the [government's] priority*

[1310] PRSE0000411.
[1311] WITN5423001, §36.1.

list, and hepatitis and HIV were the major part of the cost of that".[1312] The government was not told by those best placed to advise it that blood products posed urgent, severe health risks, and the government accordingly deprioritised the issue. This is not to excuse the government's actions: it had alternative sources of information which it could and should have drawn on and was responsible for protecting public health which it failed to do. The government could readily have asked clinicians to take a more precautionary approach or liaised with the US government to emulate their more proactive response to the illness.

Self-sufficiency

51. The UKHCDO had a leading role to play in supporting the national efforts to achieve self-sufficiency. However, it's failure to encourage minimisation of blood products, discussed above and in our chapter on self-sufficiency, hampered those efforts. Professor Bloom wrongly believed that UK concentrates were not necessarily safer than imported US concentrates, which may have influenced this approach.

52. The UKHCDO and its leadership failed to explore with DHSS what role it could play in helping the UK achieve self-sufficiency. Leading haemophilia clinicians could and should have proactively taken steps to minimise blood use and inform DHSS that there were alternative treatment options for mild/moderate haemophiliacs. It failed to do so.

Apology

53. We consider that a formal, public apology from the UKHCDO is appropriate in light of the above failings. To the best of our knowledge, no such apology has been issued to date. An apology is long overdue and should take full responsibility for the incomplete and misleading information provided by the UKHCDO.

[1312] WITN3429001, §148.

The Haemophilia Society

54. In 1950, the UK Haemophilia Society was established and acquired charitable status. Its purpose was to provide information and support for haemophiliacs and those suffering from bleeding disorders, as well as their family. It also developed an important advocacy role, arguing on behalf of its members to government and clinicians.

55. While we recognise that there is much to praise the Haemophilia Society for, particularly in more recent years, we cannot overlook the serious failures it has made historically, especially around the outbreak of the AIDS epidemic. In early 1983, its bulletin published an interview with Dr Kernoff of the Royal Free Hospital's Haemophilia Centre, who described the links between AIDS and haemophilia as "*very tenuous*" and characterised the idea of an "*epidemic of AIDS amongst haemophiliacs*" as "*ludicrous*".[1313] The Haemophilia Society was not itself a clinical body and could reasonably expect to rely on the views of leading haemophilia clinicians, particularly Professor Bloom and the UKHCDO, however the contemporaneous evidence shows the Society to be anxiously asking for further information.[1314] The response received was one of reassurance, as discussed above, but the Society could have been more frank in publicising its concerns to the community it served.

56. On 4 May 1983 the Society published a response to recent press reports about the risks of imported US concentrates, which included advice from Professor Bloom. It referred to those reports as "*alarmist*" and quoted Professor Bloom's statement that "*the cause of AIDS is quite unknown and it has not been proven to result from transmission of a specific infective agent in blood products … We should avoid precipitate action and give those experts who are responsible a chance continually to assess the situation*".[1315] Again, this substantially understated the evidence. There was strong evidence by this time linking AIDS to blood products and Professor Bloom's tone encouraged patients to continue concentrate treatment and again offered false

[1313] PRSE0004120.
[1314] BPLL0001351_071.
[1315] DHSC0001228.

reassurance. May 1983 was not a time for assessment and reflection; it was already too late to take urgent action in light of known, serious risks.

57. Acting on Professor Bloom's advice, the Society advised it members to continue with their pre-existing treatment programmes, thereby endorsing ongoing treatment with imported factor concentrates.[1316] As late as October 1983, Professor Bloom was allaying "*unfounded fears*" and putting AIDS *"into a helpful perspective"* in a talk to the Society.[1317] This was at a time in which arrangements were still being made to assess the prevalence of AIDS amongst UK haemophiliacs,[1318] so it could not be said with any confidence that their concerns were unfounded. Even in late 1983, the Society's publication, Haemofact, was still conveying a very strong message that members should continue to treat themselves with factor concentrates.[1319] Like Professor Bloom, the Society set an inappropriately high bar for recommending even a temporary ban on the use of imported concentrates; requiring "*definite*" evidence that it would be "*necessary*".[1320] The Society appeared to give Professor Bloom a *de facto* leadership role, with him directing them on matters including what advice to circulate to its members, for instance.[1321] This deference was not appropriate for an independent charity and involved the inevitable risks of overdependence on one view point. In the event, Professor Bloom's view was shown to be fundamentally flawed in many respects. Waiting until there was evidence to prove that blood products were as unsafe as feared was wrong and deprived patients of an opportunity to explore alternative treatments (or stopping treatment).

58. The Society failed to provide specific information for members who suffered from milder or more moderate forms of bleeding disorder.[1322] This should have been done even before the risk of HIV/AIDS emerged for the reasons explored above. It is submitted that the Society's (and other organisation's) failure in this respect is reflective of a wider issue that was explored in Counsel to the Inquiry's presentation

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[1316] HSOC0029476_024.
[1317] CBLA0000060_050.
[1318] See e.g. PRSE0003439.
[1319] Transcript, 10/02/2021, p62, ll16 – 21.
[1320] HSOC0020344.
[1321] CBLA0000060_048.
[1322] Transcript 12/02/2021, p64, l21.

about self-sufficiency and the domestic production of blood products, namely there was widespread adoption of the philosophy that haemophilia patients should lead a 'perfectly normal' life and linked inextricably to this was the demand for the immediate implementation of prophylaxis and home therapy regimes with factor concentrates. On this basis, risk mitigation was deprioritised if not altogether ignored.

59. The Haemophilia Society recognised in early 1984 that it had not done enough to date to campaign strongly for self-sufficiency in blood products.[1323] Despite this recognition, it decided not to push for self-sufficiency at that time on the basis of its thinking that "*now is not the time to ask that all our blood products eggs should be placed in one basket… we should take Mr Asquith's advice of 'wait and see'.*"[1324] That reasoning was fallacious; as discussed in our chapter on this topic, self-sufficiency was the essential route to improving blood safety and protecting against the risks posed by imported factor concentrates. This reflected an attitude of undue caution and hesitancy on the part of the Society. In the event, the Society took an even more cautious approach than the UKHCDO and expressed a "*firm conviction*" even late in 1984 that "*haemophilia, itself, is more dangerous than AIDS*".[1325] That statement was not correct, given the known high mortality associated with AIDS, in the context of alternative treatment options being available for bleeding disorders.

60. The Society could have looked further afield or been more robust in challenging the information received from the UKHCDO. We appreciate that the Society had very limited resources and was described by David Watters as "*tiny, tiny, tiny, and certainly not equipped to replace the medical advice of clinicians*".[1326] That said, the Irish Haemophilia Society, with far fewer resources, proactively raised the risks of AIDS with the Irish Blood Transfusion Service after the Daily Mail's coverage in May 1983.[1327] With almost no resources to draw on, the Irish Haemophilia Society was willing and able to undertake its own research into the risks of blood products.[1328] It was thus

[1323] BPLL0001351_093
[1324] Ibid. In fairness, it should be noted that Professor Bloom did not fully endorse this view: BPLL0001351_094.
[1325] DHSC0000684.
[1326] Transcript 11/02/2021, p60, ll10-14.
[1327] WITN7418001, §6.
[1328] Transcript 08/11/22, pp5 – 6, ll9 - 6

possible even for a smaller charity to know further action was needed, but the Haemophilia Society instead accepted the reassurance offered by the UKHCDO. A representative of the Society would sit in on UKHCDO meetings and therefore could have heard their discussions about risk and formed a more critical and objective view.

61. The Society also lobbied the UK government in favour of the continued importation of commercial products from the US well into the pandemic.[1329] That decision was made in the context of the falsely reassuring advice being received from the UKHCDO but was still a significant mistake. By May 1983, there were substantial reasons for caution but the Society's actions in pushing for more US concentrates show a fundamental failure to exercise caution.

62. We consider that the Society was seriously at fault for consulting Professor Bloom regarding its advice given to members about proposed litigation for infection with HIV. This was, in effect, consulting a potential defendant to litigation on what advice to give to potential claimants. That error was compounded by the Society disclosing legal advice on the prospects of litigation to the government, despite this concluding that the proposed claims were unlikely to succeed.[1330] This was a serious breach of trust and actively undermined haemophiliacs' ability to litigate or negotiate for a better financial outcome. This approach certainly did not assist to improve the financial support arrangements which were finally provided. No adequate justification was put forward for this decision in the evidence heard by the Inquiry. These were unnecessary and damaging steps which the Society knowingly took against and in direct conflict with the interests of its members.

63. We recognise that in subsequent decades the Society has acted as a dedicated advocate for its members and has been instrumental in obtaining support for the IAP community. The Society has professionalised and provides valuable advice and support to its members today.

[1329] BPLL0001351_076.
[1330] HSOC0003459.

64. We welcome the Society's actions in issuing a public apology for their role in the infected blood scandal.[1331] However, it is striking that this was not done until 2017 and forms a small, final part of a statement which foregrounds the wrongdoing of other bodies. The statement does not mention the dissemination of confidential legal advice and appears to minimise the Society's failings. In the interests of transparency and lesson-learning, we suggest that the Society should make a further, fuller apology.

Treloar's

65. Key failings at Treloar's appear to be the following:

    a. The heavy use of many different types of imported factor concentrates;
    b. The failure to ensure consistency of treatment, with the result that children were treated with a variety of concentrates;
    c. The failure to reduce the use of imported factor concentrates as the AIDS epidemic grew;
    d. Failures to consult parents or ensure informed consent of children;
    e. HTLV-III testing without children's knowledge or consent; and
    f. Poor communication of diagnoses, including sharing test results in group settings.

66. One of our clients explains that "*[w]hilst at Treloars I imagine I was originally one of the previously untreated patients ('PUPs')– patients used as guinea pigs without anybody knowing. It's disgraceful that parents were not told about this.*" This is representative of the paternalistic culture at Treloar's, in which patients were given treatment and subjected to testing without consent.[1332] Mr Macpherson, the school's former headmaster, expressed his view that "*doctors are god, let's face it, aren't they?*".[1333] Treloar's was over-enthusiastic about administering blood products, including prophylactically, despite the known risks involved.

[1331] https://haemophilia.org.uk/wp-content/uploads/2022/04/Board-Statement-on-Contaminated-Blood-March-2017.pdf
[1332] See e.g. WITN0297001, §12; WITN1243001, §44.
[1333] Transcript 24/01/2021, p77, l15.

Recommendation 1: Haemophilia Centres, Clinicians, the UKHCDO, and the Haemophilia Society

a. The UKHCDO and government offer an apology for their failures to prioritise patient safety, in particular for the dilatory actions in responding to the unfolding HIV/AIDS pandemic. They should also take responsibility for encouraging patients to remain on life-threatening treatment without proper information on risk; and

b. The Haemophilia Society offer a fuller apology for its actions, which recognises its serious errors in disclosing privileged legal advice and takes responsibility for its failure to provide accurate advice to protect its members' health.

CHAPTER 5: THE ROLE OF OTHER NHS BODIES

"I feel that, in general, after I was diagnosed with HCV I was always battling with the authorities and governmental and NHS officials to try and get the care and support I needed. It was a very lonely battle indeed"[1334]

Introduction

1. We have already explored the Role that Medical Practitioners played in the wrongs and harm suffered by our CPs over decades. However, there are also various ways in which NHS and other medical bodies[1335] - such as those clinicians' employers, regulators or professional bodies - have failed our CPs by omitting to implement effective systems to protect them or provide them with safe and adequate care and treatment to alleviate their suffering.

2. We note that these bodies did not generally act in an isolated fashion but were and are often "*plugged in*" to broader structures. There are inextricable links, therefore, not only with our submissions on medical practitioners but also on the actions of Government and the Blood Services.

Summary

3. In summary, we make the following submissions in relation to the Role of Other NHS Bodies:

    a. NHS Bodies, particularly hospitals, failed in the Relevant Period to implement systems to ensure that blood transfusions were recorded and then audited. This allowed poor practice to continue without action being taken to correct it;

[1334] W1829, §33.

[1335] This chapter addresses the actions of bodies such as NHS England, commissioners, Trusts, NICE, regulatory bodies such as the GMC, as well as Royal Colleges and other professional medical societies that have an educative function or role.

b. They also failed to put in place systems, such as Hospital Transfusion Committees, to ensure that clinicians were adequately trained in all aspects of blood transfusion medicine, including the importance of patient informed consent;

c. While BBT has undoubtedly improved safety in the field of transfusion medicine, a significant body of evidence before the Inquiry demonstrates that there are still serious issues with patient safety and consent;

d. As well as failing to record transfusions in the first place, NHS bodies have operated a chaotic and disorganised system of record keeping, which has been compounded by disjointed attempts to move to a semi-digital system. The loss and destruction, intentional or otherwise, of our CPs' records has, very reasonably, eroded their already diminished trust and confidence in the medical institutions they are forced to rely on;

e. Other NHS Bodies with education and training functions have failed to ensure that medical practitioners, particularly GPs, are aware of the significance of a blood transfusion, and the risks of TTIs. This has created a particular blind spot in terms of diagnosis, and has also severely impacted the standard of care and treatment given to our CPs;

f. The absence of a standardised, national guideline system, linked to GMC regulation of medical practitioners, plays a particular role in allowing the entrenched practices of clinical freedom and hierarchical learning between senior and junior doctors to prevail over evidence-based medicine;

g. As well as failures to educate medical practitioners, Other NHS Bodies have failed to ensure the public and patients are aware of the risks of blood transfusions and blood products, and the signs and symptoms of TTIs and BBV;

h. There have been a number of care and treatment commissioning failures (explored primarily in the chapter on the Role of Medical Practitioners), including the delayed and unequal roll-out of directly-acting antiviral treatment for HCV.

A systemic failure to record and audit blood transfusion information

4. The other side of the coin to the issues explored in relation to Medical Practitioners – over and unnecessary use of blood and the failure to properly record transfusions in patient records – are the failings of Hospital Trusts (in particular their Blood Banks) to implement a proper system to record and audit the use of blood in their hospital.[1336] There is overwhelming evidence before the Inquiry to demonstrate that there was seriously poor management of blood in hospitals throughout the Relevant Period. By and large steps taken to improve practice were triggered only by BBT, launched in 1998. BBT has not eliminated bad practice, however, and there is still a significant way to go.

What went wrong?

5. There was clear guidance available to Trusts on how to create an effective system around the use of blood in hospitals, such as the British Committee for Standardisation in Haematology (of the British Society for Haematology)'s 1984 report, "*Guidelines on Hospital Blood Bank Documentation and Procedures*"[1337] and the various iterations of Notes on Transfusion/the Handbook of Transfusion Medicine.

6. This guidance, however, we can infer from evidence to the Inquiry, was universally breached. That this was the case was identified in reports such as the 1982 Report of the Central Management Services for the DHSS, "*Blood: Record Keeping and Stock Control*",[1338] which demonstrated that hospitals were operating defective blood record keeping systems.

7. Instead, and notwithstanding the identification of the issue, hospitals routinely failed to ensure the following basic tenets of blood management were systematically followed:

[1336] Of course, a third "*side of the coin*" is the failure of the NBTS to trace blood and blood components once they had left regional transfusion centres. This is explored in the chapter on the Role of the Blood Services, but all of the failures below should be read in the broader context of RTCs failing to fulfil their own haemovigilance functions.

[1337] NHBT0111389_001.

[1338] DHSC0002221_011.

a. That the fact of a blood transfusion occurring was recorded;

b. That the number of units transfused, and the batch or serial numbers of blood components were recorded;

c. That the clinical justification for the transfusion was recorded;

d. That the ordering and use of blood by clinicians was controlled, monitored and (in appropriate cases) limited or curtailed, to ensure that use of blood components was clinically justified and evidence-based;

e. That the use of blood and blood components was audited after the fact to ensure the same;

f. That there were effective means to report and follow-up on post-transfusion infection or signs and symptoms of that (such as jaundice);

g. That there was some kind of body or system to fulfil and coordinate these functions, such as a hospital transfusion committee. The evidence before the Inquiry shows that these were introduced too late and/or were ineffectual where they were introduced, prior to BBT.

8. Clinicians gave first-hand evidence of these failings:

a. Dr Bogod said that there was no process for auditing the number of patients who received a blood transfusion in the peri-partum period in his hospital.[1339]

b. From a haematology perspective, Dr Wallis said that there was no formal system for a clinician to report a case of post-transfusion jaundice to him.[1340] Similarly, his evidence was that there was no formal process to follow if, following discharge, a patient presented to their GP with jaundice or hepatitis. As such, he cannot recall ever having received a report from a GP of a case of post-transfusion hepatitis.[1341]

[1339] Transcript 23/02/2022, pp143-144, ll23-3.
[1340] Transcript, 24/02/2022, pp33-34, ll18-24.
[1341] Transcript, 24/02/2022, pp34-35, ll25-16.

c. Dr Murphy described a system at St Bartholomew's Hospital for recording a blood transfusion that (until 1996) did not include the recording of a blood component number in a patient's clinical records, but instead in a "*compatibility report*", which would go separately in the back of the records.[1342] The evidence of Professor Armstrong demonstrates that such a system would most likely have led to the component information being destroyed or lost. This indeed appears to have been the case at St Bartholomew's, whose own audit in 1994 of transfusion practice[1343] demonstrated that "*on the day after the transfusion, the [compatibility] report was found in the notes in only 30% of cases*"[1344] and that "*there was some documentation of the blood transfusion in 72% of the medical notes. This was usually a brief note such as 'transfuse 4 units of blood tomorrow'.*"[1345]

What were the consequences?

9. The consequences of these systemic failures were grave for our CPs and other patients:

a. Failures to control, monitor and audit blood use to ensure it was consistent with best practice and evidence-based guidelines meant that malpractice was not being recorded, and therefore addressed. It can be inferred, therefore, that infections occurred that were avoidable;

b. It was impossible or very difficult to trace recipients of infected blood in the context of any lookback exercise (this occurred, for example, in the 1995 national lookback programme where approximately a quarter of transfused components could not be traced whatsoever)[1346] meaning recipients were not aware of their potential infections, with fatal consequences in some cases;

[1342] Transcript, 24/02/2022, pp114-116, ll11-8.
[1343] NHBT0135088.
[1344] Transcript, 24/02/2022, p117, ll8-9.
[1345] Transcript, 24/02/2022, p117, ll20-23.
[1346] This is discussed in more depth in the chapter on the Role of the Blood Services. The English National Blood Service HCV lookback collation collaborators, *"Transfusion transmission of HCV infection before anti-HCV testing of blood donations in England: results of the national HCV lookback program"*, *Transfusion*, vol. 42, 2002, pp. 1146-1153 [NHBT0097156_004].

c. Potential TTIs were not reported to hospitals, and therefore RTCs, meaning infectious donors may have remained in the system, leading to further avoidable infections;

d. A true epidemiological picture of TTIs was not being developed. This was particularly significant for non-A non-B hepatitis prior to the identification of HCV;[1347]

e. Ultimately, a substantial number of our CPs have been denied financial assistance because they could not prove that they had received a blood transfusion by way of documentary evidence.[1348]

What should have been done?

10. The UK CMOs convened seminars in 1998, 2002, and 2007 resulting in three BBT Health Service Circulars.[1349] These provided specific recommendations to improve blood transfusion practice with action plans for hospitals and the blood service in England. The development of Hospital Transfusion Committees and Hospital Transfusion Teams incorporating clinicians, laboratory staff and transfusion practitioners, and the establishment of the NBTC and Regional Transfusion Committees in England have driven major improvements in transfusion practice.

11. In short, however, the BBT Initiative was implemented far too late.

12. Dr Wallis gave evidence of a post having been created in the 1990s in his hospital, eventually occupied by a qualified nurse, whose role was to audit blood usage, conduct research, follow up reactions, and train nurses and medical staff on the ward.[1350] Similarly, he described the development from the year 2000 onwards in his hospital of a *"more assertive laboratory policy to question requests for transfusion components where these appeared to be inappropriate according to established guidelines"*[1351] for example where a clinician wanted to transfuse post-operatively

[1347] This is discussed in more depth in the chapter on the Role of the Blood Services.
[1348] This is discussed in more depth in the chapter on the Trusts and Schemes.
[1349] Set out in NHBT0083701_002 RLIT0000848; NHBT0062177_001.
[1350] Transcript 24/02/2022, pp35-36, ll17-22.
[1351] Transcript 24/02/2022, pp43, ll4-9.

when a patient was haemodynamically stable but was relying on a haemoglobin measure to justify transfusion.

13. These measures represented a positive a shift towards a safety-focused system, but we submit that these clinical governance structures and positions, which played an important function of allowing a clinician's "*freedom*" or authority to be challenged,[1352] should have been introduced earlier in time and consistently across all hospitals. This would have meant that clinical decisions were more likely to have been evidence-based and not based simply on the whim or idiosyncratic transfusion practice of an individual doctor.[1353]

14. Hospital Transfusion Committees were an important structure to achieve better blood management. The evidence of clinicians demonstrates that they were introduced patchily across the UK and too late. Having described the illogicality of a "*two not one*" unit transfusion practice, Dr Thomas gave evidence of how easy it was to change this practice in his hospital once the Hospital Transfusion Committee was formed. This was because it carried out an audit function and thus, "*...it was quite easy to identify the ones that were offending. Repeat offenders, if you like. You then focus on those individuals and see if you can persuade them to change their practice.*"[1354]

15. Finally, various clinicians discussed the benefits in terms of reduction of unnecessary blood usage occasioned by the introduction of blood ordering schedules, whereby standard "*orders*" for blood for certain kinds of procedures were pre-determined, with more blood being available in an emergency. Dr Thomas described this as, "*a sudden change from cross-match transfusion, which was a retrospective, to a schedule that was prospective*" and as a kind of "*safety blanket*" for clinicians, who could refer to such schedules and feel confident in the amount of blood they were using.[1355] There was no evidence that these schedules were in place in the Relevant Period for the vast majority of hospitals.

[1352] What Professor Steer described as a kind of "*flat hierarchy*": Transcript 23/02/2022, p103, l14.
[1353] A phenomenon aptly described by Dr Wallis: Transcript 24/02/2022, p46.
[1354] Transcript 02/03/2022, p112, ll1-7.
[1355] Transcript 02/03/2022, p114, ll11-25.

Blood use education failures

16. BBT[1356] has brought about a welcome emphasis on continued education and training for clinicians involved in transfusion. This education is aimed at facilitating what is now known as "*Patient Blood Management*" – a term used to describe a more particular focus on appropriate clinical transfusion and use of alternatives to transfusion for individual patients.

17. We explore in the chapter on the Role of the Blood Services the failure of the NBTS to fulfil its own duty to provide this education to clinicians prior to the BBT era.

18. There was also, however, a woeful failure on the part of hospitals to ensure their clinicians were adequately trained and educated on safe blood transfusion practice (including the risk of transmission of BBVs, particularly non-A non-B hepatitis) and provided with appropriate advice and guidance.

19. This education should have been provided to all staff who may have been involved in the administering of blood transfusions, not just haematologists. It should have addressed the safe use of blood, safe record keeping and, crucially, the patient consent process and the importance of consent. How this manifested in terms of individual practitioners' treatment of patients is discussed fully in the chapter on the Role of Medical Practitioners.

What went wrong?

20. The evidence of clinicians demonstrates a near universal omission by hospitals (and other bodies involved in providing clinical education to doctors in training) to provide adequate education and training on the risks of blood transfusions and BBVs[1357]:

[1356] And associated structures such as the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee and the NBTC (as well as its associated regional committees). NHSBT also plays an important role – discussed further below.

[1357] This is reflected in the evidence of clinicians as to their knowledge of risk, in the Role of Medical Practitioners.

a. Professor Steer cannot recall any education in his early career on the viral risks of transfusion.[1358] Moreover, he said that his obstetrics and gynaecology training would not have included anything about blood transfusion and viral risks, and this was the responsibility of the haematologist.[1359] Having said that, he could recollect *"very little"* interaction with hospital haematologists about safe blood transfusion practice.[1360]

b. Similarly, Dr Bogod suggested that, although he thinks he would have been made aware of the viral risks of transfusion as part of his general medical school training, *"it certainly wasn't a major part of the curriculum."*[1361] However, it is revealing that he cannot recall being aware of non-A non-B hepatitis at the start of his training as an anaesthetist in 1982.

c. Like Professor Steer, throughout his training as an anaesthetist, he did not have any input from haematologists, either from the RTC or within the hospital.[1362]

d. Many clinicians whose practices involved administering blood transfusions could not recall ever having seen the Notes on Transfusion/the Handbook of Transfusion documents. This suggests a widespread failure on the part of hospitals, as well as other education and training providers, bodies that set curriculums and regulators, to ensure that clinicians were aware of and were following the most fundamental and nationally accepted guidance on safe transfusion practice from the NBTS.[1363] This had real practical consequences: for example, Dr Thomas, as an anaesthetist, said that he was not aware of up-to-date guidelines on haemoglobin levels and the associated appropriateness of

[1358] Transcript 23/02/2022, p10, ll22-25.
[1359] Transcript 23/02/2022, p12-13.
[1360] Transcript 23/02/2022, p85, ll8-11.
[1361] Transcript 23/02/2022, p111, ll5-9.
[1362] Transcript 23/02/2022, p115, ll1-5.
[1363] For example Professor Steer: Transcript 23/02/2022, p5, ll10-16. The same applied to Dr Bogod: transcript 23/02/2022, p116, ll8-17. Similarly, Dr Thomas was *"completely unaware that that was a book in existence at all":* transcript 02/03/2022, p98, ll22-25. Professor Dame Sally Davies could not recall ever having been given the book either: p4, ll12-17. C.f. to Blood Services chapter, as this is also a failing on their part to ensure that this important document was adequately known about and followed.

transfusion set out in the *Handbook of Transfusion.*[1364] We submit that this lack of knowledge would almost certainly have led to unnecessary transfusion.[1365]

e. Clinicians generally said that, in the Relevant Period, hospitals did not have functioning transfusion committees, which could have performed an educative function, or indeed other informal mechanisms to share best practice and guidelines.

f. By way of exception, Dr Murphy referred to the hospital transfusion committee at St Bartholomew's Hospital, which was set up in the late 1980s and which acted as means to distribute guidelines on transfusion to other specialities. He attributed failures of hospitals to create hospital transfusion committees in the 1970s-90s to a *"lack of leadership for transfusion in hospitals".*[1366]

g. The discussion in the chapter on the Role of Medical Practitioners regarding consent speaks for itself – there was plainly a failure to educate clinicians about the importance and mechanics of patient consent for transfusion, including informing patients of the risks of transfusion transmitted infections.

What should have happened?

21. Safe blood transfusion practice should have been an integral part of clinicians' medical education and training, including continuing professional development. This should have been constantly reinforced by an education system within the Hospital Trust itself, which was updated as knowledge of risk developed.

22. Much like blood use audit discussed above, many clinicians gave evidence of the hospital transfusion committee in more recent years fulfilling this important function. There is no reason why this could not have occurred earlier.[1367]

[1364] Transcript 02/03/2022, pp98-101.
[1365] See the Role of Medical Practitioners for a full discussion of how this manifested.
[1366] Transcript, 24/02/2022, p126, ll15-22.
[1367] See for example, Dr Wallis: Transcript, 24/02/2022, pp13-16; Professor Steer, Transcript 23/02/2022, pp87-88.

Blood transfusion practice in the present day

23. Notwithstanding the obvious improvements occasioned by BBT and a clear change of direction to a more patient-safety focused approach by NHSBT and other stakeholders, including NHS bodies, issues remain in the present day in terms of safe blood transfusion practice. Dr Murphy suggested that "t*he leadership for transfusion in hospitals and the resource for delivering really good transfusion practice in hospitals is lacking.*"[1368] Professor Mark Bellamy further suggests that "*the mechanisms required to support haemovigilance are not adequately resourced, and indeed, in many trusts and health boards in the UK are prioritised significantly below other clinical and safety initiatives*". This, he suggests, is leading to an increase in error rates and incident reporting.[1369] There is therefore a significant risk, which Professor Bellamy raises, that if this is not addressed, the type of harm suffered by our CPs is and will continue to be suffered by others. In our chapter on the Role of Medical Practitioners, we explored how this manifests in continued medical malpractice and non-compliance with the most fundamental clinical guidelines. Professor Bellamy described this as follows: "*there's still a huge amount of transfusion-related error going on, a huge number of near misses*".[1370] He also confirmed that the problem of patients being given transfusions when incapacitated, and not being told of it when they regain consciousness (or the potential risks of infection) makes it likely that infection is being underreported. Professor Bellamy also attributed this to an education "*lacuna*".[1371]

24. Moreover, Dr Murphy raised an important question about which body has the lead duty to promote and oversee improvement in transfusion practice. He suggested that in the most recent iteration of BBT, a document called "*Transfusion 2024*",

[1368] Transcript, 24/02/2022, p136, ll2-4.
[1369] Professor Mark Bellamy WS, §39-40 (WITN7312001_0013) and see also §62-63 (WITN7312001_0020). See also transcript 16/11/2022, pp50-51, ll12-20 and indeed throughout his oral evidence.
[1370] Transcript 16/11/2022, p84, ll19-21.
[1371] Transcript 16/11/2022, p87-89. Please see also our associated recommendation in the Chapter on the Role of Medical Practitioners, that the Mental Capacity Act Code of Practice be amended to cover this scenario.

recommendations fall to many different groups, such as NHSBT, NBTC, NHS England and Improvement, Higher Education England, Royal Colleges, and individual Trusts.[1372]

25. NHSBT has various functions under the NHS Blood and Transplant (England) Directions 2005. Under Direction 2(2)(g), "*In order to promote or secure the effective supply of blood, stem cells and tissue for the purposes of the health service, the Secretary of State directs NHSBT— to promote, through advice and guidance, the appropriate use of blood, stem cells and tissue (having regard in particular to the need to promote the effective use of blood) and, as it considers appropriate, to provide a reference laboratory for donors and patients*".[1373]

26. NHSBT's 5-year Service Strategy[1374] cites "*variable transfusion practice in hospitals in a landscape of inconsistent education*" as one of the eight major challenges to which it must respond in the next five years and also cites the following as two of its priorities to achieve by 2027:

    a. 20% increase in adherence to NICE Transfusion Quality Standards[1375]; and

    b. 20% increase in education to promote safe and appropriate use.

27. We query whether a 20% increase in education is sufficient, given its stark findings in its own audit of NICE quality standards and the recent evidence of Professor Bellamy.

28. Moreover, in a section entitled, "*What will be different for hospitals and patients*?" it refers to the following:

> "*From strong collaboration to excellence in Patient Blood Management*
>
> • *A strengthened resource to support clinical transfusion practice in hospitals.*

[1372] Transcript, 24/02/2022, p171.

[1373] NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005.

[1374] https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/26903/nhsbt-5-year-blood-service-strategy-2022.pdf.

[1375] Professor Ian Roberts and Dr Murphy gave evidence of how a recent NHSBT audit demonstrates serious non compliance with four important NICE Quality Statements for blood transfusion. RLIT0001824_004. As referred to in the chapter on the Role of Medical Practitioners, one of the most significant findings is that this audit showed, even in the present day, *"there was an absence of any documentation that any written or verbal information was provided to 36% of patients, and fewer than 30% of patients received any written information*".

• *Improved hospital practice delivered through National Blood Transfusion Committee (NBTC) collaboration and benchmarked national quality improvement systems such as NICE and the Model Hospital.*"

29. It is clear, therefore, that NHSBT is best placed, and statutorily empowered and arguably required, to take a lead role on blood transfusion education. We suggest the following recommendations.

Recommendation 1: NHSBT's responsibility for improving blood transfusion practice and education

a. Transfusion 2024 should be amended to make clear that NHSBT has a statutory function to promote appropriate use of blood.

b. NHSBT should revise its education increase target of 20% to a more ambitious level, given the serious issues of non-compliance with NICE quality standards.

c. NHSBT should be required to report each year to the Secretary of State and to the public on its progress in promoting the appropriate use of blood and development of educational activities to achieve this.

d. The issue of patient consent for transfusion should be explicitly mentioned in NHSBT's 5-year Service Strategy and within the context of clinician education. It should include the scenario where a patient has been given a transfusion while incapacitated and the need to post-operatively engage in a dialogue with the patient about the transfusion and its material significance in terms of risks.

e. The NHS Blood and Transplant (England) Directions 2005 should be amended to define "*appropriate use of blood*" as including "*that patients have given informed consent to a blood transfusion where possible*".

f. NHSBT should work with all relevant stakeholder bodies to develop an effective system for auditing whether patients have given informed consent to transfusion, for example, by the use of patient questionnaires and surveys to determine whether patients are aware of the risks of transfusion.

g. NHSBT should conduct research to determine why there is such poor compliance with the most important NICE Quality Guidelines (as per its 2021 audit) and how cultural change could be established around blood transfusion.

h. NHSBT should spearhead an educational campaign for all doctors for whom blood transfusion practice is a relevant part of their practice, using a mantra such as "*the safest blood is the blood that is not given*".[1376] It should work with all relevant stakeholder bodies, such as education providers and regulators such as the GMC, to ensure this is adequately transposed into clinicians' knowledge. This campaign should stress the vital importance of informed consent, as well as recording blood transfusions and including relevant details in discharge letters to GPs and other relevant clinicians. It should stress the alternatives to transfusion and means of minimising blood use, including specifically the use of tranexamic acid. This campaign should use the infected blood scandal as a case study for learning.

i. NHSBT should work with all relevant stakeholder bodies to develop an effective system for auditing whether blood transfusions have been appropriately recorded in a patient's records and in discharge letters.

j. NHSBT should work with other stakeholders to collect data on the number of transfusions on an annual basis and ensure there is adequate information to allow for traceability. Analysis of transfusions should also take account of age, gender and ethnicity (to identify if there is any disparity or differential use of transfusion).[1377]

Recommendation 2: Statutory requirement for Hospital Trusts to fulfil important transfusion and laboratory roles

a. All Hospital Trusts and Foundation Trusts must have a named individual, who must specialise in transfusion medicine, whose role is to report, monitor and audit adverse incidents from blood transfusion.

b. There should be a statutory requirement that this role is always filled.

[1376] The mantra of Dr George Galea. Transcript 07/12/2021, p25, ll11-12.

[1377] Confidentiality should not have primacy, providing that data can be suitably anonymised and subject to trusted research environment criteria as identified by the Goldacre review.

c. This role must be adequately resourced depending on individual hospital circumstances.

d. This individual should report to the Trust's Patient Safety Officer under the Patient Safety Incident Response Framework when that comes into force.

e. Trusts should be legally mandated, via this individual, to report adverse incidents to SHOT in accordance with SHOT's reporting framework.

Hospital Trust record keeping and retention

30. In addition to failures to make adequate records of blood transfusions in the first place, there have been systemic failings by Hospital Trusts in the years and decades thereafter in relation to record keeping, retention and destruction.

31. Professor Armstrong's evidence painted a picture of widespread and longstanding disorganisation and chaos, particularly around the retention and destruction of paper records and their subsequent digitalisation.[1378] This is entirely reflective of the experiences of our CPs.[1379] Professor Armstrong's evidence is also consistent with CTI's presentation on record keeping.[1380]

32. Clinicians painted a similarly chaotic picture. For example, Dr Thomas gave evidence of the disorganised and systemic issues with paper record keeping and recording of blood transfusions. He referred to labels becoming loose and the loss of fluid balance sheets (which might contain details of blood transfusions).[1381]

33. In summary, we consider that what went wrong was as follows:

    a. Hospitals operated disorganised paper record keeping systems, which meant that there were often multiple clinical record files for one patient and thus that information was not all kept in one place;

[1378] Transcript 14/09/2022.
[1379] Please see the chapter on the Role of Medical Practitioners Chapter, where this is explored.
[1380] INQY0000378 - Presentation on the Destruction and Retention of Medical Records.
[1381] Transcript 02/03/2022, pp121-122, l25-5.

b. There was frequent loss or destruction of paper records that may have contained information about a blood transfusion, whether by accident, incompetence or intentionally;[1382]

c. Loss and destruction of records was common in the context of hospital mergers;

d. In the case of purposeful destruction, this was often driven by retention and destruction policies, which generally required the destruction of records six to eight years after the last treatment;[1383]

e. Moreover, records were lost through hospitals' attempts to "*prune down*" records based on relevance and importance. This may have increased the likelihood of transfusion records detailed outside the main clinical notes, for example in fluid balance sheets or anaesthetic sheets,[1384] being destroyed. Further or alternatively, it was more likely that records of a blood transfusion would be destroyed in this process, because of a failure to appreciate the significance and risk of the long-term consequences of a blood transfusion and/or the absence of any guidance advising the retention of blood transfusion records because of these factors. Of course, this failing is inextricably linked to a lack of knowledge of TTIs;[1385]

f. There was potential for further loss and destruction as record systems were progressively digitalised; and

g. Moreover, as patients gained increasing access to their own records, old records may have been "*sanitised*", as Professor Armstrong termed it, retrospectively, to avoid embarrassment of clinicians who had referred to their own patients in derogatory or inappropriate terms or for confidentiality reasons.

34. It is important to note that there are very real fears among our CPs that the destruction of records containing details of blood transfusions was a deliberate act on the part of some hospitals, in order to cover up evidence of avoidable infections or

[1382] See the following paragraph for a discussion of how this has affected our CPs.
[1383] Although, as Professor Armstrong and CTI confirmed, even these policies themselves have been subject to destruction in many cases.
[1384] Or, for example, a "*compatibility report*" as referred to by Dr Wallis – see above.
[1385] Something that is discussed above and below and in the Role of Medical Practitioners chapter.

malpractice. Because of the widespread and almost universal failings, there is a reasonable perception among some CPs that there may have been a direction from within the NHS or Government to destroy records. This is further compounded by the lack of candour, transparency, and accountability that our CPs have experienced from medical practitioners, Government and various public bodies over decades. A perception that their former or current health care provider has destroyed important medical records creates further obstacles and strains on the already fractured trust that many of our CPs have in these providers and medical practitioners. This has had a lasting impact on their ability and confidence to access NHS services in general. We invite the Inquiry to acknowledge this deleterious impact, as well as these reasonable fears and concerns.

35. As evidence from Professors Bellamy and James Neuberger demonstrates, there are many ongoing problems with patient records. Professor Bellamy even stated that in his own Trust, "*blood transfusion does not feature in the electronic patient record. It is still prescribed, administered and recorded on paper, which then sort of disappears into some giant library somewhere and, in theory, gets scanned and put on the system.*"[1386] It is clear that urgent reform and digitalisation is required to ensure patient safety in the field of transfusion and more generally.

Recommendation 3: A truly interoperable and accessible patient record

a. NHS England and Improvement and/or NHS Digital (and/or any other NHS body or agency charged with the reform and digitisation of NHS patient records) should prioritise the development and roll out of a digital patient record.[1387]

b. This digital patient record should be truly "*interoperable*" between different health care providers and settings to allow for effective multi-disciplinary care and treatment – it should include records from secondary care, primary care, as well as other health and

[1386] Transcript 16/11/2022, p93, ll16-20.

[1387] This is completely consistent with the NHS Long Term Plan: https://www.longtermplan.nhs.uk/areas-of-work/digital-transformation/ [accessed: 01/11/2022]

social care settings, such as hospices, mental and community health services, and even clinical research organisations.[1388]

c. With this in mind, it should contain a repository of all medications a patient is on, or has been on recently, so that a clinician managing a patient with multiple morbidities has the information to make a judgment on drug interactions.

d. It should provide means for easy and quick digital communication between different clinicians and providers.

e. Any digital infrastructure required to support this digital patient record should be prioritised for investment and development by the NHS and Government.

f. Patients should have unfettered access to this record, and it should be available as an app, like the existing NHS App (which currently only includes primary care records and some other test results where there has been a referral from a GP).[1389]

g. Significant opportunities for patient involvement and interaction through this digital record should be grasped and explored, with a particular view to improving the quality of the patient consent process. This would also assist doctors in fulfilling the subjective element of their *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 duty of care. For example, we invite the Inquiry to consider recommending that the app should allow for:

   i. An area to write notes after or before a consultation, as an aide-memoire for the patient, which could also be visible to practitioners if the patient elected;

   ii. A means of answering a pre-consultation questionnaire, or posing questions to a clinician in advance of a consultation;

[1388] Subject to strict confidentiality and consent processes.Please note the evidence of Professor Mark Bellamy, who highlighted the benefits of an interoperable system in terms of passing transfusion records onto GPs, and also in the case of "*shared care*" for patients with conditions such as sickle cell disease: at §58 of his witness statement: WITN7312001_0018.

[1389] The ALD/Palliative Care Experts extolled the virtues of patient "*ownership*" of their records. They described this as a "*hugely important step*" that would be "*empowering*" and "*a good way for patients to advocate for themselves*": Transcript 04/03/2022, pp121-124.

iii. A feature allowing a patient to input some basic details about themselves. This could be by way of prompts such as "*Who am I?*", "*What is my job or occupation*", "*How do I like to spend my free time*", "*What are my religious beliefs or other cultural or spiritual values?*", "*What is my ethnic and cultural heritage and how does this impact on my choices around care and treatment*", "*What is my personal pain threshold*", "*What particularly concerns me about my care and treatment*", or "*What is important to me in life?*". This would allow doctors to gain a snapshot of a patient's lifestyle, values and preferences in a manner that is consistent with *Montgomery* as well as GMC guidance on informed consent[1390] and is potentially a solution to the fact that clinicians have very little time to conduct these conversations in person during appointments, which may be further exacerbated when a patient requires any form of adjustments because they have a disability, or if English is not their spoken language.

iv. Opportunities for advanced planning of palliative and end of life care.

v. Opportunities for advanced planning before surgery, for example by indicating preferences around transfusion.

vi. The digital record should allow for a tickbox for the medical practitioner to say whether a patient has had a blood transfusion, which should trigger access to a link within the app to information about the risks of blood transfusion.

Recommendation 4: Lifelong hospital records for all patients

a. Secondary care records should no longer be kept for eight years after the last treatment. They should be brought in line with primary care records and should be retained for ten years after the patient's death. This should be ensured by way of legislation.

b. This has been made possible by the progression towards full digitalisation and there is no longer any justification for more premature destruction when modern medical practices demand MDT working and integrated care and treatment, nor where there is

[1390] See: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/the-dialogue-leading-to-a-decision#paragraph-16 [accessed 01/11/2022].

increasing treatment for chronic disorders and interrelated morbidities. A failure to retain records could lead to vital missed opportunities to "*join up the dots*" in patient symptoms, which has occurred for our CPs with viral hepatitis.[1391]

c. Further or alternatively, there should be a process by which a patient is notified and given the chance to object to and/or receive a digital or paper copy of their records in the event that a Hospital Trust intends to destroy them.

Recommendation 5: Retention of hospital policies (on record keeping)

a. Trusts should be statutorily required to retain copies of their policies on record keeping, retention and destruction for fifty years.

Recommendation 6: Flagging blood transfusions on patient record

a. GP records should include a "*flag*" or some form of mechanism to alert the GP that a patient has had (or is suspected of having had) a blood transfusion.

b. To the extent that that this system is being trialled and/or developed in pilot studies coordinated by NHS England, this system should be fully implemented across the United Kingdom after lessons have been learnt from the trial results.

c. However, it should also be a mandatory requirement that every patient is asked when they join a surgery if they have or suspect that they have had a blood transfusion at any time in the past and an affirmative answer should translate into a "*flag*" on the system.

d. Many records omit details of transfusions (even in the present day). The absence of any such record should not be seen as conclusive proof that a transfusion has not taken place, particularly prior to the 21st century.[1392]

[1391] See the discussion in the chapter on the Role of Medical Practitioners chapter regarding "*constellations*" of symptoms.

[1392] Indeed, the evidence of Professors Neuberger and Bellamy demonstrates that this occurs even in the present day.

Recommendation 7: Infected blood record task force

a. NHS England and/or NHS Digital should create a targeted infected blood record task force, with a brief to find historic records of blood transfusions and add them to patient records.[1393]

b. Such work would complement the GP "*flagging*" system discussed above, because it would identify "*missing*" patients who do not know they are infected.

c. It would be of value to CPs whose records of a transfusion are missing, both because of the trusts and schemes' approach to documentary evidence (which is still ongoing in the case of EIBSS etc)[1394] and because of the likelihood that an individual will be advantaged in any future compensation scheme if they have records of their transfusion.

d. It would also have a cathartic function for patients whose doctors did not believe that their hepatitis was caused by a TTI and who have faced the trauma of finding that there was a gap in their records with regards to transfusion history.

e. Particular attention should be paid to examining hospital blood bank records[1395] for this missing information and correlating with patient records.

f. This task force should also identify as far as possible where records have been destroyed, and by whom, when and for what purpose, or in what circumstances.

Other education and guidance failures

36. As well as the specific issues around Patient Blood Management and the lack of education and guidance given to clinicians on transfusion by hospitals, we consider that there have been failures across the board from various other bodies tasked with providing adequate and correct education and guidance to clinicians on matters

[1393] We note Dr Hewitt's similar recommendation that, if practicable, a database should be compiled of all those who had received blood transfusions and those listed on it should be notified of their right to be tested: transcript 10/12/2021, p140.

[1394] Such approach is the subject of criticism and discussion in our chapter on Trusts and Schemes.

[1395] Which, as far as we are aware, are a separate system of records to patient medical records.

relevant to the Inquiry. These bodies include NHS England, Royal Colleges, medical professional societies, regulators (such as the GMC) and NICE.

37. The evidence of our CPs and the evidence before the Inquiry suggests that, in the Relevant Period, clinicians were not properly educated by these bodies on the following pertinent matters:[1396]

    a. BBVs in general, but especially HCV and HBV (and, previously, non-A non-B hepatitis) and their signs and symptoms (both hepatic and extra hepatic manifestations);

    b. The risks of blood transfusions, including TTIs, and the significance of a patient having had a historical blood transfusion;

    c. The clinical triggers for referrals for tests for BBVs and the clinical pathways for care and treatment, including signposting to other relevant clinical and non-clinical services such as palliative care, counselling and psychological services and patient representative groups.

    d. Informed consent and the need for this to be bespoke and patient-centred;

    e. Candour, honesty and transparency with patients;

    f. Communication skills and how to ensure patient dignity and confidentiality.

38. Of particular note, given the disproportionate level of transfusion in this field, was the fact that the first edition of a guideline from the Royal College of Obstetricians and Gynaecologists on blood transfusion in obstetrics was published as late as February 2007.[1397]

39. Coupled with this lack of education and guidance was a lack of oversight by these bodies of compliance with any guidance that was available. Instead, a concept of "*clinical freedom*" – addressed above in the context of idiosyncratic transfusion practice – was allowed to predominate. Professor Steer articulated this in his

[1396] The evidence for this in terms of clinical practice is set out in the Chapter on the Role of Medical Practitioners.
[1397] Presentation by Counsel to the Inquiry about the guidance available to clinicians about the use of blood transfusions: Transcript 21/02/2022, pp166-167.

evidence, as he described his experience as a junior doctor in the 1970s and 80s, when teaching was largely verbal and by apprenticeship rather than by reading guidance documents and/or policies.[1398] This was reinforced by a strict hierarchy between senior and junior doctors, rather than the "*flat hierarchy*" Professor Steer suggested was needed.[1399]

Education and guidance problems in the present day

40. Unfortunately, we consider that there remain a number of serious problems with the education and guidance available to clinicians on matters relevant to the Inquiry, even in the present day.

Lack of national guidance system

41. First, there remains no formal system for making guidelines and the latest best practice information easily available across the entire NHS system. Nor is there any formal requirement (beyond the GMC-regulated appraisal and re-validation processes) to demonstrate knowledge of best practice. In our submission, the current system is insufficient to ensure that doctors have the requisite knowledge to fulfil their ethical duties to their patients. This was explored by various clinicians in their evidence to the Inquiry:

    a. Professor Steer explained that there was a lack of formalised training for junior doctors (namely all doctors below consultant level), particularly concerning the latest knowledge of best practice from guidelines and papers.[1400]

    b. Linked to this, he said that *"there isn't a generalised system for promulgating these sort of policies or decisions within the NHS. It is still very ad hoc and left to people sort of reading about it in the BMJ or something."*[1401]

[1398] Transcript 23/02/2022, pp8-9.
[1399] Transcript 23/02/2022, p103, l14.
[1400] Transcript 23/02/2022, pp80-81.
[1401] Transcript 23/02/2022, p86, ll8-11.

c. This has also been confirmed by Professor Roger Kirby from the Royal Society of Medicine: *"Currently there is no overarching system for ensuring that clinicians are kept up to date with guidelines, guidance and best practice."*[1402]

d. One relevant example of this is the BBT guidance and policies, which Professor Steer had no knowledge of.[1403]

e. Dr Thomas also made the pertinent point that specialist doctors do not usually read guidelines primarily published for other specialists (for example, "*anaesthetists don't read haematological guidelines on platelet transfusion.*") Instead, he suggested that a system was required whereby "*they need to be fed that information in a specific, digestible way so that what you really want to do is to have a change in behaviour. You don't necessarily want them to read all the documents. And so they have to have a trusted individual, a conduit of that information, to give them best guidance."*[1404]

f. In the absence of a standardised, national system, Professor Bellamy suggested that the hierarchical culture described by Professor Steer remains the dominant means for training and passing information between senior and junior doctors: "*a culture in medicine of beliefs handed down from generation to generation to generation and 'I do it because that's how I was taught to do it' without ever looking at things critically*".[1405]

42. Professor Cave gave evidence of how harms and wrongs can occur not just to patients but also to clinicians when "*they aren't given sufficient guidance or resources to be able to make the patient their first concern"*.[1406] We consider that creating a proper, national guideline repository for all doctors against which they could be assessed would protect doctors, and thereby, crucially, their patients.

[1402] WITN7255001_0001, §6.

[1403] Transcript 23/02/2022, p91, ll8-16. Another example is Dr Bogod, who had no recollection of guidelines for transfusion for massive blood loss - NHBT0000037_013 – published by the British Society of Haematology in 1988, nor of the Better Blood Transfusion Initiative (Transcript 23/02/2022, p147, l14).

[1404] Transcript 02/03/2022, p101, ll8-15.

[1405] Transcript 16/11/2022, p164, ll21-25.

[1406] Transcript 26/01/21, p57, ll6-14.

43. We therefore invite the Inquiry to make the following recommendation, which we note is complementary to an "*Action for Improvement*" in the Report of the IMMDSR.[1407]

Recommendation 8: National guidance system

a. NHS England, NICE, the CMO or another appropriate body should be charged with creating a national guideline system, available digitally, for all doctors. This system should:

   i. Act as a central repository for all relevant guidelines;

   ii. Allow practitioners to easily access, view and understand the significance of guidelines in other areas of practice (for example by way of "*important flags*" or summaries);

   iii. Crucially, include guidance statements of best practice relevant to blood transfusion medicine, and these should be flagged for all specialities of medicine, but particularly those where surgery is more likely;

   iv. Should cross-refer between relevant guidelines.

b. This system should be tied to the GMC-regulated revalidation and appraisal process for all doctors. This could be by way of some kind of test, which utilises information in the national guidance system, or through a declaration by an individual doctor when confirming that they have complied with their CPD requirements.[1408]

[1407] "*Annual appraisal of doctors should include providing evidence of awareness of relevant guidance in the doctor's area of practice. Colleagues should report failure to follow guidance which is detrimental to patient safety. This should apply in the private or independent sector as well as in the NHS*". Please see the Government response at §9.32, which accepts this Action, although appears to merely cite the current regulatory framework. This does not address the fact that the current regulatory framework is not working, and so we consider that it remains appropriate for this Inquiry to make similar recommendations.

[1408] As well as the IMMDSR, this was also suggested as potential mechanism for improvement by the ALD/Palliative Care Experts: Transcript 04/03/2022, pp104-105, ll18-11. We consider that the existence of a national system, which makes guidelines easily accessible, makes the IMMDSR Action for Improvement fairer and more workable for doctors.

c. There should be consideration of integrating this guidance system with a national system for electronic prescribing, to ensure that prescriptions are based on best practice and evidence-based guidelines.[1409]

d. Dr Finlay, consultant in palliative medicine, made a recommendation, which we endorse, that high level guidance should be disseminated not only to clinicians but also to charities and other advocacy groups (we suggest, like the Hepatitis C Trust).[1410]

Viral hepatitis-specific education and guidance issues

44. Current medical education and information on HCV in the UK is focused heavily on current or former intravenous drug users and other at-risk groups, such as MSM, sex workers, and those who have had tattoos. While NICE guidance on "*Who should I test for hepatitis C?*" suggests clinicians should "*Offer hepatitis screening to asymptomatic people who are at high risk of hepatitis C virus (HCV) infection*", including "*People who received a blood transfusion before 1991 or blood products before 1986*", there is a significant weight of evidence from our CPs and the Hepatitis C Trust that this is not adequately transposed into medical practitioners' knowledge or practice.

45. This needs to be corrected by emphasising the risk of hepatitis due to transfusion and giving doctors (i) better education; and (ii) information to identify and support those infected with HCV or HBV as a result of infected blood and blood products.

46. As referred to above, and in the chapter on the Role of Medical Practitioners, there is a blind spot in GPs' knowledge of viral hepatitis and the risk of it being transmitted by blood transfusion. This is particularly important to address given GPs' front-line role in finding, diagnosing and managing the care of patients whose infections are caused by treatment with NHS infected blood.

47. Samantha May on behalf of the Hepatitis C Trust aptly described GPs, and their lack of knowledge, as the "*sticking point*".[1411] Dr Scott Jamieson, the GP expert within the

[1409] See, for example, the suggestion of Professor Neuberger at transcript 16/11/2022, p170.
[1410] Transcript 04/03/2022, pp101-102, ll22-1.
[1411] Transcript 04/03/2022, p162, l15.

Hepatitis Expert Group, was not aware of any standardised information about HCV that a GP could refer to, and said the closest thing was a RCGP liver toolkit.[1412] He explained why this was particularly important given GPs in many localities will not often come across a patient with HCV and why there therefore need to be "*systems to support patient*s" that GPs have access to.[1413] Dr Hudson, in the context of ALD more broadly, referred to a Scottish study of GPs that highlighted widespread gaps in knowledge and confidence in terms of understanding the prognosis for ALD and managing its complications.[1414]

48. In addition, the NICE guidance referred to above fails entirely to identify the cohort of patients who have received a blood transfusion or blood products as at risk of HBV infection, notwithstanding the evidence that the Inquiry has heard of the technological shortcomings of HBV screening tests.

49. Moreover, we consider that the guidance that is available regarding the clinical appropriateness of testing when there is a history of blood transfusion is unduly restrictive when it comes to the "*at risk*" time periods. It does not accurately reflect the evidence which the Inquiry has heard about (i) the technological shortcomings of early generation HCV screening tests meaning that infected blood donations "*slipped through the net*" or (ii) the possibility of untested blood remaining available for transfusion after routine screening was introduced. In particular:

    a. Dr Boulton accepted that there might have been some untested blood left in the system in Wessex and he had concerns about it at the time,[1415] accepting that he could not exclude the possibility of untested blood being issued.[1416]

    b. Dr Wagstaff accepted that there was a very small chance of untested blood being in circulation after September 1991.[1417]

[1412] Transcript 26/02/2020, p205-206, ll24-7. As Dr Mary Ramsay from the UKHSA confirms in her written evidence, the RCGP HCV course is not a freely accessible resource and is only available to members of the RCGP: WITN7375001, §2.10(b).
[1413] Transcript 26/02/2020, pp205-210
[1414] Transcript 04/03/2022, p77, ll15-22
[1415] Transcript 04/02/2022, p157.
[1416] Ibid, p177.
[1417] Transcript 25/01/2022, p126.

c. Dr McClelland recognised that it was a *'judgment call'* whether stocks were tested for HIV.

d. Professor Contreras accepted that in some parts of the country materials which had not been tested for HIV may have been supplied for use in patients after 14 October 1985.[1418] She also accepted that untested fresh warm blood was being used in Harefield Hospital as late as March 1999;[1419] and that untested blood and blood components possibly remained in the NHS system in the weeks or months after 1 September 1991, sometimes for up to ten years (in the case of frozen red cell concentrates) and would not necessarily have been tested before use.[1420]

e. NHS England has recognised that Factor VIII was not safe in Scotland before April 1987.[1421]

50. Screening of blood and viral inactivation were not panaceas. Moreover, the JPAC's transfusion handbook accepts that, even with modern screening methods, blood transfusions are not completely safe, and this was also the evidence given to this Inquiry by a number of clinicians.[1422] Therefore, the limitation on the NICE Guidance HCV testing recommendation to those who received blood products before 1986 and blood before September 1991 should be amended.

51. To address these education and guidance failures outlined above, we invite the Inquiry to make the following recommendations:

Recommendation 9: HCV medical education generally

a. Even against the backdrop of aiming for elimination by 2030, HCV should be re-emphasised within the current medical curriculum alongside other TTIs.

b. All specialists whose practice involves (i) blood transfusion, (ii) obstetrics and gynaecology, (iii) anaesthetics, and (iv) surgery should be required to undertake CPD on

[1418] Transcript 03/12/2022, pp37-45.
[1419] Ibid, p131.
[1420] Ibid, p144.
[1421] See *Hepatitis C: guidance for GPs*, dated 25 November 2020.
[1422] Transfusion Handbook, §5.3.

the topic of HCV and other viral and non-viral risks associated with blood transfusion. This should be assessed as part of their revalidation/appraisal process.

Recommendation 10: Accuracy around the risk period for receiving a transfusion in clinical information and education

a. We consider that there should be no temporal limitation within the NICE Guidance. The Guidance should recommend testing for HCV and HBV (not currently included) for: "*All people who have received blood transfusions. People who received blood transfusions before* [any more reasonable longstop date to be determined by the Inquiry based on accurate evidence about when testing was no longer fallible] *in the UK may be at particular risk*".

b. The information on testing on the NHS website should be amended in the same manner. Furthermore, the risk of transmission related to blood transfusions should be included on the first page – known as the "landing" page – on the Hepatitis C and Hepatitis B websites, and not solely on the page specifically related to risk factors.

c. The UKHSA Hepatitis in England 2022 Report refers to the same risk period and this report, and associated UKHSA risk assessments for the purposes of the elimination campaign, should be amended similarly.

Recommendation 11: GP education

a. An education and awareness campaign (involving, if required, the issuing of CMO letters/guidance to all clinicians following the conclusion of the Inquiry) should be run to remind GPs about the signs and symptoms of viral hepatitis, its prevalence in groups outside the "at risk" groups identified above, and the need to investigate whether a patient *may* have a history of blood transfusion (noting that some patients may not be aware that they have received blood or blood products).[1423]

[1423] Such training must emphasise that even where there is no record of a blood transfusion, where an individual has had obstetrics or gynaecological interventions, or surgery before (for example) 1995 and presents with

b. The ideal outcome would be for each GP to undertake a course of learning such as the RCGP Hepatitis B & C course,[1424] however, this should be alongside bespoke information about the risks attributable to infected blood. NHS England, or another appropriate body, should ensure that all GPs have access to this course and to bespoke training.

c. Any GP educational or training resource should:

   i. include guidance on using clear, simple language to explain both the disease, the treatment available, and what tests involve. This should be supported by clear and accessible guidance provided in leaflets/online.

   ii. ensure GPs ask questions to identify those infected through blood transfusion. Doctor-facing guidance should include a "tick box" or similar feature reminding GPs to explore histories of blood transfusion. This could be done, for example, at the NHS health check currently offered to all 44-year-olds, or any other form of routine discussion (for example when registering with a new surgery).

   iii. include training on how to communicate an HCV diagnosis to patients, signpost patients to support schemes, and to ensure their cases are appropriately followed-up.

d. There should be at least one GP in every large practice and/or several GPs in every commissioning area with this expertise and with a particular knowledge of the history of infected blood. This could be ensured by way of a contractual mechanism (supported by a financial incentive), which may require legislative change.

   i. This GP or practice should link with the current HCV "*hub*" (ODNs)[1425] to facilitate the creation of a clinical pathway from GPs to appropriate HCV care for each patient within the hub.

symptoms of HCV, they must be offered a test.The onus must be shifted onto the service provider to proactively explore and exclude the diagnosis of TTI from blood transfusion, rather than leaving patients to selfadvocate.

[1424] Available here. We endorse the UKHSA's recommendation that *"All stakeholders should work to improve awareness of HCV and national guidance on testing for HCV among health care professionals, for example by encouraging participation in, and audit of RCGP e-learning*" but it must be made freely available.

[1425] Please see the recommendation on HCV commissioning in the chapter on the Role of Medical Practitioners.

ii. GPs must be made aware of the specialist lead HCV nurse in their area and be able to refer patients on to the hub easily.

e. The Inquiry should consider that any GP database or sources of information promulgated or required to be accessed by GPs should provide information about the position of those infected by way of blood or blood products, the payment schemes, and any future compensation framework.

f. We endorse the current Public Health England Guidance: "*Whenever a liver function test is returned with unexplained raised transaminase levels, consider testing for HCV as part of further investigation, even when there are no overt risk factors*".[1426] However, the experience of our CPs suggests that this is often overlooked in practice and should be re-emphasised as part of GP education.

g. The NHS HCV pages[1427] should contain a link to the Hepatitis C Trust in a similar way that organisations are linked which help and provide support for patients diagnosed with other conditions (such as HIV).

h. All medical training and GP education should focus on the up-to-date clinical understanding of HCV as a multi-system disease and not simply a disease affecting the liver. This should include an emphasis of the disease's extrahepatic manifestations, including rheumatoid arthritis, thyroid problems and type 2 diabetes, autoimmune disorders, musculoskeletal problems and mental health problems (as set out in the Inquiry's Hepatitis Expert Group Report, pp58-61). This should be for the purposes of testing (namely identifying symptoms) and ongoing management of the condition.

i. GPs should be "*spot-checked*" for HCV CPD and for compliance with national guidelines on HCV, as part of any routine inspection process. The Inquiry should consider whether this should be part of a GPs' contractual requirements and/or their appraisal and re-validation.

[1426] NB – this guidance is still promulgated under PHE name, notwithstanding its dissolution and replacement with UKHSA and OHID: *Hepatitis C: information for GPs*, updated 25 November 2020 (accessed 10 November 2022).
[1427] In particular this page.

j. NHS England should consider how they might incentivise GPs to ensure that adequate HCV treatment and follow up is undertaken. This must be maintained beyond the current elimination programme end date (2030). This could be by way of the Quality and Outcomes Framework.[1428]

Failures to inform and educate the public and patients

52. A substantial amount of evidence before the Inquiry has demonstrated the importance not only of communication with and education of doctors, but with patients and the public too.[1429]

53. In relation to the risks of blood transfusion and BBVs such as hepatitis, however, there has been an absence of any specific targeted campaign and indeed patient-friendly resources.[1430] Patient representative groups, such as the Hepatitis C Trust, have been left to fill this gap.

54. Many of our CPs report relying on google and the internet (often with distressing consequences) because of an absence of patient information and signposting from clinicians. Many CPs contrast this situation with other areas of medicine, such as cancer, where resources and signposting routes are more established and plentiful.

55. This lack of information has also led to an associated problem around accessing tests. Emma Prescott, HCV Nurse, said that testing was needed *"nowadays even more so than ever because we have all these treatments... looking at the prevention of long-term problems, it's vital."*[1431] While the need for testing should (as discussed above) primarily be for clinicians to recognise, the lack of knowledge among GPs creates a need for patients to self-advocate. Our CPs' experience demonstrates that many individuals may lack the information or ability to advocate for testing and, when they do so, they may be refused. It is essential the NHS be responsible for identifying this

[1428] As Dr Mary Ramsay from the UKHSA suggests in her written evidence: WITN7375001, §2.10(d).
[1429] The importance of candour and transparency about known and emerging health and medical risks with patients and the public is something, we submit, that has been reinforced by all expert groups to the Inquiry with a clinical or public health remit.
[1430] That are published by the Other NHS Bodies we address in this chapter.
[1431] Emma Prescott, Transcript 03/03/2022, p133, ll9-18.

cohort via a public information campaign and/or other means, and proactively offer testing, to complement clinician educational efforts.

56. NICE has recommended for a number of years that commissioners and providers of public health such as the UKHSA and Office for Health Improvement and Disparities should conduct awareness-raising campaigns about HBV and HCV.[1432] This campaign should squarely highlight the risks for those who received infected blood.[1433]

57. We therefore invite the Inquiry to make the following recommendations:

Recommendation 12: Public information campaign

a. A targeted public education campaign[1434] is necessary to enable infected but undiagnosed people to identify themselves and come forward.

b. The campaign should highlight the variety of symptoms associated with viral hepatitis and emphasise the possibility of contracting HBV or HCV as a result of a transfusion.

c. We recommend undertaking a one-off publicity exercise in a range of media, including social media, with a focus on addressing those aged 50 and over.

d. Patient representatives, such the Hepatitis C Trust, should be invited to advise on the most effective and value for money means of targeting the cohort of people most likely to be affected by infected blood.[1435] If the Inquiry considers that it is more appropriate for an organisation like the Hepatitis C Trust to run such a campaign, it is essential that it is fully funded by NHS England or by the Government.

e. Leaflets and information posters regarding HBV and HCV, encouraging patients to ask their doctor for a test, should be prominently displayed at GP surgeries or in material

[1432] See *Hepatitis B and C testing: people at risk of infection, Public health guidance PH43*. Published 12 December 2012. (Accessed on 18 April 2022). As Dr Mary Ramsay from the UKHSA also suggests in her written evidence: WITN7375001, §2.10(a)-(b).

[1433] This would also be a useful opportunity to address the concern raised by the Palliative CareExpert Group, namely that *"increased public awareness of the burden of liver disease in the UK is vital"*.

[1434] Consistent with the evidence of the experts on HCV elimination.

[1435] See Dr Ramsay: WITN7375001, §2.17, who suggests that any media campaign would likely be co-developed with input from The Hepatitis C Trust and other target audience patient representative groups to ensure appropriate and impactful messaging and channels were used.

used by patients to access appointments and the doctor (such as patient access apps/the NHS app).

f. Issues with lost records and inadequate reporting from hospitals to GPs also means that GPs are often unaware that their patients have had a blood transfusion. Given this, any awareness campaign (and associated materials) should alert individuals that their GP may well not know this and will need to be told about this in order to be able to consider the issue of transmission of infection by blood.

Recommendation 13: Finding undiagnosed patients - testing[1436]

a. All those who meet the amended (as per our recommendation above) guidance for testing for patients who have previously received blood or blood products should be offered HCV and HBV tests.[1437]

b. Moreover, all those with potential HCV symptoms (including chronic extrahepatic symptoms) should be offered an HCV test.

c. The non-specific symptoms of HCV (for example, fatigue, digestive problems, joint pain and brain fog) can easily be dismissed or misdiagnosed, particularly given the ageing nature of the infected population, menopause and more recently the rise of long Covid. HCV testing should be part of the standard battery of tests for patients presenting with these symptoms. We are aware that some of the NICE guidance does recognise this, but not all of it.

d. In the USA, all adults born between 1945 - 1965 have a chance to have "*one off HCV testing*" because of the higher rates of transmission in that group. The Inquiry should carefully consider if this type of screening programme would be beneficial to ensure that all those who may possibly have HCV are identified and can access treatment upon diagnosis.[1438]

[1436] Please note this is additional to our endorsement of the existing NHS England algorithmic flagging pilot, and our recommendation that it is fully rolled out.

[1437] This also intends to build on the recommendation of the Penrose Inquiry, which has not been satisfactorily implemented and which does not fully address the position of those who continued to receive infected blood after September 1991, including some CPs.

[1438] Hepatitis Expert Group Report, p21.

e. If our primary recommendation is not practicable, we recommend that all women aged 45 or older who have given birth before the longstop date/a date to be determined by the Inquiry, should be offered a test.

f. We understand that NHS England has tendered for the development of a "*web portal*" so that individuals can order a test online in a discreet and private manner. We understand that this is due to be implemented /come into force at some point in 2023.[1439] We consider that this may well provide a quick and easy mechanism to ensure or roll out widespread testing: and that the experience of Covid has made the population more willing to access and use online mechanisms for the ordering of tests.

g. This testing programme should be publicised through the media campaign discussed above.

Care and treatment commissioning failures

58. The inability of our CPs to access proper care and treatment for their TTIs – including integrated care for their HCV as a multi-systemic disorder, adequate monitoring and follow-up, psychological services and palliative care is dealt with in the Chapter on the Role of Medical Practitioners. Similarly, that chapter contains recommendations to remedy the situation. It is mentioned here again to emphasise the role of NHS Bodies in failing to commission and provide these services.

DAA Treatment for HCV: NICE and NHS England failures

59. Finally, however, we address one discrete issue here: the problems our CPs faced in the mid-2010s in accessing DAA treatments for their HCV and the role played by NHS England and NICE. As set out in the chapter on the Role of Medical Practitioners, many of our CPs experienced delays in obtaining access to these treatments.

60. In summary we consider that:

[1439] https://www.contractfinder.service.gov.uk/Notice/348b567-ebef-4122-b8f6-005bdc8b2031.

a. There were serious problems in terms of patient access to these drugs until approximately 2017.[1440]

b. There were serious ethical issues around the fact that many of our CPs were not granted early access under the initial NHS England programme because they were not considered to be close enough to death, when many of their lives had been ruined by the physical and mental health impact of their infection;

c. There were similarly serious ethical issues around the fact that the NICE guidance, once implemented following an NHS England requested delay, left clinicians to implicitly ration the drugs, depending on who was most at need based on perceived physical and mental harm. We submit that this led to unfairness and inconsistency in treatment provision around the country;

d. Many of our CPs felt a profound sense of injustice at this inability to access the DAAs because of the way they had contracted their infections resulting from NHS treatment, and the delays many had experienced in getting diagnosed because of the lack of candour around their transfusion and its risks;

e. There should have been consideration given, and early access granted, to victims of infected blood; and

f. NHS England's request to delay the mandatory implementation period of the NICE technology appraisal guidance, even where it recognised its cost effectiveness, is an example of the perverse effect of the NHS annual financial planning cycle, and further disadvantaged our CPs.

[1440] As acknowledged by Professor Cooke – see Role of Medical Practitioners chapter where his evidence cited.

CHAPTER 6: SELF-SUFFICIENCY, FRACTIONATION AND PHARMACEUTICAL COMPANIES

"Our life together was destroyed not by his haemophilia, but by the poisonous drugs that were administered to him by the NHS."[1441]

Introduction

1. This chapter seeks to address the three distinct but overlapping topics of (a) the UK's self-sufficiency in blood and blood products, (b) its domestic fractionation efforts, and (c) the role of pharmaceutical companies in supplying the demand for imported factor concentrates which arose in particular in late 1970s and early to mid-1980s. We consider these issues compendiously given their substantial degree of overlap.

2. We make four key submissions:

   a. Imported factor concentrates were widely known from at least May 1975 to be substantially more dangerous than domestically-sourced blood products. While the emergence of HIV/AIDS drew attention to the risks of imported concentrate, the UK authorities ignored the risks of HCV or considered that they were not significant and so failed to provide adequate information to patients, or to the public/government (please see the Government chapter and also the chapter on Haemophilia Centres and Clinicians).

   b. England and Wales were unnecessarily (over)dependent on imported concentrate due to:

      i. A failure to maximise domestic blood (and in particular plasma) supply;

      ii. The limited capacity of BPL, and its delayed redevelopment, caused by under-investment;

      iii. The growing demand for factor concentrate, which was not recognised by the Department of Health and unnecessarily inflated by its prescription where

[1441] W2004, §59.

not clinically essential, without proper warnings as to risk. Alternative treatments were not adequately explored, and patients were not given an informed choice.

iv. The failure to work with the Scottish Government and blood authorities and/or to seek to use the availability of a newer facility in Edinburgh to expand this supply: there was too much "*territorial*" possession of blood and not sufficient consideration of a UK wide blood policy. The failure to maximise domestic supply was a governmental failure of control, direction and oversight, and a failure to provide adequate monies from the late 1970s – mid 1980s, largely because there had been insufficient planning of the scale and nature of demand for concentrate by the UK government and its clinical and scientific advisers. Once HIV / AIDS was faced as a significant issue, this approach did change, but the length of time it took to properly redevelop BPL was caused by the factors set out above.

v. The government's preference for the short-term financial cost-saving option of commercially purchased products which were also more readily available despite it being widely known by 1976 that the domestic production of blood products was the lower-cost option in the long-term.

c. The government failed to adopt a sufficiently precautionary approach to the use of blood products, or to promote a policy of minimising the use of blood and blood products.

d. The government's decision to licence and its approach to licensing unsafe imported factor concentrate and the aggressive marketing by pharmaceutical companies encouraged an unquestioning approach to the real risks associated with imported factor concentrate. This was unacceptable, naïve and clinically very risky, given the sources of blood used by pharmaceutical companies. The lack of curiosity and/or "*turning a blind eye*" to the practices of commercial providers and the clinical autonomy and "*freedom*" enshrined in the approach to prescription at this time were inimical to the type of rigorous review and oversight in the interests of patient safety.

3. As a result of these factors, the UK failed to achieve self-sufficiency in factor concentrates and exposed users of such products (primarily haemophiliacs) to avoidable but life-threatening health risks. While the risk of viral transmission may not have been completely avoidable, it could and should have been materially reduced.

4. That failure was compounded by the failure of both pharmaceutical companies and clinicians to provide adequate warnings regarding the risks of blood products, in particular imported factor concentrates. Package labelling by pharmaceutical companies was poor and sub-standard, while clinicians consistently failed to ensure informed consent was taken from patients.[1442] This made a material difference to patients' outcomes as, had the risks been properly explained, it is likely that mild/moderate haemophiliacs, children and others who required smaller amounts of blood products in particular would have used less product, diminishing the use of imported concentrates. Had patients been warned of the risks regarding imported products and offered alternatives, the evidence before the Inquiry is that many patients would have opted for an alternative.

5. This chapter draws on and adopts the helpful presentations prepared by counsel to the Inquiry on these issues, which we do not intend to repeat.

Risks associated with blood products

6. Blood and blood products have always been known to pose a risk of blood-borne infection, including the risk of novel viruses. The risk of haemophiliacs dying from hepatitis transmitted by blood products was clear from at least 1969.[1443] From 1982 the government was aware of clinically compelling material and evidence that blood products could carry AIDS, even though this was not finally confirmed until the end of 1983.[1444] Clinicians were aware from at least the 1970s that imported factor

[1442] The requirement to inform patients of relevant risks, subject only to the therapeutic exception, was expected from at least the early 1950s: see MOJU0000001_014.
[1443] WITN6914005.
[1444] DHSS circular from Deputy CMO, *'British Plasma-Derived Vaccine against Hepatitis B'*, pp. 5-6, DHSC0002321_035.

concentrate products posed a greater risk of infection than cryoprecipitate. Lord Owen was aware by at least 1971 that imported blood products posed greater risks to health and failed in terms of economic efficiency.[1445] However, it appears that the Department of Health did not identify and act on concerns over the safety of imported blood products until 1978.[1446]

7. This awareness of the risks of imported factor concentrate should have informed the UK's self-sufficiency efforts. Much of the focus of the evidence which the Inquiry has heard has naturally been on the UK's failure to achieve self-sufficiency by the time of the outbreak of HIV/AIDS in the US. We consider that this failure was largely avoidable and it is beyond dispute that the dependence upon imported factor concentrate led directly to the death and / or serious illness of many patients. Scotland provides a template which shows that self-sufficiency could have been achieved, or very largely achieved, before the outbreak of the HIV/AIDS epidemic. However, evidence to the Inquiry illustrates clearly that the recognition of the symbiotic importance of blood and blood product safety, and self-sufficiency pre-dates the emergence of HIV/AIDS. Lord Owen recognised that the UK should become self-sufficient in light of the known and future risks associated with blood products.

8. This included all forms of hepatitis, which should have featured more prominently in the thinking around self-sufficiency and should have been sufficient by itself to elicit a UK-wide commitment to ensuring the safety of blood and blood products. Civil servants and decision-makers within relevant government departments responsible for formulating policy on self-sufficiency were not properly confronted with the risks of hepatitis,[1447] nor the inherent risks of viral transmission posed by blood and blood products. As early as the mid-1970s, a new site was being planned at Liberton to meet demand for albumin, which posed a lower hepatitis risk than freeze-dried plasma. This reflects a recognition that hepatitis was a real and significant risk, but this attitude sadly was not sufficiently prevalent.

[1445] LDOW0000343.
[1446] DHSC0200111_0019, 2006 Department of Health Report *'Self-sufficiency in Blood Products in England and Wales: A chronology from 1973 to 1991'*.
[1447] Transcript 24/03/2022, p142, ll3-10.

Why self-sufficiency was not achieved

9. The evidence heard by the Inquiry demonstrates that efforts to achieve self-sufficiency in the UK were inherently flawed due to:

    a. Persistent organisational and funding failures;

    b. The lack of any agreed definition of self-sufficiency and understanding about the appropriate targets for the production of domestic blood products;

    c. The failure to commit to and coordinate a UK-wide response to achieve self-sufficiency;

    d. The failure to minimise demand by informing patients appropriately about risk and exploring alternative treatment options; and

    e. The actions of pharmaceutical companies and shortcomings of the domestic licensing regime, which left the UK dependent upon unsafe blood products. This is dealt with at the end of this chapter.

10. The outcome of these failures was that the UK's self-sufficiency drive did not succeed in time to reduce the risks of blood products prior to the introduction of other safety measures; principally testing and heat-treatment.

Persistent organisational and funding failures

11. The UK's efforts to achieve self-sufficiency in blood products began with a recognition of the dangers of imported concentrate but also accepted a role for imported concentrate. The Expert Group on the Treatment of Haemophilia met for the first time on 20 March 1973 and made recommendations that:[1448]

    a. The UK should aim to become self-sufficient in factor concentrates as soon as possible;

[1448] PRSE0004706_0004.

b. The UK reduce and as soon as possible end the purchase of imported factor concentrates; but

c. The DHSS should give early consideration to purchasing commercial concentrates from Immuno and Hyland, which had been licensed for this purpose.

12. The recommendations were based on evidence that the lack of factor concentrates led to a "*dangerous selection between more or less urgent cases*".[1449] Cryoprecipitate was seen as a poor substitute for reasons including the volume required, the variable activity of a dose, and the requirement for storage at very low temperatures. It was not considered that freeze-dried concentrates posed a great risk of hepatitis to severely affected patients, although mild sufferers who received very little treatment had a high incidence if large pool fractions were used. Dr Biggs concluded that "*[s]ince the majority of patients are in the multi-transfused category the increased risk of exposure to hepatitis would not seem to be an important disadvantage to the use of concentrates from pooled material*".[1450]

13. These recommendations were broadly accepted by DHSS, which anticipated that commercial concentrates would only be needed for approximately two years until domestic production could meet demand.[1451] That expectation proved to be wildly optimistic, largely due to DHSS's unwillingness to provide adequate funds for it to be realised and their failure to anticipate the substantial growth in demand for factor concentrates. That unwarranted optimism was supported by expert advice; Dr Maycock considered that the Elstree and Liberton plants would have capacity to meet UK demand for concentrate "*provided that the necessary additional funding could be made available*".[1452] This resulted in the long-term use of commercial factor concentrates in England and Wales despite the initial intention to pursue this only as

[1449] PRSE0002553_0003

[1450] Ibid, p. 9. This is a slightly more optimistic view than that taken in *Hepatitis and Clotting Factor Concentrates*, Kasper, C.K. and Kipnis, S.A. Journal of American Medical Association (1972) 221, 510, who concluded that there was a high risk of hepatitis for minimally-treated patients and single donor products were preferable for them, but that concentrates should not be denied to appropriate cases of severe haemophilia. See further the discussions of pool sizes below.

[1451] DHSC0100005_012; DHSC0100005_011; DHSC0100005_010.

[1452] DHSC0100005_022. It was noted in the same document that it was "*most unlikely*" that further Treasury funding would be forthcoming.

a short-term measure. The Scottish Health and Home Department ("**SHHD**"), conversely, was much more proactive, with Dr Macdonald – apparently motivated by the risks of commercial concentrates – taking the view that the transfusion service should be "*self-sufficient in all respects*".[1453] In practice, Scotland achieved self-sufficiency far before other parts of the UK. This was driven by the premise that *any* risk of contaminating the country's blood supply was sufficient to justify action being taken.

14. By January 1974 it was clear, in light of the Medical Research Council's report,[1454] that demand had been substantially underestimated and that up to 720,000 blood donations would be needed to allow for "*on demand*" treatment. There was strong demand for the products amongst both patients and clinicians, which showed no sign of abating. This required substantial investment, which was already long overdue from DHSS. However, DHSS was facing "*severe*" cuts at the time which led to this funding being deprioritised.[1455] As with many other decisions about blood examined by this Inquiry, the issue of funding for transfusion and blood products was never sufficiently high on the political agenda, nor viewed as sufficiently compelling to go to the top of the priority list. The Inquiry may wish to consider that this was a surprising and gross error as (a) it was one of the most common clinical treatments for a wide variety of different conditions and was used on a very large number of patients, (b) it was a treatment where patient safety could have been improved and this was known by both clinicians and officials, and (c) there was at least some political will at some stages to prioritise it.

15. The drive for domestic self-sufficiency was boosted by the World Health Organisation's ("**WHO**") May 1975 resolution[1456] which stated that each country should be able to supply sufficient quantities of its own blood and blood products to meet clinical need. Further international support for this principle was later found in the Council of Europe's recommendation R(80)5[1457] that member states should

[1453] Ibid.
[1454] PRSE0002350
[1455] DHSC0003616_026
[1456] PRSE0003476, Resolution 28.72 "*Utilization and Supply of Human Blood and Blood Products*".
[1457] PRSE0002575.

pursue the goal of self-sufficiency in anti-haemophilia products and plasma for their preparation. Whilst neither international body provides binding directions, the UK government and public health experts who have given evidence have made it clear that they would wish, as far as possible, to follow their guidelines and to be seen in the forefront of nations in respect of public health.[1458] The UK government's stagnancy and failure to embed these guidelines into policy and practice constitutes a significant missed opportunity to protect patients from a known, prevailing and future risk. This is reflected in Dr Biggs's predictions in 1967[1459] and occurred against the backdrop of the UK government extolling the virtues and the importance of actively defending and protecting altruistic, voluntary blood donations in the UK, while simultaneously catering to commerce.

16. At a domestic level, Lord Owen had endorsed the WHO's guidelines and accepted on 22 January 1975 that it was "*vitally important that the NHS should become self-sufficient as soon as practicable in the production of Factor VIII, including AHG concentrate.*"[1460] He recognised that this would ensure that haemophiliacs received the "*best-known treatment*". Lord Owen had recognised since at least 1971 that the private blood market was "*seriously deficient in quality … fails in terms of economic efficiency, [and] involves considerable consumer exploitation*".[1461] This attitude should have informed later decision-making. We invite the Inquiry to find that Lord Owen's clarity of vision[1462] and the guiding principles set out by the Expert Group in 1973 were not pursued energetically by subsequent government ministers and leading clinicians, resulting in an unnecessary overreliance on harmful commercial blood products, which in turn caused or contributed to an increase in the number of people who were infected.

17. In December 1974 £500,000 was earmarked by the Department of Health to improve domestic Factor VIII supply.[1463] This cost was warranted in light of the high actual and

[1458] Expg0000045_0034-35
[1459] **DHSC0100025_062**
[1460] LDOW0000032_0001. See also **LDOW0000045**
[1461] LDOW0000343.
[1462] He described government policy as being "*to make the NHS self-sufficient in the production of Factor VIII as soon as practicable*": DHSC0000281.
[1463] CBLA0000239.

anticipated costs of imported factor concentrates. Lord Owen brought genuine enthusiasm and application to the task of achieving self-sufficiency,[1464] committing the UK in January 1975 to self-sufficiency in two to three years, and he was assured that self-sufficiency targets could be met.[1465] The increase in funding provided during Lord Owen's tenure resulted in the increased targets for domestic fractionation being achieved in 1977. We invite the Inquiry to find that Lord Owen's proactive approach, represented best practice and should have been adopted by his predecessors[1466] and successors. Lord Owen, his officials and clinical advisers may however fairly be criticised for failing to recognise the exponential growth in demand and the structural barriers to increasing domestic production.[1467] That failure was reflected in the fact that England and Wales continued to import substantial quantities of concentrate, with as much concentrate being imported in 1977 as was produced domestically.[1468]

18. The shortcomings of financing were widely recognised, as is reflected in the DHSS's note prepared in September 1986 entitled *"Problems facing the National Blood Transfusion Service – particularly with regard to the provision of blood components."*[1469] This reported that:

> *"The customary method of financing the NBTS is not conducive to the development of such a partnership and it was probably this more than any other single factor which led to the delay in mounting the AHG (Factor VIII) Concentrate production programme."*

19. After Lord Owen's departure, the department's efforts towards self-sufficiency dropped off considerably, as reflected by his successor's Parliamentary answers, which showed far more money being allocated to the purchase of commercial concentrates (£1,180,000) than to increasing domestic supply (£145,000).[1470] This reflected the de-prioritisation of self-sufficiency which took place at this time. That

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[1464] **LDOW0000015; LDOW0000016; LDOW0000017; LDOW0000018; LDOW0000019; LDOW0000020;**

[1465] LDOW0000023.

[1466] Lord Owen recognised in oral evidence that *"you could ideally have made the decision a lot earlier to go for self-sufficiency"*: Transcript 22/09/2020, p173, ll1-2.

[1467] See **DHSC0002181_045**, p. 2ff.

[1468] DHSC0000291.

[1469] DHSC0002181_045.

[1470] DHSC0000291.

de-prioritisation was particularly inappropriate as demand for these products continued to rise rapidly, causing criticism of the Department of Health.[1471] The Department of Health also failed to achieve a consensus about the appropriate target for Factor VIII production,[1472] resulting in its targets being set inappropriately low. Dr Walford described the delay at this time as being "*unconscionable*".[1473]

20. The Inquiry has also heard evidence that supply targets did not shift, but in fact were misinterpreted and that the DHSS did nothing to intervene, clarify and promote decisive action. Dr Snape confirmed these issues in his evidence and expressed the view that despite BPL and PFL achieving a great deal and working tirelessly towards the goal of self-sufficiency, due to influences external, they achieved *"too little too late"*.[1474]

21. We endorse Dr Lane's analysis that, despite the impressive efforts of Lord Owen, his approach consolidated the demand for Factor VIII in the UK and, after his departure, "*there was no sequel to the first financial initiative and therefore no on-going DHSS provision for the inevitable increase in use of Factor VIII which ensued*".[1475] The impact of this was described by Dr Maycock in September 1977, who noted that BPL's "*stretched*" capacity would be reached by the end of the year and there was "*an atmosphere of uncertainty about future development. There are no means at present of matching future fractionation potential with the potential availability of plasma collected by the RTCs and of relating both to therapeutic demand*".[1476] Dr Lane further emphasised that the atmosphere of uncertainty would be improved if DHSS were able to commit to further funding.

22. By the end of the 1970s BPL had a number of major drawbacks which interfered with its ability to support domestic efforts to achieve self-sufficiency and rendered the plant fundamentally incapable of meeting demand for fractionated products.[1477]

[1471] **DHSC0100006_033** DHSC0100006_036; OXUH0000838_003; PRSE0002133.
[1472] PRSE0002268
[1473] Transcript 20/07/2021, pp29-30, 72, 84.
[1474] Transcript 30/03/2022, p174, ll5-7.
[1475] BPLL0001508, p. 7.
[1476] CBLA0000664.
[1477] CBLA0000938; CBLA0000952, p. 4; CBLA0000005_002, p. 81; DHSC0001812. See also Dr Lane's 1979 paper, BPLL0001508.

While Dr Vaughan approved spending £1.3 million on the redevelopment in July 1980,[1478] this was still far short of the sums needed for a full development. There were lengthy and unnecessary delays thereafter.[1479] In the event, funds for a full redevelopment were approved in September 1982 and a figure of £22.6 million allocated in November 1982.[1480] Construction did not begin until the following May, despite its "*fast track*" designation.[1481] Costs increased substantially, as did the anticipated length of the project.[1482] The redeveloped site eventually opened in April 1987, with self-sufficiency anticipated to be "*completely achieved*" by 1989.[1483] This was due to both a failure to act expeditiously enough, and the mismanagement of the redevelopment project.[1484]

23. Safety had emerged as an additional reason to promote self-sufficiency in the UK by at least 1976, alongside the widely known fact that the domestic production of blood products was cheaper in the long-term than commercially purchased products (which might cost less in the short term and were more readily available). Despite these findings and the UK government extolling the virtues and the importance of actively defending and protecting altruistic, voluntary blood donations in the UK, this did not translate into earlier, meaningful financial investment by the DHSS in order to increase the output of safe NHS products; to invest in research and development; and to establish a centralised, cohesive National Blood Service. Initial DHSS investment was minimal, ineffectual and hard fought.

Lack of agreed definition of self-sufficiency; unclear targets

24. There was no commonly agreed definition for self-sufficiency which would have allowed for a concerted nation-wide effort. Forecasts of future demand were far too low, leading to fractionators chasing an ever-rising target. The data on actual levels of

[1478] WITN4461036; DHSC0002397_023.
[1479] CBLA0002339 p. 4, CBLA0000005_002, pp. 115-116.
[1480] DHSC0002309_017; CBLA0001696; DHSC0002319_013.
[1481] DHSC0002309_047.
[1482] DHSC0002309_047; DHSC0002309_114; DHSC0002309_113; WITN0771058; HSOC0003411; WITN0771066.
[1483] DHSC0101068.
[1484] See e.g. WITN0771060 and WITN0771061.

demand was poor and out of date. No long-term principled or evidenced view of demand was ever identified over a sustained period.

25. In the mid-1970s the UK seriously underestimated likely future demand for factor concentrate in its move towards self-sufficiency. Factor VIII was a life-changing treatment for severe haemophiliacs and therefore highly popular amongst both patients and doctors. The failure to appreciate demand, which could and should have been anticipated by officials and clinicians, was exacerbated by the UKHCDO delay in processing data on Factor VIII usage, which was so extreme that by the time data was available it was already 18 months or even two years out of date.[1485] The Inquiry might query whether the CMO or other officials within the Department of Health could have liaised with the UKHCDO to ask for swifter analysis and/or to design a more effective system for data collection. The lack of clear data on current and future demand for factor concentrate meant that any self-sufficiency efforts would fall short of their goal.[1486]

26. On 20 October 1976 the DHSS held a meeting during which the need to identify the likely clinical demand for blood and blood products over the next five to ten years was highlighted.[1487] This meeting recognised that the Department lacked a clear picture of realistic future demand. The Inquiry should conclude that adequate modelling and data should have been obtained at that stage to provide a clear evidential basis for treatment recommendations and clinical guidance. The meeting also recognised that any assessment of the need for Factor VIII would be complicated by the "*readiness*" with which haemophilia centres purchased concentrate from commercial sources. This closeness stemmed from a combination of the friendly relationship between pharmaceutical companies and haemophilia doctors and, what flowed from that, a failure by some of those clinicians to recognise and communicate to patients the risks of imported factor products.

[1485] Peter Foster, Transcript 24/03/2022, pp95-96, ll22 – 5.
[1486] There has been some discussion about the correct definition of 'self-sufficiency' in this context. We suggest that the only workable definition is the UK's ability to meet the actual clinical demand for blood products. While we are critical of the failure to reduce that demand, we consider it to be the relevant metric.
[1487] DHSC0003738_023.

27. The Inquiry repeatedly heard evidence from transfusion directors and others working in blood services that they could have increased the supply of blood, plasma and plasma-derived products such as cryoprecipitate.[1488] Professor Cash in fact offered to produce more cryoprecipitate in 1984 but was declined.[1489] It is clear from this evidence that there was not any absolute obstacle to increasing the supply of domestic plasma. A working group was established to look at trends in the next 5-10 years on the demand for blood products in January 1977. Their second report dated 17 October 1977[1490] emphasised the need for additional major investment to increase further blood collection and the output of concentrates. Although self-sufficiency efforts ramped up in the 1980s, they were occasionally hindered by the lack of domestic plasma. In the late 1970s the supply of plasma dedicated to Factor VIII began to tail off after the initial £500,000 injection from central funds. Dr Lane proposed a system to incentivise regions to produce more high-quality plasma, by returning plasma derived from that region so that the excess could be sold to other regions at NHS prices, well below the commercial cost. This approach was not taken up.

28. The capacity of domestic fractionation facilities was always going to be at the heart of any self-sufficiency campaign. This was initially overestimated, both as a result of incorrect estimates of future demand and due to unduly optimistic assessments of BPL's capacity. In June 1973 it was considered that BPL would likely have sufficient capacity by 1975,[1491] an attitude which appears to have led to the failure to redevelop BPL at this time. We suggest this was a fundamental error on the part of government, its advisors and blood services. By the end of the 1970s, Dr Lane was correctly criticising what he described as "*…the pattern in the past of always aiming for the lowest current usage as a target with the inevitable consequences*".[1492]

29. In January 1984 Dr Gunson provided a report to the Central Blood Laboratories Authority ("**CBLA**") entitled "*Plasma Supply for self-sufficiency*",[1493] which noted that

[1488] E.g. Transcript 25/01/2022, p39, ll9-14; p45-46, ll20 – 8; Transcript 25/03/2022, p14.
[1489] Transcript 25/03/2022, p33, ll13-20.
[1490] CBLA0000672
[1491] PRSE0004359.
[1492] CBLA0000005_002, p. 82.
[1493] CBLA0001800.

the expectation in 1983 that new techniques would allow the RTDs to meet their plasma targets had not been realised. Only three of the RTDs he contacted were confident that they would be supported by their Regional Health Authority ("**RHA**") to increase the plasma supply, largely due to cost. Dr Gunson identified two factors as being of particular significance:

a. Many RHAs were unwilling to consider proposals on more than a year-by-year basis, whereas plans for long-term self-sufficiency required a plan over three to five years;

b. "*The most economical way to achieve self-sufficiency*" had been identified as encompassing the purchase of additional Factor VIII where required.

30. The lack of funding for self-sufficiency led directly to RTCs being unable to provide additional plasma for fractionation: see, for example, Dr Collins' correspondence to DHSS in May 1985, where he explained that he was not able to increase his region's plasma supply because funding was not forthcoming.[1494] This was also Dr Lloyd's experience.[1495] This lack of funding meant that, by the time BPL's capacity had increased substantially, it ran into plasma supply issues.

31. While plasma formed part of the picture in which the UK failed to achieve self-sufficiency, it is clear that sufficient plasma likely could have been sourced domestically to meet demand and the insuperable hurdle was the lack of domestic fractionation facilities.

Lack of a coordinated response

32. As explored in other chapters, the precautionary principle should have been at the heart of the UK's blood policy from its inception. However, this was not seen in its drive for self-sufficiency. Instead, there was a localised, fragmented and piecemeal response without any unifying force behind it. There was no united approach to achieving self-sufficiency, with Scotland embracing the principle much more enthusiastically than England and Wales.

[1494] DHSC0002269_021.

[1495] Transcript 08/02/2022, p143, ll8-19.

33. The management of England and Wales' blood supply on a regional basis through RHAs was an error. It led to a scattergun approach to funding; it prevented coherence and direction and led to tension between regions. The fragmentation of the NBTS into 14 regional centres led to a lack of effective decision-making. The lack of a formal structure led to inefficiencies and inconsistent approaches. Blood was a national issue and should have been treated as such during the 1970s and 1980s. If that was not politically practical, there should, at the very least, have been a circular and/or directions to the RHAs to ensure that sufficient funding was given to the RTC for these purposes given their political priority within central government.

34. Scotland did not face similar issues, due to Protein Fractionation Centre ("**PFC**") sitting within SNBTS. Peter Foster referred to this as a "*huge advantage…there were systems in place to ensure we could get the raw material we needed and have a dialogue*".[1496] While there were examples of good practice in England and Wales, this proximity between the blood service and fractionators was missing. We suggest that a UK-wide body which brought fractionators and haematologists together would have been of great benefit to patient safety and product development.

35. PFC had capacity to fractionate up to a third of the plasma from England and Wales,[1497] but this was not used. Dr Lane advised against this in 1977 on the basis that it would lead to spare capacity at the Elstree plant.[1498] Dr Lane's mistaken view is also evident two years later when, in late 1979, he expressed the view that "*PFC was not in a position to provide any significant help with BPL problems*".[1499] This was not simply Dr Lane's individual view, but reflects a broader failure at governmental level to plan self-sufficiency efforts on a UK-wide basis, stemming from a belief that PFC could not meaningfully add to national fractionation capacity. That view is clearly unjustified and reflected the failure to anticipate future demand for blood products. Furthermore, it was unjustified as the evidence shows that Scotland offered on several occasions to provide assistance and made attempts to integrate PFC and BPL into more of a "*UK-*

[1496] Transcript 24/02/2022, p87, ll3-8.
[1497] Peter Foster, Transcript 24/03/2022, pp144-145, ll21-12.
[1498] WITN6914043.
[1499] CBLA0001005, p. 4.

system". Regrettably these efforts were met with a "*dead end*". It is not clear why, in the late 1970s and early 1980s, steps were not taken by the Secretary of State for Scotland and the Secretary of State for Health to work together on this issue. It is suspected that this is because it was not brought to their attention. Personality conflicts inhibited collaboration north and south of the border,[1500] with John Watt being excluded from meetings of the Fractionation Working Party.[1501] The failure to collaborate effectively and maximise use of PFC for UK-wide fractionation efforts was a missed opportunity which could have substantially increased domestic fractionation efforts. We appreciate that the difficulties in achieving and agreeing shift-working at Liberton created a barrier to this being rolled out initially, but these were not insuperable and would have freed up capacity at BPL.[1502] PFC also benefitted from its continuous flow small volume mixing, which maximised capacity.

36. This disjointed approach also led to a failure to develop virally-inactivated NHS blood products. PFC and BPL should have coordinated to achieve this but failed to do so, no doubt in part due to the lack of any responsible body with oversight of these issues.

Failure to minimise demand

37. As discussed above, in the mid-1970s the UK seriously underestimated likely future demand for factor concentrate in its move towards self-sufficiency. Factor VIII was a life-changing treatment for severe haemophiliacs and therefore highly popular treatment amongst both patients and doctors. Demand for commercial concentrate was also unnecessarily high throughout the 1970s and 1980s, due to a failure to warn patients appropriately about risk or to explore alternative treatments. This became an ethical issue for some clinicians, who considered that withdrawing established treatment in the absence of a viable domestically produced alternative would not be ethical.[1503]

[1500] See e.g. CBLA0001181.
[1501] CBLA0001138.
[1502] Peter Forster, Transcript 24/03/2022, p133, ll1 – 12.
[1503] OXUH0000673.

38. Some clinicians often preferred imported concentrate, which they considered to be easier to use, without proper consideration of the relevant risks of imported and domestic concentrate. While some guidance was initially given in the late 1970s about using cryoprecipitate in mild cases,[1504] the government subsequently complied with the demands of clinicians for imported factor concentrate. Had Dr Lane's view that the UK should start producing small pool freeze-dried cryoprecipitate been taken up more widely and used in appropriate cases,[1505] on the balance of probabilities it is likely that far fewer infections would have resulted. One can understand the view of clinicians that they wanted to provide their patients with the easiest product for them to use – and it is undoubtedly the case that the invention of factor products was a genuine and significant breakthrough in haemophilia care – but this blinded the clinicians to the adverse consequences. The "*precautionary*" principle was absent. The correct approach should have been as described by Dr Tedder: "*I would have recalled, prevented or very strictly controlled the use of imported commercial blood products, especially those from the USA, which were known to have a significant risk over and above the expected […] we would only have used such products if it was the only option to avoid serious harm to a patient*".[1506]

39. Most importantly, had patients been properly informed, or informed at all, about the risks posed by blood products, demand for them would have fallen. Doctors should have been informing patients of risks and alternative treatment options as part of obtaining informed consent. Few of our clients were given any information about the risks posed by blood products or the comparative risks of imported and domestic factor concentrate. Many of them would not have agreed to take this treatment had they been aware of the risks it posed, especially patients with mild/moderate haemophilia and previously untreated patients. Some of our CPs were given blood products unnecessarily, such as in the case of a nosebleed or before minor surgery.[1507]

[1504] Transcript 22/09/2020, p42, ll13-21. It is also worth noting the view of Dr Carmichael of the North-east Thames Haemophilia Working Party in 1979 that haemophilia centres should be making *"best use of available resources"*, including using cryoprecipitate wherever possible and avoiding elective surgery: BART0000683.
[1505] CBLA0000005_002.
[1506] WITN3436003_0132, §440.
[1507] See statements of W1111 §3-4, 22 and W1938 §9.

This should not have been done. Instead, Factor VIII was often viewed as a "*miracle cure*".

40. The Inquiry has heard evidence regarding the tension between some clinicians favouring the immediate implementation of home treatment in order for their patients to achieve "*a normal life*", and others who took the more precautionary approach, believing that their patients should be treated, but otherwise learn to live with their condition. There was widespread public demand for factor concentrates to be made more widely available. The treatment was – wrongly – seen as only bringing benefits to haemophiliacs. This demand has been characterised by SNBTS as "*propaganda… along two main lines – a demand for immediate implementation of home therapy regimes … and a philosophy that the haemophilia patient should lead a perfectly normal life*".[1508] While the desire for those outcomes was understandable, clinicians should have pushed back against this demand by providing accurate information about risks and alternatives. The risks of and demand for these products were exacerbated by increasing pool sizes and the lack of clear labelling as to risk, which are addressed further below.

41. Politicians had an important leadership role here but did not ensure the risks were publicised. Similarly, pharmaceutical companies failed to ensure there were adequate warnings included on their products. As Lord Owen put it, "*if they were of age then they should have been told and the parents should have been told and I'm sure the medical profession failed them a little on this as we as politicians have failed them*".[1509]

42. Had proper risk warnings been given, they would have in all likelihood led to mild or moderate haemophiliacs choosing alternative treatments, including Fresh Frozen Plasma ("**FFP**"), cryoprecipitate, DDVAP, bedrest and desmopressin.[1510] The risk assessment was relevant for all haemophiliacs, but was particularly stark for mild to moderate haemophiliacs: in 1977 – 1984 death rates in this category were 4 in 10,000 but rose to 85 in 10,000 thereafter, with 85% of those deaths attributable to AIDS or

[1508] PRSE0002133.
[1509] Transcript 22/09/2022, p. 167, ll. 9-13.
[1510] Desmopressin began to be used in the UK in the late 1970s but had been in use in Italy since 1975 and its use was not widespread in the UK until 1985-1991.

AIDS-related conditions.[1511] Had demand for factor products fallen, this would have left greater quantities of domestic factor available for severe haemophiliacs. We appreciate that the need for factor concentrates was much more acute and unavoidable amongst severe haemophiliacs but, at a minimum, we consider that all haemophiliacs (especially previously untreated patients) should have been allowed the opportunity to make an informed risk/benefit analysis in determining what treatment they wanted. The demands for widespread use of imported factor products, including home treatment and prophylactic use should properly have been met by an informed public dialogue about their risks and benefits.

Pool sizes

43. Clinicians also failed to minimise demand by warning about the risks posed by pool sizes. The pool sizes used in England and Wales increased substantially over time, from fewer than 200 in the early 1970s,[1512] to over 800 by the late 1970s[1513] and over 5,000 by the early 1980s.[1514] From the late 1980s no donation limit was imposed.[1515] Increasing pool sizes was part of the UK's efforts to increase domestic production of factor concentrates[1516] but inevitably increased the risk of infection. Dr Maycock justified the increasing pool sizes by reference to the fact that they were tested for hepatitis B surface antigen,[1517] but this wholly ignored the risks of non-A non-B hepatitis the existence of which was known to clinicians from at least the late 1970s.

44. Whilst there is evidence that many clinicians considered that non-A non-B hepatitis was "*not serious*", this was on the basis of limited and uninformed views. In particular, the risks of chronic liver damage and severe illness were not adequately appreciated.[1518]

[1511] Expert report on bleeding and blood disorders, January 2020, p. 70.
[1512] HCDO0000581.
[1513] BPLL0003721.
[1514] CBLA0009269.
[1515] BPLL0002039.
[1516] See e.g. CBLA0000149; BPLL0003721.
[1517] BPLL0003721.
[1518] See e.g. WITN4461001_0154, §63.5.

45. When, belatedly, the risks of non-A non-B hepatitis were appreciated, the continuing use of large pools was justified on the basis that any pool over the size of 100-200kg would pose the same risk of infection, assuming a 1% non-A non-B virus carrier rate.[1519] We accept, as Dr Foster did, that an increase in pool sizes was inevitably necessary to achieve self-sufficiency and that this carried with it an effectively unavoidable risk of non-A non-B hepatitis. However, the Department of Health and clinicians can be criticised for failing to recognise the seriousness of this disease and providing appropriate advice, including about alternatives to concentrate. The authorities should also have considered whether it was feasible to create small-pool products for particularly vulnerable patients or those who did not require regular treatment.

Labelling and warnings

46. In our impact chapter we have addressed the fact that clinicians woefully failed to advise their patients about the risks of blood and blood products. The labelling and written warnings included with products therefore became particularly important, especially as many patients would be using these products at home without clinical supervision and therefore dependent on labelling and packaging for information about the risks they posed.

47. By 1980 products were being labelled with a warning that they "*cannot be assumed to be free of hepatitis virus*".[1520] A warning about hepatitis in clearer, more forceful language should have been included at a much earlier stage given the longstanding awareness of the presence of hepatitis in blood products. By 1985 domestic factor products carried a warning that they "*had been subjected to heat treatment in the vial to reduce the risk of infection by viral agents including hepatitis and AIDS viruses but cannot be assumed to be free from risk of infection*".[1521] There was no specific reference to non-A non-B hepatitis until late 1985,[1522] and even at that stage the risks were not clearly stated. The overarching impression given by the warning labels was

[1519] CBLA0000005_002, §511.
[1520] CBLA0009269.
[1521] BPLL0002039.
[1522] Transcript 25/03/2022, p31, ll4-10.

of a very slight risk of transmission of hepatitis, without any articulation of the risks of non-A non-B hepatitis. The label should have expressly stated that these products were likely to transmit hepatitis,[1523] which was known to be fatal in at least some cases. Similarly, there was no meaningful articulation of the level of risk of HIV/AIDS which these products posed well into the mid-1980s,[1524] nor does it appear that there were any discussions as HIV/AIDS emerged about warning users of this novel risk.[1525]

48. The labelling, in particular package inserts, were principally designed for doctors and pharmacists[1526] rather than aimed at ensuring patients could make an informed decision about the risks they posed. The labelling and licensing process assumed that doctors would discuss risk and support patients in weighing comparative risks and benefits of treatment, but this was not carried through to practice and patients were left without adequate guidance. Labels did not give clear advice to laypeople and were often liable to fall off or be ignored by users.

49. The Inquiry is aware that labelling of medicines has become more "*lay person*" friendly since the mid-1980s, but it should be stressed in any report and recommendations that where treatments will be used by patients themselves, licences should not be provided without adequate warnings which a lay person can understand. In comparison to the early 1980s, the pressures on the NHS mean that staff may well not have time to have a nuanced discussion about risk/benefit on a face-to-face basis. The packing insert or label warning is therefore essential.

50. This problem was exacerbated in warnings given by pharmaceutical companies, as discussed further below.

[1523] Transcript, 1/04/2021, pp37-39, ll9 - 16.
[1524] BPLL0002039 Transcript 30/03/2022, p64, ll4 – 16.
[1525] Ibid, p42, ll6 – 9.
[1526] Dr Perry, Transcript 31/01/2022, p177, ll6-7. He also explained in his evidence to the Penrose Enquiry that the warnings were targeted to "*expert and experienced prescribers of the product*": PRSE0002620, p. 2.

When was self-sufficiency achieved?

51. Scotland achieved self-sufficiency before England and Wales. Northern Ireland did not have its own fractionation capacity and so could never achieve self-sufficiency.

52. SNBTS showed clear leadership on this issue, with fractionation increasing steadily over time, in particular from 1979 when Professor Cash came into post. In early 1981 he identified that: "*[t]he aim of the SNBTS is to eliminate the necessity for the purchase of factor VIII concentrates from commercial concerns*".[1527] He identified ambitious fractionation targets, which were substantially higher than those being set in England at the time. That early vision and commitment was not matched by his colleagues in England and Wales, who were in any event hampered by the facilities at Elstree. By 1985 Scotland was not using commercial concentrates[1528] and it had consistently been using much lower rates compared to than NHS factor VIII since the mid-1970s.[1529] Scotland had spare fractionation capacity by 1981[1530] and was almost exclusively using domestic factor products by 1983/1984, by which time the use of commercial concentrate was at such minimal levels that it appears to reflect clinical preference rather than an inability to meet domestic demand. As Terry Snape identified, the fact that England and Wales did not get close to self-sufficiency in the late 1970s and early 1980s meant that it was inevitable that clinicians who wanted to use factor concentrates would become reliant upon them and would be reluctant to abandon a treatment with which they were familiar.[1531]

53. Self-sufficiency in England and Wales was delayed principally by the slow and piecemeal redevelopment of BPL, discussed above. By the late 1980s, when BPL's capacity had meaningfully improved, there were still issues around the shortage of plasma. It could fairly be said that England and Wales never achieved meaningful self-sufficiency as these parts of the UK continued to use commercial concentrates

[1527] CBLA0001252. This approach is also reflected by others working in Scotland at the time: see e.g. PRSE0006011.
[1528] It did re-start using commercial concentrates from 1988, at which time heat treatment rendered them adequately safe for use.
[1529] INQY0000344_0002.
[1530] SBTS0000053_055.
[1531] Transcript 29/03/2022, p128-129, ll5 – 13.

throughout the 1970s and 1980s. That outcome was the direct result of the failures outlined above. By the time the UK became largely self-sufficient in blood products, the need for them on the basis of patient safety had been substantially reduced by the introduction of heat treatment.

How could self-sufficiency have been achieved?

54. In principle, the shift to factor concentrates for all haemophiliacs was a positive and beneficial move that, for severe haemophiliacs, was both life-changing and life-extending. Those benefits inevitably resulted in a high demand for concentrate, including in cases where concentrates were prescribed and used in the absence of a clear clinical need; it was promoted as a 'wonder product' to the detriment of sound judgment. The UK was unable to meet that demand, leading to heavy reliance on commercial imports. The demand was also undoubtedly encouraged by the lack of appropriate warnings from pharmaceutical companies, clinicians, and the government about the higher risks of these imports. While imported concentrate was likely essential to provide life-saving treatment to some patients, for many haemophiliacs, especially mild to moderate sufferers and previously untreated patients, the blanket approach to treatment was a calculated risk of which they were not informed. This both stimulated demand and deprived patients of their right to give informed consent to treatment.

55. This issue could have been substantially avoided had the UK government been willing to allocate substantial funds and efforts to redeveloping BPL and increasing domestic blood supply. The UK was willing and able to bear the very substantial cost of importing blood products and knew that domestic products would be safer and cheaper in the long term. Evidence heard by the Inquiry in reliance on the constraints on public funds during the relevant period is logically indefensible as the UK was willing and able to bear the substantial cost of importing blood products. This was a political choice, not a financial necessity. The Department of Health and Treasury did not adequately engage with the fact that it would be more cost-effective in the longer

term to redevelop BPL urgently.[1532] In addition, costs could have been saved by reducing demand and using PFC's spare capacity. Most importantly, the lives lost as a result of the use of unsafe imported products simply cannot be justified on a cost/benefit analysis.

56. There were also other alternatives open to the government and blood services which were not taken. PFC had spare capacity which was not used to fractionate English and Welsh plasma, in part on the unrealistic basis that this might cost jobs at Elstree. Professor Cash rightly urged the government to adopt a broad nation-wide strategy for UK plasma fractionation, describing the current situation as "*fragmented, uncoordinated and unproductive*".[1533] It is our submission that, had the UK government approached the issue of fractionation through a national gaze at the outset or indeed at any point during the Relevant Period, this would have ensured that PFC and the facilities in England were able to meet the requirements for patients in the UK. In addition, we consider that a more joined up approach in general would have assisted across the issues such as treatment options, patient knowledge and consent, research and development, pool sizing, batch dedication, testing, and viral inactivation programmes. In the context of a cementing knowledge of risk, a concerted and coordinated approach to the elimination and mitigation of patient risk was what was required.

57. Today, the UK is largely self-sufficient in blood products. Recent reports from NBTS show that approximately 10% of plasma in the UK is imported.[1534] While testing has substantially improved, the UK cannot claim to have achieved self-sufficiency. Imported blood products today come largely from the EU and are currently subject to retained EU law[1535] incorporating the EU's regulatory and safety standard for blood products. As the government has proposed removing all retained EU law in the near

[1532] CBLA0001004_004 and Diana Walford, Transcript 19/07/2021, p178, ll6-13.
[1533] SBTS0000611_034.
[1534] https://www.bbc.co.uk/news/health-45641186; https://www.pharmaceutical-technology.com/analysis/blood-plasma-production-ok-for-the-uk/
[1535] As set out here: https://www.gov.uk/guidance/quality-and-safety-of-human-blood-and-blood-products.

future, we invite the Inquiry to recommend that those regulatory standards be maintained and that the UK continue to mirror any future EU safety standards.

58. We also invite the Inquiry to recommend that the UK should finally achieve complete self-sufficiency in blood products, given the difficulties of ensuring quality and tracing of products created non-domestically.

Pharmaceutical companies, Licensing and Regulatory Oversight

59. Academics have recently characterised the pharmaceutical industry's attitudes as being that "*patients may die…, but the business model must come first*".[1536] Written several decades after the events described in this chapter, those words accurately capture the attitude which pervaded many of the companies selling blood products to the UK at this time.

60. The key failures by pharmaceutical companies were:

    a. Obtaining blood from paid donors in notoriously high-risk environments such as prisons;[1537]

    b. Failing to provide proper labelling and warnings with their products (as discussed above);

    c. Promoting widespread use of these products, including in cases where there were adequate alternatives; and

    d. Failing to ensure their representatives communicated the risks posed by their products.

61. Each of these decisions was motivated by the commercial drive to maximise profit and shareholder value, rather than acting in the public interest. In this section we also

[1536] *'That high design of purest gold: A crucial History of the Pharmaceutical Industry 1880-2020*, Graham Dufield (2020), World Scientific, p. 2.
[1537] WITN0838001; WITN0838014; CGRA0000291.

consider the failures by domestic bodies to prevent abuse by the pharmaceutical industry via rigorous licensing and regulatory oversight.

Decisions and actions of pharmaceutical companies; what should have been done differently

62. The blood products supplied by pharmaceutical companies posed a near-universal risk of non-A non-B hepatitis[1538] and pharmaceutical companies had reason to be aware from the early days of the pandemic that their products posed a risk of HIV/AIDS.[1539] It was widely known that blood was being sourced from dangerous locations such as prisons or from individuals who were homeless,[1540] which had been identified as unsafe from the 1970s.[1541] The industry had also explicitly targeted the gay community for blood donor recruitment. Whilst it could not be known that this community had HIV/AIDS in the late 1970s, pharmaceutical companies would have been aware that the rates of HBV transmission in these groups were high and therefore should have exercised greater caution.[1542] Despite this, pharmaceutical companies continued to sell commercial factor products to the UK in large numbers throughout the 1970s and 1980s before the advent of heat treatment.

63. Pharmaceutical companies were aware that their products posed a risk of blood-borne infection and did on occasion recommend that patients with mild bleeding disorders should use single donor products whenever possible.[1543] However, this was not industry standard and was not rectified by licensing requirements or clinical advice to patients. Indeed, pharmaceutical companies' submissions to licensing authorities lacked candour, in particular about donor screening processes.[1544] In many cases, pharmaceutical companies failed to ensure their products were appropriately labelled to identify the risks they posed.[1545] These companies also made "*unjustified claims*

[1538] Transcript 19/07/2021, p108, ll12-16; WITN0282008.
[1539] JREE0000019 p. 279.
[1540] WITN0838001
[1541] See CGRA0000495.
[1542] UCSF0000058.
[1543] WITN4514001, §3.
[1544] MHRA0033322_060_0013.
[1545] Transcript 04/11/2021, p170, ll1-5.

concerning the safety of heat-treated Factor VIII".[1546] They included reassuring language on warning labels, which implied that there was nothing to worry about.[1547] This reflects a greater interest in maximising sales and usage rather than ensuring appropriate risk/benefit assessment and risk minimisation.

64. This attitude can also be seen in the way in which pharmaceutical companies marketed their products, including to the UK licensing authorities. Speywood claimed that their Hyate:C posed only a "*small degree of risk*" which was "*amply justified*" by its benefits,[1548] whereas the clinical supporting evidence referred to the existence of a "*relatively high risk of adverse effects [which] is acceptable only because of the inherently serious nature of the disorder and the lack of reliably effective alternatives*".[1549] Alpha made the unsustainable claim that it had "*never used plasma from homosexuals, intravenous drug abusers or recent Haitian emigrees*".[1550] In May 1983 Armour made the false claim to haemophilia centre directors that there was "*little evidence to associate plasma component therapy with the transmission of AIDS*",[1551] despite the Food and Drug Administration ("**FDA**") having recommended in March 1983 that products should not be made from high-risk donors due to the risks of AIDS. Consistently, the evidence the Inquiry has seen demonstrates that pharmaceutical companies were willing to understate the risk of their products and present them without objectivity or candour.

65. Demand for imported commercial product was stimulated by the reckless actions of pharmaceutical companies, which ran successful marketing campaigns to haemophilia doctors that purposefully underplayed the greater risks their products posed.[1552] They also offered clinicians who used their products excessive inducements by the way of "*lavish entertainment*",[1553] in what Dr Parapia described "*extravagant hospitality*"

[1546] ARCH0001710_003.
[1547] MHRA0033320_006; SHPL0000197_078; SHPL0000071_181
[1548] **IPSN0000007_001, p20**
[1549] IPSN0000005_019
[1550] CGRA0000262. The Chair of the Inquiry very fairly noted that *"there were a number of potentially high risk groups the blood banks weren't prepared to ask and find out"*, Transcript 06/10/2021, p36, ll16-17.
[1551] BART0000863.
[1552] Transcript 04/11/2021, p119 ll1-14; p177-178, ll1 – 6.
[1553] Transcript 22/10/2020, p133, ll21-2; pp 134-135, ll1 – 7.

being provided to Centres using large amounts of their products (among other inducements) part of "*normal practice*", explaining that pharmaceutical companies had bigger marketing budgets than the entire budget for BPL.[1554] Dr Parapia also explained that pharmaceutical companies "*largely educated clinicians about haemophilia treatments*" as a result of their large marketing budgets.[1555] These financial incentives were regularly offered and accepted despite professional guidance at the time which said that such inducements should not be accepted. That marketing targeted senior clinicians who were advising government.[1556]

66. The industry's response to the outbreak of AIDS can rightly be criticised as dilatory and reckless. It was only in December 1982 that pharmaceutical companies, apart from Cutter, agreed to exclude plasma collected from prisons and took some steps to improve donor self-exclusion. This was a serious failure by pharmaceutical companies and reflected the more serious failure of the FDA to regulate, instead leaving it to individual companies to decide whether they wanted to continue to source blood from high-risk locations.[1557] Even after they agreed to stop using prison-sourced blood, they were willing to export such products overseas.[1558] The companies were also unacceptably slow in obtaining approval for and selling heat-treated concentrate, during which time they continued to sell untreated products. There was every opportunity for pharmaceutical companies to make their products safer, which they failed to take, as to do so would reduce their profits.

67. We suggest that the obvious explanation for the pharmaceutical industry's downplaying of risk and harm associated with their products was due to a desire to maximise profits. The culture of these firms, as presented across the evidence the Inquiry has seen and heard, is one of dismissing and minimising the risks their products posed. This attitude is reflected in the speech given by the president of Alpha in February 1980, who characterised concerns about paid donors and the risks they

[1554] WITN0785003_0004; Transcript 29/10/2022, pp162-167, ll15-13.
[1555] WITN0785003_0004, §4
[1556] Transcript 29/10/2022, pp16.5, ll9-14.
[1557] Ibid, §131.
[1558] Ibid, §133.

might pose as a "*phony moral issue*".[1559] We invite the Inquiry to find that pharmaceutical companies, either recklessly or knowingly, concealed evidence of the risks of their products. This was reflected in Mr Bishop's evidence which confirmed that Armour was aware of strong evidence of risks of hepatitis and HIV/AIDS in its products which it failed to disclose.[1560]

68. Even when the UK was unwilling to purchase US blood products, pharmaceutical companies continued to sell non-heat-treated products to markets in Asia and Latin America, causing further HIV and AIDS infections. Their conduct has been described as involving "*violations of basic principles of medical and business ethics*".[1561]

69. Christopher Bishop, Armour's sales and marketing manager, who oversaw the largest importation of factor products by a single pharmaceutical company, rejected any wrongdoing even with the benefit of hindsight, arguing that "*we did everything we could with the information that we had … I'm very proud of the fact that we did do everything the right way*".[1562] He confirmed that no specific lessons had been learned.[1563] This encapsulates the ongoing failure of the industry to recognise fault or learn lessons. We would invite the Inquiry to send copies of its report to the commercial successors of the contemporary pharmaceutical companies and invite them to offer apologies to the IAP communities.

70. This approach to patient safety has been seen in other cases involving the pharmaceutical industry over the past twenty years (for example the use of opiate pain killers and the lack of candid information given to regulators about their long-term addictive qualities). The regulatory oversight of the pharmaceutical industry in this country, and around the world, and the licensing of products must not assume that the pharmaceutical industry has "*laid all its cards on the table*". There needs to be a system (whether that is developed on a national or a supranational basis) equipped with the skills, resources and capacity to undertake a rigorous independent

[1559] IPSN0000328_008, p. 3.
[1560] Transcript 04/11/2021, pp29, ll16-25; p30, ll1-24, p82, l10, p83 ll1 – 25.
[1561] *McHenry L, Khoshnood M. Blood money: Bayer's inventory of HIV-contaminated blood products and third world haemophiliacs*. Account Res. 2014;21(6):389-400. doi: 10.1080/08989621.2014.882780. PMID: 24785997.
[1562] Transcript 4/11/2021, p170, ll1-5.
[1563] Ibid, p170, ll6-11.

assessment of products requiring licences. Too often in the story of infected blood, there was limited oversight or ability of national or supranational licensing bodies to match the "*behemoth*" of research and development of the pharmaceutical companies. Even if they cannot replicate the data created by these companies, it needs to be carefully interrogated, analysed and probed. The need for candour must apply to these bodies as much as to government, clinicians and others.

Domestic response: decision-making of the Committee on Safety of Medicine and its Biological Sub-Committee

71. The licensing authorities existed to avoid the type of problems caused by imported factor concentrate. There were substantial flaws in their work, including the '*nodding through*' of the Committee on Safety of Medicine's Biological subcommittee's ("**CSM(B)**") recommendations by the Committee on Safety of Medicines ("**CSM**");[1564] the licensing process was slow and inefficient;[1565] and difficulties recruiting properly qualified staff for these specialised roles.[1566] This lack of oversight and rigour in the licensing process led to high-risk decisions being made without adequate scrutiny. The 'rubber-stamping'[1567] of CSM(B) advice by the CSM was particularly problematic. For instance, the CSM(B)'s conclusion made serious errors in July 1983 when authorising the continued use of imported factor concentrate, which were not overturned by the CSM or Licensing Authority. The CSM(B) concluded that:[1568]

a. AIDS posed only a "*small*" risk in concentrates;

b. The "*life-saving*" benefit of the product for haemophiliacs justified the risks of AIDS (without consideration of mild/moderate haemophiliacs); and

c. The UK should use plasma collected after the FDA implemented new regulations on 23 March 1983, without recognition that those regulations would do little to ensure the exclusion of high-risk donors.

[1564] Transcript 23/09/2021, p38, ll2-4.
[1565] Ibid, p42, ll8-11.
[1566] WITN0771006_0005, §5.
[1567] Transcript 07/06/2022, p38, ll7-19.
[1568] ARCH0001710.

72. We invite the Inquiry to find that this was a serious, avoidable error which reflected a government-wide failure to act on the known risks of imported factor concentrate. Sir Joseph Smith has sought to justify the committee's conclusions by reference to the level of likely mortality amongst haemophiliacs, without addressing the alternatives open to the UK at the time.[1569] As discussed above, the CSM(B) was placed in this position by the UK's wider failure to achieve self-sufficiency.

73. The licensing authorities' risk/benefit analysis regarding the withdrawal of US concentrates was not a one-off; the CSM also justified the risk of hepatitis on the basis that haemophiliacs, without treatment with those concentrates, would otherwise die.[1570] This was demonstrably untrue for a large number of haemophiliacs but was not challenged at the time.

74. Blood products were also imported on a named-patient basis under the Medicines Act 1968 and Medicines (Exemptions from Licenses) (Importation) Order 1978, which circumvented the licensing requirements. There was very minimal oversight of these products and it is striking that the 1978 Order was revoked merely six years later. We invite the Inquiry to find that such exemptions to the general licensing regime should only have been used in exceptional circumstances and assessment of the imported products should have been undertaken in any event. Unlicensed products were also imported for use in clinical trials. That apparently narrow exception to the licensing regime allowed very large quantities of unlicensed products to be used in the UK, with 1.928 million units of unlicensed FEIBA being used in 1978.[1571]

75. The shortcomings of the UK licensing regime were exploited by pharmaceutical agencies. As noted by the Inquiry, companies such as Immuno considered that the UK was willing to buy a less safe product if it was cheaper than alternatives.[1572] This attitude is also seen in the government's dealings with Bayer, who understood the price of their products to be *"important…and will probably affect the success of our*

[1569] WITN5281001, §3.44.
[1570] SHPL0000665_142
[1571] OXUH0000212_002.
[1572] Transcript, 23/09/2021, p83, ll4-8, considering SHPL0001094. See also MHRA0033321_085 for another reference to the UK market's preference for cheaper product.

application".[1573] Companies and the UK authorities were willing to place cheaper products on the market even if they posed greater risks to health[1574] and it can readily be inferred that they were not the only company to do so, given the UK's stance on risk. This stance was not warranted by the 1968 Act, which does not include cost as a primary criterion. In 1987 Hyland/Travenol explained that "*[b]y demanding the lowest possible price for coagulation factors, you contribute to the need for plasmapheresis establishment owners and operators to operate in less desirable areas, prisons and locations where plasma is available at lost costs*".[1575] The UK should have known that there was no acceptable risk/cost trade off here, in light of the well-established risks posed by blood products. For their part, the pharmaceutical companies acted unacceptably by marketing their products as much safer than they were.

76. In short, the pharmaceutical industry was a powerful and wealthy body with strong vested interests in exporting dangerous blood products to the UK. The licensing authorities in this country were ill-equipped to combat unjustified claims about the safety of products. Much more robust licensing decisions were possible, but were not made due to lax attitudes to product safety and due to the failure to achieve self-sufficiency in blood products.

Recommendation 1: Self-Sufficiency, Fractionation and Pharmaceutical Companies

a. That the corporate successors to the pharmaceutical companies who supplied blood products to the UK in the 1960s-1990s offer an apology to the IAP communities and recognise the role of their predecessors in contributing to the infected blood tragedy;

b. The government should consider whether it is appropriate to seek compensation from the corporate successors of relevant pharmaceutical companies;

c. The UK should allocate proper resources to its licensing system, ensuring that it has the precautionary principle at its heart;

[1573] **BAYP0000022_097**
[1574] Ibid, p101, ll4-12.
[1575] **CGRA0000290**

d. The UK should mirror or exceed all relevant EU regulations for safety in blood products, including future regulations; and

e. Pharmaceutical companies should be subject to a duty of candour in licensing applications.

CHAPTER 7: "FORCED TO BEG FOR SCRAPS OFF THE TABLE": TRUSTS AND SCHEMES

"Proper compensation is all I can hope for now so that I know my wife will be looked after when I die. However even this will not take away the anger at the damage that this has done to our lives."[1576]

Introduction

1. Our CPs, like all IAP, have experienced serious failures and unacceptable and unfair delays in recognising their entitlement to adequate financial compensation and support. When, often after decades of ill health and financial struggle, support was provided, the sums on offer were too often made almost impossible to access and were no more than tokens rather than substantial sums to alleviate pain, suffering and economic loss. Some IAPs have still not received any financial support from the government.

2. These submissions focus principally on the failures in the trusts and schemes[1577] set up to assist individuals infected with HCV (including those co-infected with HIV), as this is the most prevalent issue across our client group. We also address the need to consider the situation of those infected with HBV, who have historically been excluded from financial support.

3. These submissions concentrate on financial support, as this is largely what has been supplied under the trusts and schemes to date. This is not intended to imply that financial compensation, without wider social and non-financial support, is adequate. Any adequate scheme for financial compensation must be read alongside our recommendations for non-financial support.

[1576] W1997, §97.
[1577] Namely, the Macfarlane Trust, the Eileen Trust, the Skipton Fund, the Caxton Foundation, and the Infected Blood Support Schemes.

Summary

4. The UK government, in particular the Department of Health civil servants and Ministers working in blood policy, have repeatedly and over successive administrations failed to acknowledge that financial compensation for IAP should be a matter of entitlement. The decisions made over decades to provide sums on a discretionary, charitable basis, were misguided and left people both in severe financial hardship but also feeling as if they had to "*beg*" for help. The approach of the trusts and schemes has, at times, been redolent of the "*deserving*" and "*undeserving*" distinctions drawn by Mayhew and aspects of the Poor Law. They were Victorian in design and implementation. Furthermore, there was a failure to engage with those who had suffered in the setting up and ongoing management of the trusts and schemes. Whilst some of the members of the various boards of trustees had first-hand experience of HIV or HCV, many did not. In fact, some of the trustees were appointed by the Department of Health.

5. The trusts and schemes, when created, provided too little, too late. Their very design and the motivations behind them were not what the IAP needed or deserved. Specific categories of IAP continue to be wrongly excluded.

6. The schemes were a curious hybrid between discretionary gift and replacement minimum income benefit. Their funding and administrative oversight accordingly failed to have either the rigour of the benefits system or the independence of a charitable trust.

7. These failures were such that the Inquiry should accept Sir Robert Francis' suggestion that all previous payments received from the trusts and schemes should be disregarded. They also justify a high level of payment. There are lessons to be learned for the operation of any future government compensation scheme for IAP.

Governmental attitudes

8. The approach by successive governments to financial support for those affected by the infected blood scandal is characterised by three principal flaws:

    a. The decisions made by the Department of Health and its ministers were based on inaccurate, incomplete, and often misleading information which continued to be considered as "*accurate*" despite many IAP indicating that it was incorrect;

    b. They were focussed solely upon the fear of "*floodgates*", and on the idea that this was the beginning of "*no fault compensation*". The significant fear of the civil service and ministers (alongside clinicians who advised them), led them to devise a scheme of parsimonious charity. Whilst some ministers who gave evidence spoke of their compassion for those who were unwell and their relatives, this did not translate into an effective system when they were in office;

    c. There was a refusal to accept and acknowledge that which is now seen as accurate – that it was a treatment disaster of the most significant magnitude; the response to it should be seen in that context.

9. These flaws had a particularly severe impact on those infected with HCV, who received no financial support until the establishment of the Skipton Fund in 2004.

Decision making by the government.

10. The UK and devolved governments consistently underestimated their own responsibility for the scandal as well as the seriousness of the illnesses, particularly HCV and HBV before the late 1990s, caused by infected blood.

11. The departmental line regarding how people came to be infected and the action taken in response was largely unchanged over successive governments[1578] all of which unquestioningly treated received wisdom as true. As late as 2009, the government was still relying on the same outmoded and inaccurate lines to take:[1579]

[1578] See e.g. DHSC0041305_038 for the 2001 lines to take.
[1579] As set out in MHRA0024725_0002.

a. *"the treatment given to haemophiliacs was the best available at the time and action was taken in good faith;*

b. *Such treatments markedly increase the life expectancy (formerly 25 years) and quality of life of haemophilia patients;*

c. *As soon as technologies (heat treatment and testing) were available to improve safety, they were introduced;*

d. *Evidence in relation to hepatitis C emerged over time, and the very severe long term consequences of infection were only fully recognised by the scientific community during the late 1980s;*

e. *legal proceedings in relation to HIV were settled … without the Government being found liable;*

f. *special payments were set up for people infected with HIV, who waived their right to take further action against the Government;*

g. *Although litigants won damages against the blood service in 2001 […] this was under the Consumer Protection Act 1988* [sic]*…It did not imply negligence;*

h. *The present Government resisted calls for further funding until Scotland decided to make hepatitis C payments in 2003, when England followed suit.*"

12. This information, which was provided to ministers over two decades, was fundamentally flawed. Had the full and accurate information been given, there is at least the possibility that a different approach may have been taken to the provision of financial support. The very rationale for the schemes was therefore based upon a series of false assumptions and misinformation, therefore it is no surprise that they were ineffective in design and delivery.

Best treatment available

13. The failures in blood policy and practice are set out in greater detail in the Role of Blood Services, The Role of Medical Practitioners and Haemophilia Centres and Clinicians chapters. In light of these failings, it simply cannot be said that recipients of

infected blood and blood products received "*the best available treatment at the time*", which was the mantra on which successive governments relied in refusing to pay or extend financial support to IAP. Blood was often used unnecessarily and excessively, which materially increased the risk of infection. In addition, factor concentrates were often given to those with bleeding disorders when alternatives were available. We accept that there are some individuals who were infected through receiving essential treatment at a time when no effective test had been developed. However, they were nevertheless entitled to receive full information about, and to be treated in a way which reflected, the known and likely risks of blood and blood products.[1580] The experiences of our CPs consistently show a failure by clinicians to inform patients of the risks associated with transfusion and the use of blood products.

Increase in life expectancy

14. While Factor VIII was life-changing for severe haemophiliacs, the bald assertion relied upon here does not reflect the experiences of mild and moderate haemophiliacs, for whom other treatments carrying far less risk could have been appropriate. The situation of mild/moderate haemophiliacs was never adequately raised by civil servants in briefings, leaving ministers unaware that there were alternatives for a significant number of patients. Dr Gunson informed the Deputy CMO Dr Walford that it was not feasible or practical to produce sufficient cryoprecipitate[1581]. However, in her evidence Dr Walford acknowledged that she was not aware of whether this possibility was explored with each of the Regional Transfusion Centres[1582]. Indeed, a number of Regional Transfusion Directors confirmed that more cryoprecipitate could have been produced, but no such request was ever made. It was incorrect for the government to tacitly assert that the benefits of the treatment in question justified the harms in all cases.

[1580] We appreciate that attitudes to disclosure of risk changed substantially over the course of the late 20th and early 21st century and that such conversations face the challenges discussed in the Public Health and Administration Expert report at EXPG0000047_0049- EXPG0000047_0051. We nevertheless consider that disclosure of a known substantial risk of these serious diseases should have taken place and the failure to do so justifies compensation.

[1581] Transcript 21/07/2021

[1582] Transcript 21/07/2021

Technologies introduced as soon as available

15. This assertion is flatly contradicted by the judgment of Burton J in *AA v National Blood Authority* [2001] EWHC QB 446, which concluded that screening for HCV could have been brought in earlier than 1991. The government's failure to acknowledge that finding nearly a decade after it was made suggests a lack of curiosity about the shibboleths on which it was relying.

Seriousness of HCV

16. As discussed in the Role of Medical Practitioners chapter, non-A non-B hepatitis was known to be a serious disease from at least the early 1970s. It was simply not correct to proceed on the basis that non-A non-B hepatitis or HCV were not known to be severe and even life-threatening diseases before the late 1980s.

HBV

17. The government decision-making also wholly overlooked HBV, which was a known risk of blood from the late 1960s. HBV testing was known to be highly unreliable well into the 1990s,[1583] which inevitably meant that many of those treated with whole blood and blood products would become infected. Nevertheless, there was apparently no consideration of including HBV within any of the financial support schemes.

No fault

18. The final four assertions all broadly rely on the lack of legal liability. Even where there was liability under the Consumer Protection Act 1987, this was dismissed on the basis that there was no finding of negligence. That view, which was shared by Alan Milburn in his evidence,[1584] suggests a very narrow interpretation of fault whereby the only compensable fault is clinical negligence. These arguments reflect a myopic focus on legal responsibility rather than fault, systems failures, or wrongdoing as it may be seen by the public. The absence of consideration of whether or not the system failed as a whole to provide adequate protection, and to examine whether and if, in cases of such

[1583] DHSC0004709_153.
[1584] Transcript 14/07/2022, p75, ll15 – 25.

failures, those who had diseases transmitted to them should receive recompense for such was never seriously considered or examined by either the CMO, the senior civil servants or ministers. There was a vacuum of ethical debate or discussion around what happens when a system fails. That should have been the question asked. It has largely been suggested that it was not asked simply because no-one could contemplate the idea that there could be such failure or the cost of such a failure in financial terms. That was both an inadequate ethical response and an inadequate political response. The job of a politician should be to acknowledge failures in the design of a system – and to seek to remedy them. As our elected representatives, they have a valuable role to play in examining the system from the perspective of their constituents

Irish scheme

19. The government also consistently refused to emulate the schemes for HCV compensation set up in the Irish Republic on the grounds that "*[t]he Irish Government set up their [HCV] compensation scheme following evidence of negligence by the Irish Blood Services. Compensation is therefore being given in very specific circumstances which do not apply in the UK. It does not create any precedent for us.*"[1585] That argument, which had been consistently criticised by campaigners for many years, was definitively rejected by the Administrative Court in *R (March) v Secretary of State for Health* [2010] EWHC 765 (Admin). The Government's argument regarding the comparability of the Irish Scheme was found by Holman J to be a reason which "*does contain an error and does not withstand scrutiny*" (§52). This "*error*" was available to the government long before Holman J's judgment. In February 1996 civil servants prepared a submission on financial compensation for those with HCV which noted that claimants in Ireland were "*not required to provide evidence of negligence on the part of the blood service*" in order to obtain compensation.[1586]

20. We therefore invite the Inquiry to find that the basis upon which the government made decisions was fundamentally flawed. The received wisdom in early 1991, after

[1585] DHSC0041305_038_0002.
[1586] WITN5426065_0007.

the establishment of the MacFarlane Trust but before the Eileen Trust, when Sir William Waldegrave was Secretary of State, was that: "*Payments for haemophiliacs recognise their unique combination of circumstances. These do not apply for blood transfusion recipients*".[1587] The note on this line explained that "*[a]ny special treatment for HIV infected blood transfusion recipients would repercuss by exciting expectations which could be difficult to contain in other groups of patients harmed as an unintended consequence of NHS treatment…The more exceptions are made, the closer we move to 'no fault compensation'…*".[1588]

21. This thinking and decision making was not "*party political*". Alan Milburn, who prided himself as being a '*window-breaker*' capable of challenging established orthodoxy,[1589] accepted and continued with the approach of the previous Conservative administration when he became Secretary of State for Health in 1999.

22. Throughout the period when the trusts and schemes were being considered and implemented, the Government was unjustifiably confident in its belief that it understood the nature and causes of the infected blood scandal. As Alan Milburn expressed it: "*what was not in dispute at all was the scale of what happened… How it had happened was reasonably well understood… people understand exactly what happened*".[1590] But what is reflected in the government's lines to take is that it did not understand what had happened, the information upon which it based its belief was inaccurate. This led to its refusal to provide adequate financial support or to pay compensation. Even when new information was brought to the government's attention, this did not lead to a change in the line to take. Even after the Archer Inquiry and nearly twenty years of concern, the Department of Health did not change its view. Rowena Jecock accepted that in 2009 the Department of Health took into account Lord Archer's comments but nevertheless decided to continue with the Departmental line that there had been no wrongdoing.[1591]

[1587] DHSC0042272_143_0001
[1588] Ibid.
[1589] Transcript 14/07/2022, p33, ll24-25; p36, l8.
[1590] Ibid, pp186-187, ll23-14.
[1591] Transcript 13/07/2022, p54, ll16-22.

23. The government must reflect in light of this Inquiry's findings on how it came to be so mistaken and must ensure that adequate redress is made to those who it excluded from support for erroneous reasons.

No fault compensation – a slippery slope?

24. During this period, there was a widespread view across government that establishing and/or extending the schemes would set a precedent for no fault compensation. In fact, the thinking by nearly every civil servant both in the Department of Health,[1592] and Treasury, and in the very many submissions seen by the Inquiry was a fear that this was the beginning of a scheme of no fault compensation. It was largely this fear that led the schemes to be devised expressly not to look like compensation schemes, but to provide, at least at their inception, monies for financial hardship or small fixed sums. At various points in time (for example during the early 1990s to early 2000s) there were wider political discussions around no fault compensation schemes and the position of those with HIV and HCV became unnecessarily tangled up in wider questions about liability for medical injury. Instead of seeing it as a unique issue which should be dealt with on its own terms, the wider policy implications always seemed to trump taking action even where the sympathy and compassion of the individuals making the decisions were engaged.

25. In 1991 Treasury officials tried to persuade Sir William Waldegrave not to create any compensation scheme for those infected with HIV via blood transfusion on the grounds that "*it could cost much more by leading to a no-fault compensation scheme – even if one restricted to medical negligence*".[1593] In 1996 the Department of Health's position, as expressed by the Permanent Secretary, was that "*…any move to pay compensation to a restricted group of Hepatitis C sufferers (eg haemophiliacs) is likely to lead to irresistible pressure to extend it to a much wider group. There is no obvious basis for distinguishing between people infected via blood products and those infected*

[1592] With the notable exception of Martin Campbell, who recognised in 2003 that he did not consider that setting up a scheme for Hepatitis C sufferers would create any adverse precedent as it would be on a no-fault basis: HDSC0004421_049.
[1593] HMTR0000003_043_0003. See also DHSC0002931_005.

by blood transfusion… The unfortunate truth is that this is a very slippery slope".[1594] That view was endorsed by Lord Horam, who explained that "*the slippery slope argument was uppermost in [the government's] mind*".[1595] Alan Milburn shared this view[1596] and expressed his fear of creating a "*cascade effect*".[1597] This issue was not confined to ministers; Andy Burnham also fairly suggested that these concerns were "*…embedded deep within the Civil Service psyche … the response to this particular issue was primarily driven by a fear of financial exposure*".[1598] Repeatedly financial considerations were treated by the civil service as paramount, without recognition of other crucial issues.

26. John Reid correctly identified that the fear of a 'slippery slope' could be used as an argument against almost any policy.[1599] In reality, the only precedent which was set by any of the trusts and schemes was the correct one, namely that those IAP infected with blood and blood products should receive financial support. As recognised by the Permanent Secretary in 1996, there was no obvious or justifiable reason for distinguishing between different infected or affected groups. Hazel Blears and Alan Milburn, amongst others, both accepted that no precedent beyond the context of infected blood was ever created by the establishment or extension of the trusts and schemes. The fact that the schemes have now been in operation since the late 1980s and have not led to no fault compensation for numerous groups of individuals demonstrates that these concerns were unfounded.

The moral imperative

27. The government's fear of financial exposure led it to lose sight of the devastating impact of infection on the lives of both IAP. Government witnesses insisted that civil

[1594] DHSC0003883_100_0001. See also the submission to the minister of February 1996, which strongly advised against implementing a financial support scheme for those infected with HCV on the basis of cost, the general policy on no-fault compensation, slippery slopes and the ensuing impact on other spending priorities: WITN5426065.
[1595] Transcript 29/06/2022, p142, ll17-18.
[1596] Transcript 14/07/2022, pp91-92, ll14 – 5.
[1597] Ibid, p136, ll24-25.
[1598] Transcript 15/07/2022, pp27-28, ll25 – 4.
[1599] Transcript 21/07/2022, p27, ll4-11.

servants and ministers were empathetic and cared about these people[1600] but nevertheless defended their decision not to provide financial payments. Those in government who resisted extensions in financial support generally did not hear from IAP directly, nor did they consider whether compensation should be made as a matter of moral responsibility.[1601] There are always difficult balances to be made in decision making and policy development, but in this case there was an abject failure of moral leadership by successive governments.

28. Where ministers did set up financial schemes, this was in the teeth of advice from the civil service and the Treasury. We explore in the central government chapter the interaction between civil servants and ministers, but one strong example is the advice given by the Permanent Secretary to John Reid,[1602] which could not be clearer as to avoiding such schemes. William Waldegrave and David Mellor also acted against the recommendations made by their officials. The Macfarlane Trust was created because William Waldegrave recognised that it was morally necessarily and required in the public interest. The Skipton Fund was created because John Reid recognised that those infected with HCV had suffered similarly acutely to those infected with HIV and the previous distinctions were meaningless.[1603] He expressed the state's moral responsibility in terms of its moral duty to protect its people and that, where an agency of the state either culpably or innocently causes widespread suffering, they were entitled to justice.[1604] Jeremy Hunt's commitment to act on this issue is materially attributable to the work of his constituent GRO-A, now sadly deceased, which made Mr Hunt "*acutely conscious*" of this issue from the outset of his time in office.[1605] Similarly, Andy Burnham's introduction to infected individuals including GRO-A and GRO-A in 2010 through his friend Paul Goggins MP led him to recognise that "*something really wrong is here*".[1606] It took both a personal understanding of the human cost of this tragedy and a determined force of will for

[1600] E.g. Lord Horam Transcript 29/06/2022, p142, ll11-14; Alan Milburn Transcript 14/07/2022,p81, ll9-11.
[1601] E.g. Hazel Blears Transcript 21/07/2022, p179, l17, p183, l21-22.
[1602] DHSC5320518; DHSC0042275_010.
[1603] Transcript 21/07/2022, p25-26, ll1-8
[1604] Ibid.
[1605] WITN3499001_0005.
[1606] Transcript 15/07/2022, p92, l12.

anyone in government to change course. It was unlikely that anyone would spend the political capital and personal effort necessary to effect change without a heartfelt recognition of how seriously individuals had been harmed by infected blood. We invite the Inquiry to consider how institutional change can be achieved in the future without relying on the chance of personal relationships. Further that when considering the needs of individuals injured as a result of government policy, whether any wrongdoing has been found or not, there is a requirement for engagement with a representative group to seek their views and details of their experience at the outset.

29. Other Government ministers and MPs have belatedly recognised the UK's moral responsibility towards IAP. This has been accepted by Matt Hancock,[1607] Jeremy Hunt,[1608] David Cameron (whilst Prime Minister),[1609] and by the Department for Health and Social Care in its apology to IAP, which accepted that "*things went wrong*". Other chapters of these submissions set out the failures which led to patients being infected, misdiagnosed, and harmed with treatment for the illness with which they were infected. The government only recognised the case for compensation in the course of this Inquiry. The first call for such was in 1986. The ethical failures of government, including to listen to IAP, over nearly 40 years should be used and investigated and analysed in order to avoid such happening in the future.

Establishment of trusts and schemes

30. A common feature of the trusts and schemes was that, as they were set up on an *ex gratia* basis, they did not aim to meet the needs of infected or affected people, and the financial support provided fell well short of what would be needed to do so. We fully endorse the description used by the Chair of the Inquiry in his interim report dated 29 July 2022 at §21: "*The effect of this approach is that the payments could be (and were) significantly less than compensation would be. They were not compensation… they were not calculated by reference to any assessment of needs. The*

[1607] Transcript 21/05/2021, p126, l19.
[1608] Transcript 27/07/2022, p150, l5.
[1609] WITN4509007

consequence has been that from the very first payments made to the Macfarlane Trust until today it has repeatedly been said by many witnesses that the payments being made were simply inadequate to provide the financial relief that was needed."

Macfarlane and Eileen Trusts

31. On 16 November 1987 the Secretary of State for Health announced that the government proposed making discretionary payments to reflect the *"wholly exceptional position of haemophiliacs"*, with £10 million being allocated by way of a discretionary charitable trust that was set up as the Macfarlane Trust the next year. David Mellor explained that he *"never thought that £10 million was ever going to be enough and it wasn't, of course"*.[1610]

32. Dr Roger Moore described the creation of the Macfarlane Trust in a contemporaneous document as follows:

> *"It was never intended that the £10m should be compensation. The Trust is a charity and the Trust Deed restricts it to providing relief for those who are in need of assistance… Some applicants clearly thought they were entitled to 'compensation' and unless they could demonstrate need have not been given a grant… It is the intention primarily to make regular payments to those on low income as well as single payments for specific items. The Trust has adopted a cautious maximum regular payment of £20 per week subject to a means test. … The Macfarlane Trust was established as quickly as was practicable and our understanding is that all applications for help have been dealt with in a timely fashion. The average award of £440 reflects a cautious approach before the level of demand could be identified."*[1611]

33. The Eileen Trust was set up in 1993 on broadly the same terms as the Macfarlane Trust, but was created to support people without bleeding disorders. It was initially funded by a £500,000 payment from the Department of Health following litigation

[1610] Transcript 19/05/2022, p44, ll8-9.
[1611] DHSC0003303_005_0002.

brought by those without haemophilia who had been infected with HIV. Applicants had to sign liability waivers to access payments.

34. The low levels of initial funding reflected the bleak prognosis for those living with HIV at the time the Trusts were established. In the 1980s, few HIV infectees survived beyond five years. As life expectancy grew, it became more obvious that the limited funds available were insufficient.

Skipton Fund[1612] and Caxton Foundations

35. Of all the failures related to the trusts and schemes, one of the most striking is that the Skipton Fund was not established until 2004. HCV had been known as a potentially-fatal bloodborne infection since at least the early 1970s. Despite significantly pre-dating the outbreak of HIV/AIDS, no financial support scheme was created until more than 15 years after the Macfarlane Trust was established.

36. It is wholly unacceptable that those infected with HCV, whose suffering was well-known long before the creation of the Skipton Fund, were left without any support or assistance. The Skipton Fund was established in large part simply because HCV sufferers were finally heeded. This could have a been done decades earlier, it is a serious moral failure that it was not.

37. This delay stems in part from the failure to recognise the precedent set by making financial provision to those infected with HIV (which conceded that an *ex gratia* payment, at least, was appropriate for those infected by the state) and the failure to acknowledge that HCV was a disease which could be equal in severity to AIDS. This has rightly been criticised as "*illogical and unfair*", with a powerful example being cited in the Scottish Health and Community Care Committee's 17th Report (2001).[1613] This involved a family of three haemophiliac brothers, two of whom died of HIV and one of whom died of HCV. The third brother was not eligible for any financial help at that time. The Committee expressed its view that this was a "*fundamental question of*

[1612] The creation and remit of the Skipton fund is set out in full in the Inquiry's presentation (INQY0000245_0006), which we endorse but do not seek to repeat here.
[1613] MACK0001929_024.

fairness and consistency".[1614] In giving evidence to the Inquiry, Lord Reid accepted that there was no persuasive distinction between HIV and HCV sufferers for the purposes of compensation.[1615]

38. The creation of the Skipton Fund was attributable to the government's acceptance, in light of the leadership shown by the Scottish administration (in particular Malcolm Chisholm) in announcing their own scheme, that the Department of Health should follow suit.[1616] Lord Reid recognised that this was the "*catalyst*" for him making the decision to provide financial support.[1617] The Skipton Fund was not created because new information came to light, but because the well-known suffering of those infected by HCV and the moral case this created for financial support was finally recognised by the government. Even then, it is tolerably clear that Westminster would not have created the scheme without Scotland's unilateral action, which created a precedent for it to follow. However, that principle was not always understood by those establishing and administering the Scheme. As reflected in a contemporaneous memo from Mr Gutowski to the then-Permanent Secretary, the rationale for providing support was seen as follows:

> "*…the original philosophy of the scheme was to provide ex gratia payments to all of those who developed chronic hepatitis C as a result of inadvertent infection from blood or blood products. This would emphasise the fact that payments are not being made on the grounds of past or current suffering, but on compassionate grounds because this is the right thing to do.*"[1618]

39. Despite this, Mr Gutowski's explanation of "*compassionate grounds*" in oral evidence was "*to alleviate the suffering of these – of survivors*"[1619] and had no answer when that definition was contrasted with his earlier memo.[1620] Similarly, Sandra Falconer of the Scottish Executive Health Department explained in November 2003 that: "*The*

[1614] Ibid, p. 24.
[1615] John Reid, 21 July 2022, p. 26, l. 15.
[1616] The Scottish government's announcement was itself prompted by the Ross Report (HSOC0020367), which recommended compensation rather than *ex gratia* payments, and which
[1617] John Reid, 21 July 2022, p. 26, l. 15.
[1618] DHSC5328495
[1619] Transcript 10/06/2022, p38, ll16-17.
[1620] Ibid, p. 39, l. 8.

underlying principle behind the ex gratia payments announced is that they should go to people who are still alive and suffering".

40. Thus, even after the government recognised the moral claim IAP had to financial support, there was still not a clear and consistently articulated basis for the provision of that support. The lack of any principled basis on which financial support was being paid meant that the sums awarded were arbitrary and not calculated by reference to losses actually sustained. It was inevitable, in these circumstances, that the support offered would be inadequate and that substantial revisions to the scheme would be needed. Even when further support was provided via the Caxton Foundation, the Special Category Mechanism, and the creation of the Infected Blood Support Schemes, this remained inadequate. Without a firm basis for providing support, it was always likely to be impossible for the Department of Health to resist the reluctance of the Treasury to pay out substantial sums. Dr Gutowski accepted that the ministerial steer was that costs should be kept down.[1621] Implementing the Ross Report's recommendations in full was ruled out on cost grounds,[1622] especially as there were at the time very strict funding constraints on the Department of Health as a whole and it had been clear that no more funding would be forthcoming.[1623] It is a striking failure that the government has failed over the decades since these schemes were created to obtain any expert advice on the appropriate level at which to set payments and how to structure the schemes.[1624]

41. Had any informed input been sought on the operation of the schemes, it would have been clear to those establishing the Skipton Fund (and other Trusts and Schemes) that a reliance upon applicants supplying medical records was unfair and would exclude eligible applicants. It was well-known that due to the passage of time medical records may have been destroyed or were likely to be incomplete, and that in any event important information such as the blood transfusion and the use of blood products

[1621] Transcript 10/06/2022, p42, ll4-7.
[1622] WITN5292016_0046.
[1623] Transcript 10/06/2022, pp74-75, ll22-4.
[1624] Transcript 10/06/2022, pp64-65, ll24-8.

was often not recorded. The insistence upon evidence of the route of infection being present in medical records created a barrier to many applicants receiving support.

42. Notwithstanding the shortcomings of the Skipton Fund, which are set out in greater detail below, in March 2010 officials were still giving ministers a "*pretty strong steer*" not to bring forward a review.[1625] The review did eventually take place shortly before the 2010 general election[1626] in May of that year and resulted in the creation of the Caxton Foundation.

43. The Caxton Foundation was a registered charity set up in 2011 and funded by the Department of Health to provide discretionary and means-tested support to those who had contracted HCV through treatment with blood and blood products. Its genesis was described by Peter Stevens, then Chairman, in minutes of the first meeting of its trustees as follows:

> "*The first stage in the Government response to the HCV side of the tragedy was the establishment in 2003 of the Skipton Fund …This did not satisfy the aims and aspirations of the campaign groups, in consequence of which the Archer Inquiry was established … Caxton was a further development aimed at bringing closure to the entire issue.*"[1627]

44. The Caxton Foundation was empowered to provide means-tested income 'top-ups', one-off grants and other support such as winter payments and benefits advice.

The Infected Blood Support Schemes

45. The transition from the earlier trusts and schemes to the Infected Blood Support Schemes is perhaps best summarised by Mr Hunt during his evidence to the Inquiry, when he adopted Sir John Major's description of the government as being like a "*supertanker*", and accepted CTI's suggestion that "*…it took an awfully long time, from 2013/2013…to get to the replacement English Infected Blood Support Scheme, 2017/2018, with very little funding*".[1628] The governmental review was not produced

[1625] DHSC0041307_015, Transcript 15/07/2022, p103, l24.
[1626] ARCH0001105.
[1627] CAXT0000108_017_0003.
[1628] Transcript 27/07/2022, p114, ll6 – 12.

until January 2016[1629] and the new scheme not approved by the Prime Minister until 6 July the same year.[1630]

46. This was not a radical overhaul of the system, aimed at finally resolving the shortcomings of the trusts and schemes as William Vineall explained:

> *"…when the new EIBSS scheme was set up in 2017, it effectively inherited most of the features of the Alliance House organisations … it was effectively a lift and shift"*[1631]

47. Mr Vineall also accepted that no full-scale assessment of losses had ever been undertaken by the Department of Health. He broadly accepted the finding of the All-Party Parliamentary Group in 2015 that successive governments had failed to carry out a holistic independent assessment of the support necessary to meet the full needs of all beneficiaries.[1632] Mr Hancock accepted that it was *"very important to have a proper process around coming to a fair and just way of ensuring that people are supported"*.[1633]

48. This reflects the ongoing confusion about the nature, role and purpose of the financial support provided to IAP; even several decades on, after a formal consultation and review of the trusts and schemes, the government continued to be led by ad hoc decision-making. The first serious attempt at a principled and needs based compensatory approach was Sir Robert Francis' report.

Operation of trusts and schemes

Macfarlane and Eileen Trusts

49. As both the Macfarlane and Eileen Trusts operated as discretionary charities, they had a wide discretion as to how to allocate their funds. Given the limited funds available

[1629] CVHB0000041
[1630] WITN3903006.
[1631] Transcript 21/05/2021, pp111-112, pp19 – 2.
[1632] Ibid, pp. 123-125, ll. 8 – 9.
[1633] Ibid, p. 125, ll. 14-16.

to them, this led to a refusal-minded culture and defensive decision-making. Christopher Fitzgerald explained in his evidence both to the Archer Inquiry and to this Inquiry, that the Macfarlane Trust was chronically underfunded.[1634] Requests for additional funding were kicked into the long grass[1635] and trustees were concerned about being seen as asking to "*too much*" from the government.[1636] There was an apparent assumption by the Department of Health that applicants should be grateful for what they received.

50. Underfunding also resulted in long backlogs of applications and staff being unable to keep up with essential work.[1637] Jude Cohen criticised the Trust as not being well run, lacking clarity and consistency in the support it offered,[1638] which created a "*climate of fear*"[1639] amongst registrants. Katie Rendle criticised the Trust as "*incredibly bureaucratic*".[1640] A significant issue was the lack of clear criteria which could be applied to applications. As Ms Rendle put it, "*the only terms I ever heard were 'charitable need' and 'exceptional circumstances', which just seemed really inadequate and vague for such important decisions*".[1641] Such broad criteria, applied in an unprincipled fashion, led to insufficient support being provided unfairly.

51. Ms Rendle produced a survey for registrants[1642] which reflected very poor service, with many expressing significant concerns that they were not being listened to and were not being properly consulted. Those findings are unsurprising in light of the attitudes which permeated senior members of the Trusts. Peter Stevens characterised applicants as a "*lot of moaners*",[1643] "*thick*",[1644] and Gordon Clarke referred to them

[1634] Transcript 26/02/2021, pp6-7, ll23-5.
[1635] Transcript 23/02/2021, p99, ll3-4.
[1636] Transcript 25/02/2021, p59, ll5 – 9.
[1637] Transcript 11/03/2021, p14, ll4-11
[1638] WITN4565001_0051.
[1639] MACF0000019_130.
[1640] Transcript 11/03/2021, p. 149, l. 20.
[1641] Transcript 11/03/2021, p152, ll17-20.
[1642] WITN3372004
[1643] WITN2368016_0002
[1644] WITN2368016_0005

as the "*great unwashed*".[1645] Despite Mr Stevens' apparent view of the registrants, he continued to be heavily involved with the subsequent trusts and schemes until 2013.

52. The Macfarlane Trust can fairly be criticised for reluctance to make payments to eligible applicants. The Trust did not disclose their maximum grant guidelines, on the basis that they were worried that applicants would use them as a "*shopping list*"[1646] to obtain higher payments. Administrators were therefore required to lie to applicants if they asked for the office guidelines.[1647] The effect was to discourage registrants to apply for support to which they were entitled. That is incompatible with fundamental principles of fairness and transparency. It is unsurprising that there was a deep sense of mistrust between registrants and the Trust.

53. The Eileen Trust was set up in the image of the Macfarlane Trust and thus mirrored many of its flaws. However, as it had far fewer registrants than the Macfarlane Trust it was able to offer more individualised support and spent greater time assessing their particular needs.[1648] It was also substantially less burdened by bureaucracy as a smaller organisation, which facilitated a better relationship between registrants and the Trust.[1649]

Skipton Fund

54. As seen above, the Skipton Fund was expressly set up on an *ex gratia* basis, with the decision said to be based on "*compassionate grounds*".[1650] That limited basis led to substantial shortcomings in the support it provided, in particular:

    a. It perpetuated the non-compensation approach seen in the Macfarlane and Eileen trusts, which meant that applicants received sums far below what they needed and / or had lost as a result of their illness;

    b. Dependents and affected individuals were excluded;

[1645] **CGRA0001055**
[1646] Transcript 23/02/2021, pp156-158, ll9-9.
[1647] Transcript 11/03/2021, p50, l7.
[1648] ARCH0002992_002; Transcript 10/03/2021, p68, ll1-21.
[1649] Transcript 10/03/2021, p69, ll1-10.
[1650] NHBT0015207_002.

c. The scheme lacked any discretionary payment mechanism;

d. Stage 2 payments were only available for those who could show they had developed cirrhosis of the liver.[1651] This was a very high threshold which excluded a wide range of acute and debilitating illness, and led to high levels of applications being rejected[1652] given the difficulty of proving cirrhosis without undergoing a liver biopsy, which was highly invasive and carried a risk of haemorrhage for haemophiliacs;[1653]

e. Neither stage of payment adequately reflected the functional impacts on a person's ability to carry out daily activities; and

f. There was initially no appeals process.

55. As with other trusts and schemes, one of the principal shortcomings of the Skipton Fund was the requirement to prove the route of infection. The passage of time since original infection, the absence of and / or barriers to obtaining medical records, and poor-quality record keeping all meant that infected individuals faced often insuperable difficulties in discharging the burden of proof placed on them.[1654] In the absence of records confirming a potential route of infection, applications were destined to fail.[1655] This is particularly regrettable given the identical issues seen in previous Trusts and the government's plan when establishing the scheme to give applicants *"the benefit of the doubt (e.g. because of lost/destroyed medical records etc)"*.[1656] In practice, this was not done.

56. For the first time, the Skipton fund included a 'cut off' date for eligibility, preventing applicants who had been infected after September 1991 from receiving financial assistance. This led to the arbitrary outcome whereby otherwise eligible people who

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[1651] Professor Thomas explained that cirrhosis was chosen as an *'objective'* measure of harm, rather than assessing *"subjective symptoms of illness"*: Professor Thomas, Transcript 24/03/2021, p7 l21; SCGV0000265_004_0001. This approach was not liable to identify applicants experiencing the greatest suffering but instead excluded a large number of applicants experiencing serious pain and suffering.

[1652] SKIP0000031_100

[1653] Professor Keel, Transcript 26/07/2022, pp82-83, ll20-5.

[1654] For more details of the shortcoming in record keeping, see EXPG0000047_0076- EXPG0000047_0077.

[1655] See, e.g., DHSC0004501_045.

[1656] DHSC0004421_141_0002.

had been infected through contaminated blood or blood products, were unable to access necessary support. No such restriction was imposed in relation to HIV. In oral Evidence Mr Gutowski was unable to identify any basis in evidence for such a restriction.[1657]

57. Unlike the Eileen Trust, the Skipton Fund did not offer any assistance with locating medical records. Mr Fish could not recall any examples of the Skipton Fund approving an application in the absence of medical records confirming a transfusion (leaving to one side cases of bleeding disorders).[1658] There were widespread shortcomings in record-keeping, including frequent failures to record the fact of blood transfusions. It was not reasonable, in those circumstances, for the Skipton Fund to place such heavy emphasis on documentary evidence of transfusion.[1659] A person's oral evidence was plainly evidence capable of supporting a payment but the Skipton Fund refused to accept this. Further, it was unreasonable for the Fund to expect applicants, many of whom were living in poverty and were chronically unwell, to bear the costs (both monetary and in terms of time, stress and effort) of obtaining their records. Mr Fish confirmed that the Fund would not pay the costs of accessing medical records, going no further than telling GPs and hospitals that they should not charge applicants.[1660] This reflects a double failure on the part of the NHS; both infecting patients and then losing or destroying their records, thereby preventing payment.

58. Similarly, where there was another potential route of infection, applications would be unsuccessful.[1661] Any evidence of drug use would lead to the application being automatically declined, even where an applicant had credible evidence of having received a blood transfusion.[1662] The Skipton Fund in several cases did not distinguish between intravenous and non-intravenous drug use, which can properly be

[1657] Transcript 10/06/2022, pp. 80-83, ll. 25 – 11.
[1658] Nicholas Fish, Transcript 23/03/2021, p96, ll1-10.
[1659] We acknowledge that, from 2012, the Fund would seek the views of Professor Thomas where records did not mention transfusion. Prior to this appointment, applications were rejected due to the Fund's failure to either accept applicant's evidence or seek medical advice (see WITN4466002_0015). Further, Professor Thomas was a hepatologist and the Fund never sought input from clinicians with a wider range of expertise.
[1660] Ibid, p. 95, ll. 10-21.
[1661] ARCH0002318_0003, § 8.1.
[1662] David Mutimer explained (WITN3989001, §49) that the Fund's view was that the *"overwhelming probability"* in such cases was that injecting drug use was the source of HCV.

characterised as irrational. The Skipton Fund relied upon the 2007 report from Dr Ramsay of the Health Protection Agency.[1663] That report did not support the automatic rejection of applications in cases of intravenous drug use and concluded that the risk of acquiring HCV through short-term use was poorly documented, but on the existing data appeared to be a higher risk compared to a single transfusion of unscreened blood. This single piece of qualified advice, prepared against a limited background of evidence, did not justify the Fund's blanket policy of rejecting applications where there was any evidence of drug use.

59. The evidence received regarding the Skipton Fund paints a picture of it being more interested in protecting public money than ensuring that everyone entitled received a payment. In practice, the Fund narrowed its eligibility criteria to those who could provide medical evidence demonstrating a likely route of infection and who had no history of drug use. This incorrectly excluded many registrants who should have been eligible for support.

60. The staged payments were inadequate, as set out by the Archer Inquiry. Following the Archer Inquiry, the Stage 2 payment was doubled and the Fund introduced annual payments for all Stage 2 recipients. This did not resolve the problems with the scheme which still failed to meet the needs of its registrants.

Caxton Foundation

61. The Caxton Foundation remedied one of the principal shortcomings of the Skipton Fund, by providing discretionary payments to infected people and to their bereaved family members and dependents. However, the Foundation was not given enough money to remedy the significant shortfall in the financial assistance available. Paul Goggins MP described in Parliament how, even after the creation of the Caxton Foundation, that "*recipients feel as though they must beg even for essentials*".[1664]

62. The Caxton Foundation had no user trustees. Peter Stevens explained that this was due to "*mixed experiences*" at the Macfarlane Trust[1665] and accepted that it was

[1663] SKIP0000031_217.
[1664] Hansard, vol. 569, 29/10/2013, col. 200WH.
[1665] Transcript 24/02/2021, p129, ll17 - 20

probably inappropriate to refuse even to consider user trustees.[1666] Conversely, the Foundation did not appear to question the potential conflict of interest arising in the appointment of trustees who had worked in the NHS and Department of Health.

63. The Caxton Foundation in practice only allowed appeals for those who could adduce new evidence, excluding any challenge on the grounds that the first decision was wrong. While Mr Stevens asserted that applicants could write to the Chairman to challenge a decision, he accepted that they would not know that this was possible and could not recall any examples of it happening.[1667]

64. Very few Skipton Fund recipients were made aware of the Caxton Foundation's existence, and therefore did not ever benefit from the discretionary payments available to them.[1668] This information about the Foundation and how to apply could readily have been disseminated to eligible registrants but was not. Such a failure is inexcusable and was repeated, albeit for apparently different reasons, when the Infected Blood Support Schemes were created.

Infected Blood Support Schemes

65. The creation of the Infected Blood Support Schemes introduced the welcome change of unifying the various pre-existing schemes under one body. The regional variation in the Support Schemes led to some registrants being treated less sympathetically and generously than others. In particular, the English scheme's Special Category Mechanism was based upon clinical assessment rather than the self-assessment used in Wales and Scotland. The Welsh and Scottish Schemes applied a benefit of the doubt principle.[1669] The English Scheme also imposed a higher evidential threshold for bereavement payments, forcing bereaved applicants to engage in long battles for support.[1670] The psychological impact of this difference in treatment is articulately set out by Dr Coffey to the Welsh Government, explaining that *"the inequality provokes*

[1666] Transcript 24/02/2021, p137, l15.
[1667] Transcript 24/02/2021, pp139-140, ll12-4.
[1668] CAXT0000035_078 notes a 57% increase in beneficiaries in 2015, possibly attributable to the attention raised by the APPG on Haemophilia and Contaminated Blood's contemporaneous inquiry, which raised awareness of the Foundation.
[1669] WIBS0000002; Transcript 18/05/2021, p142, ll9-17.
[1670] Transcript 21/05/2021, pp71-73, ll10 – 10; Transcript 20/05/2021, pp18 – 21, ll10 – 18.

reactivation and reliving of past traumatic experiences and can be perceived as confirmation that fairness is not required due to the 'second-class citizen' status".[1671]

66. The Support Schemes also perpetuated many of the issues seen in previous schemes, including humiliating experiences of being required to prove status, rejections due to lack of records,[1672] and insufficient levels of support.[1673] Some of our CPs who, despite being supported under earlier schemes, were not informed about the new Support Schemes and therefore lost out on financial payments.[1674] Despite the Department of Health and Social Care and NHS Business Services Authority both arguing for automatic data sharing, as explained by Brendan Brown, "*[t]he AHOs implemented a policy of only sharing data by explicit consent following their own legal advice in this regard*".[1675] As a result, the employees of EIBSS did not know who had benefitted under previous schemes, stymying their work from the outset.[1676] This was not the first time those eligible had not been informed of assistance available to them, as noted above in relation to the Caxton Foundation.

Future trusts and schemes

67. The submissions above clearly demonstrate that previous trusts and schemes were fundamentally flawed. This is largely due to their being set up on an *ex-gratia*, concessionary basis rather than in recognition of wrongdoing and moral responsibility on the part of the state. Any future scheme must be compensatory, not *ex gratia,* and must aim to place IAP, insofar as possible, in the same financial position as they would have been but for the supply of infected blood or blood products. The principle of compensation must be buttressed by recognition of how damaging the government's actions in establishing and operating trusts and schemes to date has been.

[1671] WITN4506014
[1672] W2055 [ANON]; W1862.
[1673] W1878.
[1674] W0065.
[1675] WITN4496001, §25.
[1676] Transcript 21/05/2021, p14, ll5-8.

68. The ad hoc, piecemeal and limited support which has been provided under the Trusts and Schemes should not be set off against future payments, *per* Sir Robert's recommendation 15, for three principal reasons:

a. This would conflate *ex gratia* payments with compensation;

b. Such an accounting exercise would be time- and cost-intensive; and

c. Starting afresh would reflect the extreme failures in providing financial support to date.

69. Any new scheme must be accessible, generous, proactive and independent of government.

70. We suggest that the new scheme use the following definition of compensation, which should inform its approach:

> "*Victims of the infected blood tragedy, both those infected and affected, are entitled to financial compensation for (i) the injury, pain, and suffering they experienced, (ii) the emotional and psychological harm sustained, (iii) their financial losses, and (iv) the moral harm they have sustained both as a result of the original infections and their treatment in clinical settings and elsewhere for decades thereafter.*"

Sir Robert Francis' recommendations

71. There is much to be welcomed in Sir Robert's compensation study and his recommendations. We have no objection to his recommendations being treated as a starting point by the Inquiry, subject to the specific points made below. At the end of the chapter, we provide our views on the framework for compensation and appropriate form for the awarding body, in light of Sir Robert's report and the evidence heard by the Inquiry.

The moral case for compensation

72. Sir Robert's first recommendation correctly frames the question of providing financial support within the context of a strong moral obligation to do so. He explained:

> *"…one of the special features of this case is that whatever it can be said about fault or no fault, the injuries that have been inflicted on people, firstly have been inflicted on them by the state, putting it bluntly. The state-delivered Health Service has done this to people. It seemed to me, and without wishing to pre-judge this Inquiry, that much of what happened, and it is not for me to make the judgment, was in retrospect avoidable. In other words, if we look back on things from now it could be avoided for many if not all cases.*
>
> *And while we do not have a law in this country which promotes legal liability on that basis, it seems to me that where there is such a widespread disaster as this, there can be a strong moral obligation on the state which inflicted harm on people when the state was in effect trying to do the very opposite to put that right. And when people have suffered, as people have here, their entire lives, which is another exceptional feature of this case, then putting that right is not just a matter of an apology, sympathy and, one would hope, perhaps that's not always happened either, proper material support in relation to medical help and so on, that it can only be put right by -- insofar as anything can be -- by money, and that is a measure of the gravity with which the public, represented by the government, see this particular issue."*[1677]

73. We strongly endorse that analysis. Any future scheme must be rooted in an acknowledgement of wrongdoing and informed by principles of compensation.

Inclusion of HBV

74. As set out in our addendum submissions on interim payments, the Inquiry has already received a substantial amount of evidence from those infected with HBV as a result of receiving NHS blood or blood products. There is no justification for excluding those

[1677] Transcript 11/07/2022, pp50 – 51, ll2 – 12.

infected persons, and those affected, from support payments or any future compensation (whether interim or full payments), for the following reasons:

a. Those infected with HBV have been infected through an identical route of transmission. They have also received blood or blood products without being adequately informed of the risks and choices available to them. As a result, they have suffered materially similar ill health and physical and cognitive effects. They have also suffered similar financial and other psychosocial hardship, such as stigma, social isolation, and an ongoing lack of trust in the governmental and health service structures that they rely on for support, care and treatment.

b. To the extent that the exclusion of those with HBV is based on the introduction of routine screening, there is no equivalent provision in the existing schemes for HIV payments. The inclusion of those with HBV would be consistent with the recent amendments to the support schemes to encourage parity between different categories of IAPs (the most appropriate analogy is the Special Category Mechanism for those infected with HCV).

c. Moreover, the historic reasons why it was thought reasonable not to exclude any person infected with HIV after the introduction of routine screening apply equally to HBV. They were explored in the evidence of Dr Rejman.[1678] One of the reasons it was decided that there should not be a cut-off date was because the screening technology was fallible – some infections were not detected by the tests, including where a donor was in the "*window period*" between being exposed and the virus becoming detectable in their blood. It goes without saying that the screening technology and/or other screening methods employed by the blood services to detect HBV were fallible (particularly in the absence of anti-HBc screening), hence the significant number of persons infected notwithstanding. This was confirmed to the Inquiry by many regional transfusion directors (and others in positions of authority in the blood services), for example:

[1678] Transcript 11/05/2022, pp205-206.

i. Professor Dame Marcela Contreras;[1679]

ii. Professor John Barbara;[1680]

iii. Dr Brian McClelland;[1681]

iv. Dr Morris McClelland;[1682]

v. Dr Frank Boulton;[1683]

vi. Dr Huw Lloyd.[1684]

75. Sir Robert took a "*very generalised view of the impact of HBV*"[1685] and excluded it from his framework for compensation broadly because of his impression based on the information available to him was that generally its effects were mild. [1686]Although he did suggest that this conclusion be reviewed by the Inquiry in light of the evidence it has heard.[1687] This Inquiry has had the opportunity to hear in much greater detail from those infected with HBV and is better placed to recommend that they receive compensation. Sir Robert makes an exception for those who develop a chronic infection with serious symptoms who require treatment to prevent cirrhosis, or who have actually contracted cirrhosis.[1688] While we naturally submit that this latter category should be included in any compensation scheme, we consider it is unduly narrow. HBV has serious physical and psychological / psychosocial impacts, as recognised by Professor Thomas, who said that HBV should have been "*much more to the fore in these schemes*".[1689]

76. The expert evidence before the Inquiry also justifies inclusion of HBV, as it recognises that the disease, like HCV, varies in severity and poses a risk of "*progressive scarring of the liver (fibrosis, leading to cirrhosis) and an increased risk of liver cancer*

[1679] Transcript 02/12/2021 pp54-56; Transcript 03/12/2021, p77, ll12-17; pp118-122.
[1680] Transcript 26/01/2022; pp101-102, particularly p102, ll9-10.
[1681] Transcript 27/01/2022, p103, ll13-25; Transcript 28/01/2022 pp81-85, particularly p85, ll17-23.
[1682] Transcript 01/02/2022, p48, ll1-11; p85, ll1-14.
[1683] Transcript 04/02/2022, pp49-51, particularly p51, ll11-19.
[1684] Transcript 09/02/2022, p163-164, particularly p164, ll11-22.
[1685] RLIT0001129_0062, §4.83
[1686] Ibid, §4.84.
[1687] Ibid, §4.86.
[1688] Ibid, §4.85.
[1689] Transcript 24/03/2021, p97, ll4-5.

(hepatocellular carcinoma, HCC)".[1690] Up to 5% of sufferers develop chronic HBV and 1% develop a potentially fatal illness.[1691] There is no cure,[1692] and it poses risks of both sexual transmission and to fertility.[1693]

77. In circumstances in which Sir Robert is recommending that "*natural clearers*" of HCV are included in his proposed scheme,[1694] the exclusion of those with HBV has become untenable and a distinction without a difference.

Cut-off date

78. The Inquiry is invited to recommend that any scheme does not contain a cut-off date for eligibility. Sir Robert did not seek to advance any cut-off date in oral evidence, nor did he articulate any positive case for imposing one. Looking back, Richard Gutowski was equally unable to identify any rational reason for imposing a cut-off date for HCV when none was imposed for HIV. No start date has been identified for either HIV or HCV. No cut-off date has been imposed to date in relation to financial assistance for HIV. Conversely, an artificial and inaccurate date (1 September 1991) has been selected after which IAP by HCV from NHS blood and blood products are excluded from support.

79. The arguments set out above in relation to the moral case to include HBV apply with equal force to those infected with HCV. If, as we submit it should, this Inquiry accepts a moral case for compensation then there is no reason to exclude those infected after 1 September 1991.

80. The Inquiry has heard evidence, including from hepatitis experts, that the early generation hepatitis screening tests were fallible, although improved throughout the 1990s, meaning that there was a highly significant statistical probability that some infections would "*slip through the net*" of screening procedures. [1695] Indeed, the last

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[1690] EXPG0000001_0003.
[1691] EXPG0000001_00064.
[1692] EXPG0000001_00065.
[1693] EXPG0000001_00066; EXPG0000001_00073.
[1694] Transcript 11/07/2022, p94, ll10-25.
[1695] See Hepatitis Expert Report, p21: "*This led to the development of more sensitive and specific second-generation EIAs (EIAs 2.0) that incorporated additional synthetic or recombinant antigens from the putative core*

infection with HCV from NHS blood recorded by SHOT was in 1997. Further this Inquiry has heard evidence that although new donations were tested from 1 September 1991, retrospective testing of donations collected prior to that date were not carried out.[1696] Professor Dame Contreras confirmed that hospitals held stocks of platelets, red cells, cryoprecipitate and fresh frozen plasma and as a result untested components may have remained in the systems after 1 September 1991[1697]

81. While this evidence supports removal of the cut-off date, it would be wrong to infer that compensation should only be paid where infection was avoidable as this returns to legal questions of negligence which do not properly capture the moral harm which IAP have experienced. As Sir Robert expressed it, *"a lot of the decisions that seem to have been taken about support seemed to have been around a wish to avoid accepting a legal liability when actually what needed to be looked at was the moral case for looking after people"*.[1698]

The long-term future of the scheme

82. Sir Robert rightly accepted that there should be a formal undertaking from the UK Government that financial payments will continue for life, which he described as a "*guarantee*".[1699] Our CPs want the financial support provided to be available for life, in the same way that periodical payments in tort claims are guaranteed for life. Any new scheme must not be given a capped sum or financial limits, rather it must meet the needs of all eligible applicants as discussed below. The scheme must not be time-limited or dependent on ad hoc increments in funding and must take account of the very real possibility of new applicants. This is the only way to avoid difficulties seen with, e.g. the MacFarlane Trust, whereby assessors are more concerned about preserving funds than meeting applicant need. This is addressed further below.

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and non-structural regions of the virus (NS3 and NS4); these assays were approved for use by the Food and Drug Administration (FDA) in 1992. These second-generation assays reduced the mean window of seroconversion (time taken from infection to detection of antibody) from 16 weeks to 10 weeks. The sensitivities of second-generation (EIAs 2.0) in a high-prevalence population are approximately 95% (based on HCV RNA detection by PCR)." Also reflected in WITN3101006, §§201-202.

[1696] INQY0000308 § 175 & NHBT0000073_063

[1697] Transcript 3.12.2021

[1698] Transcript 11/07/2022, p52, ll5 – 9.

[1699] Transcript 12/07/2002, p65, l5.

83. The previous schemes sometimes created feelings of division and conflict of interest amongst potential applicants. This was due to the limited sums available, which meant the granting of financial support to one applicant could result in another applicant receiving less. It is essential that the entire community of IAP are able to receive full compensation as an acknowledgement of the harm caused and to put them back, as far as possible, into the position they would have been had they not been infected.

Back payments

84. Many potentially eligible individuals were wrongly refused by the trusts and schemes, resulting in feelings of extreme distress, anger, and disappointment. We invite the Inquiry to recommend that all those who were wrongly refused receive back payments to reflect the sums they would have been eligible for under former schemes. As earlier payments are not to be offset against future compensation, this will not put this category of applicants in a better position than those who were granted support.

85. From 2 October 2017 an individual infected with HCV who was disabled under the primary tests contained in the Equality Act 2010 was able to receive the same annual payments from the English Infected Blood Support Scheme as an individual infected with HIV. However, prior to this date individuals infected with HCV received considerably less from the trusts and schemes than those infected with HIV. This was, we submit, discrimination under the Disability Discrimination Act 1995 and subsequently the Equality Act 2010. We invite the Inquiry to recommend that all those infected with HCV and were registered with the schemes receive back payments to compensate them for the loss they suffered as a result of this discriminatory policy. This point is the subject of a court action to which the majority of our eligible CPs are Claimants. This case is stayed pending the outcome of the Inquiry.

86. As referred to above, we represent CPs who despite receiving support from the early trusts and schemes were not aware of the Infected Blood Support Schemes at their inception. Many found out years later that they were eligible for regular payments and had missed out on significant sums due to their not being informed of this earlier. We are concerned that other IAP, perhaps those who have engaged less with this

Inquiry, may still not be aware of the support available. We invite the Inquiry to recommend that all eligible individuals are entitled to back payments equal to the financial support they would have received had there been adequate publicity of the new schemes when they were established.

Bereavement awards

87. Bereavement awards should be extended beyond those to have a surviving partner to benefit the estate of those who lack any surviving partner. We propose that bereavement awards should be set in line with the statutory level, currently £15,120.[1700]

'Natural clearers'

88. We endorse Sir Robert's proposal that those who cleared HCV or have an undetectable viral load should receive a substantial award.[1701] We would suggest that the degree of pain, suffering and loss of amenity experienced should determine the award, rather than providing a single lump sum. We also endorse Sir Robert's agreement that funding should cover private precautionary six-month liver scans.

Indirectly affected

89. We welcome the broadening of categories of eligible indirectly affected individuals set out in Recommendation 5 and invite the Inquiry to confirm that this category will include affected individuals where the relevant infected individual is alive. We would wish to add that:

    a. We invite the Inquiry to treat recommendation 5(b) as referred to 'children' broadly, rather than 'minor children'. Sir Robert does not suggest at §6.20 that he proposes to restrict this category to minor children and we would strongly deprecate such a move, as very few infected individuals have minor children today. We agree with Sir Brian's comments in his interim recommendation that

[1700] Pursuant to the Fatal Accidents Act 1976 section 1A as amended by Civil Partnerships Act 2004 section 83(7) and Fatal Accidents Act 1976 (Remedial) Order 2020 SI 1023.
[1701] Transcript 12/07/2022, p133-134, ll13-13,

"*no one can doubt that a parent who lost a child, or children, or a child who lost a parent, or parents, and has lived many years without acknowledgement of that loss should be recognised as among those for whom a moral case for recompense is compelling*";

b. In relation to §6.21 of Sir Robert's report ('*parents of infected children*'), we consider that there is likely to be a small group of parents who were still living with their adult children when the latter were infected. Adult children may still turn to their parents for care and support and, in these circumstances, there is no reason to exclude parents from support. We consider that recommendation 5(f) is too narrow to encompass these individuals and suggest an alternative be included in recommendation 5(c), namely: "*parents of eligible infected persons (i) whose eligibility started in childhood, (ii) at a time when they were still living with their parents, or (iii) who returned to live with their parents after infection for care and support*";

c. We propose that affected applicants should be able to apply for a financial loss award. Affected individuals have sustained heavy losses, both loss of income due to caring responsibilities and in light of out-of-pocket expenses incurred in the course of looking after an infected person. We endorse the comments of Counsel to the Inquiry, who highlighted to Sir Robert that in many cases "*there may have been in reality no alternative for those family members in terms of care*" due to the stigma related to HIV in particular;[1702]

d. We invite the Inquiry to reject the suggestion for the residual category of recommendation 5(f) that such individuals must have suffered a mental or physical injury as a result of their relationship with an infected person. This narrow eligibility criterion is liable to exclude almost all individuals who could fall within this category, as they would require specialised medical assessments of their health to establish causation. This would be a return to the days of schemes placing an unmanageable onus on applicants which they could not discharge. No other category under recommendation 5 required medical evidence to be

[1702] Transcript 12/07/2022, p29, ll1-9.

adduced. We suggest that 5(f) be replaced with "*members of the family, or friends of an eligible infected person, whose relationship with them was so close that it can properly be compared to the other relationships in this category*";

e. We also suggest that all registrants who are eligible under recommendation 5 should be entitled to the full range of financial support; and

f. Partners whose relationship broke down less than one year after infection should be included. Such bright-line exclusions are unhelpful and liable to exclude those with strong moral claims.

Passporting of lump sum recipients

90. It is not clear in Sir Robert's Recommendation three whether those eligible for lump sum payments under current support schemes should be passported into the new scheme. We understand that to be the intention of Sir Robert's recommendation, and would certainly agree that this would be a sensible approach.

Close and multiple partners

91. Sir Robert suggests that persons who cohabited with an eligible infected person as close partners for a continuous period of at least one year after the onset of the infection should be included in the scheme. We endorse that suggestion and suggest that it should be clarified that this can extend to multiple partners.

Recommendation 1: Structure of a Future Compensation Scheme

a. HBV should be included;
b. There should be no cut-off date for infections;
c. It should have open-ended funding and provide life-long financial support on the basis of need (unless applicants choose to receive 'lump sum' payments);
d. Back payments should be paid to those wrongly refused by previous schemes; those who suffered loss as a result of the support schemes' discriminatory policies; and those who missed out on regular payments as a result of poor publication of the schemes when they were established;

e. Bereavement awards should be paid to the estates of those who have died and should be set at the statutory level;

f. Compensation should include parents of eligible infected persons (i) whose eligibility started in childhood, (ii) at a time when they were still living with their parents, or (iii) who returned to live with their parents after infection for care and support;

g. Affected individuals should be able to apply for a financial loss award;

h. Compensation should include members of the family, or friends of an eligible infected person, whose relationship with them was so close that it can properly be compared to the other relationships in this category;

i. Partners whose relationship broke down less than one year after infection should be included.

Level of compensation

92. We invite the Inquiry to recommend that a new scheme be created which is informed by the principles of compensation referred to above. This scheme should:

    a. Start from the position that those infected and the bereaved partners not currently eligible for those schemes who become eligible under any scheme proposed by the Inquiry also are paid the £100,000;

    b. The estates of those infected where there is no bereaved partner are also paid the £100,000;

    c. Identify '*tariffs*' setting out appropriate brackets for damages covering the awards set out in Sir Robert's Recommendation 8;

    d. Additionally, allow for an individualised assessment of past and future special damages, covering financial losses and caring costs; and

    e. Ensure that any award made under (c) or (d) above can be challenged on appeal.

93. As to the level of tariffs, we note Sir Robert's suggestion at §9.26 that categories of '*mild*', '*moderate*' and '*severe*' be used. While a tariff-based model is not objectionable *per se*, it must reflect the actual impact of harm. Any tariff system must

reflect the holistic functional impacts of infection on an individual's ability to carry out daily activities, rather than artificially limiting damages because a certain clinical threshold is not met. It must allow for the analysis of the physical, mental, and emotional health of the individual. This is particularly important in the case of HCV, which must be understood as a multi-system condition, and not assessed by e.g. the degree of liver damage alone. Similarly, there should be no lower award simply because a person is e.g. mono-infected rather than co-infected.

94. We endorse the suggested categories for awards set out in recommendation 8, in particular Sir Robert's recommendation that financial awards go beyond the categories currently recognised by the common law. Sir Robert's oral evidence about the nature of the autonomy award was a little unclear, and we would wish to emphasise that a very substantial number of our CPs were deprived of the opportunity to give informed consent, in particular to blood transfusions. Sir Robert suggested a range of awards for loss of autonomy[1703] and at times appeared to blur the line between the social impact award and the autonomy award. We would encourage the Inquiry to identify a clear boundary line between these two awards, to avoid the risk of their being conflated and recipients being awarded lower sums overall.

95. IAP have experienced multiple forms of moral harm. This includes additional injuries suffered as part of their treatment, such as the systemic failure to obtain informed consent and missed, late and non-diagnosis. It also extends to the severe maladministration and delay in creating and improving the trusts and schemes, discussed above, and the enormously belated recognition by the UK government of its failures. In these circumstances, we consider that there is a strong case for an award which would normally fall within the category of aggravated or exceptional damages. We suggest that a fixed token sum should be awarded to all IAP to represent these harms, the level of the sum to be decided following consultation with IAP.

96. We strongly resist the suggestion at §9.48 that social impact awards should be limited by the severity of the disease. We recognise that, in many cases, there will be a more severe social impact for those who have experienced a more severe infection, but

[1703] Transcript 11/07/2022, pp135-138, ll23-5.

equally there are cases of severe social impact and stigma even where the disease is comparatively mild. Sir Robert's suggestion of applying the '*mild/moderate/severe*' criteria to the social impact award risks conflating this category with the impact award and it should be resisted.

97. Where annual payments are currently being made under the existing support schemes, these should be continued at the same level or higher, including by merging them with a new scheme. The guarantee of continued financial payments for life is essential for our clients. However, this should not prevent applicants opting for a lump-payment in addition to or instead of annual payments.

98. Many IAP are now in later life and tragically some are facing very serious, life-limiting diseases. We consider that any compensation scheme must be set up in the expectation that significant interim and upfront payments will be made, especially in cases where applicants have more urgent needs. The awarding body should be able to expedite cases where appropriate.

99. Sir Robert recommends that the awards be final. That is a laudable aim, and we agree that awards should be made to reflect the applicant's current prognosis. There must also be no possibility of 'clawback' or deduction from payments once agreed. However, we would invite the Inquiry to recommend the following modification to Sir Robert's approach:

    a. IAP must always be able to return to the awarding body for additional compensation. For instance, an increased award must be possible in cases where injuries deteriorate beyond the prognosis on which an award was based;

    b. Applicants must be entitled to challenge awards on appeal, as set out below.

Recommendation 2: Level of Compensation

a. Any of those who become eligible for financial support under the future scheme should receive £100,000 to achieve parity with those who have received interim payments. A similar award should be paid to the estates of bereaved individuals;

b. Levels of compensation must be set in consultation with IAP;

c. There should be individualised assessment of past and future damages, including financial losses and caring costs;

d. Compensation should be tax free, not offset against any previous awards under the trusts and schemes, and disregarded in assessment of means tested benefits;

e. Awards should not be subject to 'clawback' or later deduction but applicants should be able to apply for further financial support if it becomes clear that greater damage has been sustained than that covered by an initial award;

f. Social impact awards should not be fixed according to the severity of the disease;

g. There should be a fixed sum to reflect the moral harm which IAP have suffered.

h. Individuals who have participated in and/ or received an award of compensation via previous litigation related to infected blood must not be prevented from applying the scheme. Their previous involvement in litigation should not remove their right to challenge through the courts an award decision made by the scheme or by a tribunal on appeal.

Form of awarding body

100. We support Sir Robert's recommendation 16 that the awarding body should be an Arms Length Body ("**ALB**"). We consider that there are robust precedents of these operating effectively and independently, including as a check on government. This can be seen, for instance, in the case of the Independent Monitoring Boards and Prison and Probation Ombudsman.

101. There must be a mechanism for oversight and accountability so that applicants can complain and escalate any issues to the ombudsman.

102. While these submissions reflect the broad thrust of our CPs' views, we would urge the Inquiry to recommend that the ALB only be set up following an effective consultation

of the infected and affected communities. We endorse Sir Robert's comments about the need for a high-quality consultation:

> "*This is not an area where I would be terribly happy with two panels going away in private and coming back six months later with a proposed solution and having a six-week consultation over the summer holidays to produce a result. You need some real involvement. As with everything else, but this scheme in particular, it needs to carry the trust of the people who are most deeply affected by it*"[1704]

103. We also endorse the recommendation at 16(c) that potentially eligible people and their representatives should be involved in reviewing and improving the scheme once set up, both as individuals and by consultation with relevant patients' groups. Co-production with IAP must be at the heart of the creation and administration of the scheme. We also recommend that all those involved in the creation, administration and running of the awarding body and appeal panels should be trained in the Inquiry's findings and conclusions.

104. We have no objection to an independent appointment process for medical and legal panels to populate the tariff grids, but we consider that these panels must have input from the infected and affected community. We consider that appointing medical and legal experts with some link to this Inquiry would be a sensible starting point, if viable. The awarding body must have access to relevant experts (for instance in the fields of occupational health, care, psychiatry and employment) on which it can call both in setting tariffs and making decisions in individual cases.

105. We consider that awarding panels should include legal, medical and infected/affected representation. We suggest that a three-person panel, which balances these areas of expertise would be appropriate. It will be the panel's role to obtain further evidence where necessary and make a decision on the appropriate award after receiving representations from the applicant and their representatives.

106. Initial applications should be by way of a simple written application form, which should allow for initial triaging and identification of more complex cases where more

[1704] Transcript 11/07/2022, p145, ll2-9.

information will be needed from the applicant. Plain English should be used in all materials provided to applicants. There should not be any requirement for applicants to obtain evidence from third parties and the awarding body should be empowered to do this where necessary. This has the benefit of speed and comparative ease for applicants. Applicants must have a right to free legal advice[1705] and assistance throughout the application process. Any legal fees paid should be in addition to rather than as a deduction from any compensation awarded. Applicants should also have a right to make representations to the awarding panel beyond the information contained in the application form, if they wish to do so, but this should not be a requirement.

107. Once an application is filed, the onus must be on the awarding body to undertake investigations, including by obtaining expert evidence. Mr O'Mahoney explained that the Irish Compensation Tribunal would often receive reports from experts including educational psychologists and counsellors employed by the legal team.[1706] We invite the Inquiry to consider recommending a formal role for in-house experts, perhaps employed by appropriate patient representative bodies such as the Haemophilia Society, the Hepatitis C Trust, and the Hepatitis B Trust. In any event, applicants must not be expected to pay out-of-pocket for expert evidence. The applicant and their lawyers should have a right to put questions to experts and challenge their analysis in appropriate cases. All evidence that the awarding panel considers must be disclosed to the applicant.

108. If an applicant is unhappy with the award decision they must have a right of appeal to an independent tribunal. We invite the Inquiry to recommend that this takes the form of a Tribunal sitting with HM Courts and Tribunals Service. In line with the Employment Tribunal's and Mental Health Tribunal's current practice, we recommend that the Tribunal should be chaired by a judge, with a medical and infected/affected panel member. The Tribunal panel should be required to take a sympathetic, collaborative and proactive approach to appeals, giving applicants the benefit of the doubt. The

[1705] Lawyers should be paid on a fixed-fee basis, where the fee category reflects the complexity of the case
[1706] Transcript, 08/11/2022, p. 41, ll. 2 - 6

existence of this right of appeal must not be treated as a bar to applicants bringing litigation in another forum if they wish.

109. The formality of a Tribunal setting should not result in the process becoming adversarial or requiring legal representation. However, applicants should have access to free, independent legal advice and representation for applications to the Tribunal.

110. The funding for the ALB and Tribunal and the awards they will make must be open-ended; if their funding is capped or time-limited, it will prevent the proper administration of the scheme. The independence and effectiveness of previous trusts and schemes has been constrained by the lack of a robust and independent funding scheme. This must be avoided. There is already a precedent for achieving this in the arrangements made for NHS Resolution to fund clinical negligence claims. The projected claim costs are assessed in advance each year by professional actuaries and the scheme is funded accordingly. This is the type of model which we would urge the Inquiry to recommend to ensure long-term, sustainable funding for any new scheme.

111. The scheme should be UK-wide, with parity in the compensation offered across the four nations. However, awarding panels and administrative offices for the scheme should be set up around the UK so that decision-making take place in several places rather than in a single hub. Further this will allow registrants the opportunity to build relationships with those administering the scheme in their local area, allowing a more personal approach and an improved service. Similarly, appeal panels should sit across the UK, which should not be problematic as the Tribunal Service is UK-wide.

112. Further to the submissions made regarding non-financial compensation, we invite the Inquiry to recommend that:

    a. The awarding body should apply the lower standard of proof,[1707] namely a reasonable degree of likelihood that the applicant received infected blood. If the body instead chooses to apply the balance of probabilities, the benefit of the doubt should be applied and evidence should be approached in a "*sympathetic*"

[1707] As applied in the context of international protection claims and discussed in R v Secretary of State for the Home Department, ex p Sivakumaran [1988] AC 958.

and "*inclusive*" manner without a rigid adherence to legal concepts of proof. Training needs to be given to all those making decisions as to what the burden of proof means.

b. There should be no automatic precondition to eligibility that the applicant provides supporting evidence in the form of medical records or other documentation held by third parties that they received a transfusion. The recollections of the individual or other witnesses should be considered and accepted unless there is overwhelming evidence to contradict this recollection. Where an individual does not know if they received a transfusion or blood product, this treatment may be inferred where there are surrounding circumstances which can reasonably infer that, taking into account the practice at the relevant time, blood may have been administered, and there is no persuasive alternative evidence supporting an alternative cause of the infection.

c. Other documentary requirements for applications should be reduced to the greatest extent possible. Where documents are necessary, compensation schemes should be given both powers and duties to attempt to obtain these documents themselves, rather than rely upon an individual patient who has considerably less knowledge, skill and experience of searching for NHS records than the schemes. We endorse Sir Robert's recommendation that applicants should be "*sympathetically supported*" in obtaining any required information and documentation, but this should not result in the burden of proof being placed on applicants.

    i. This recommendation extends to medical evidence; it is likely that medical reports will be required to assess damages in many cases, and the awarding body should be able to fund and arrange the production of medical expert reports where necessary.

    ii. We also consider that the awarding body should be empowered to access an applicant's medical records (only with their consent) and should be provided by the NHS with microfilms/microfiches as standard upon request.

d. When considering an absence of documentation or of entries reflecting that blood or blood products were administered, the awarding body must be aware of the evidence to this Inquiry about the severe shortcomings in record-keeping, and about the retention of records. The awarding body must not refuse applications on the basis of a consideration of best practice at the relevant time, but recognise that in many instances record-keeping fell far short of that.

e. Applicants should be able to reapply for additional / increased payments, in particular where there is a significant change in their condition or prognosis.

113. Provided the Information Commissioner's Office has no objections, there should be automatic data sharing between the Infected Blood Support Schemes, the Alliance House Organisations (insofar as they continue to hold any data), and the new scheme. Russell Cooke and other scheme administrators, if any, should write to all applicants of previous schemes who have not been moved to the Infected Blood Schemes. Applicants to all schemes (including rejected applicants) should be contacted directly and encouraged to apply to the new scheme.

114. As in Ireland, we consider that it would increase faith in the new scheme to have a monitoring body created which is responsible for ensuring that any future compensation scheme and associated support services are appropriately rolled out and do not recreate the issues seen with earlier schemes. Such a body must include representation from patient groups, especially the Hepatitis C Trust, the Haemophilia Society and the Hepatitis B Trust, as well as having meaningful infected/affected representation.

115. As set out further in our non-financial compensation recommendations, potentially eligible individuals should be informed of the new scheme by their GP and other relevant clinicians and details of the scheme should form part of their retraining.

116. An effective nation-wide media campaign should be run to highlight the new scheme and information about it should be prominently displayed on the NHS webpage.

Recommendation 3: Form of Awarding Body

a. It should be an independent ALB, created in collaboration with IAP. The approach to compensation should similarly be co-produced.

b. Awarding panels should include legal, medical and infected/affected representation;

c. Applications should be simple, with the lowest possible evidential burden placed on them. The production of medical records must not be a precondition to eligibility. The ALB should be able to obtain evidence independently from third parties.

d. There should be a right of appeal to an independent Tribunal sitting within HMCTS;

e. There must be free legal representation and advice throughout the process;

f. The scheme should avoid being adversarial and the lower standard of proof should be applied;

g. The scheme should be UK-wide;

h. The ALB and / or Tribunal should have access to expert evidence but applicants should not bear the cost of this;

i. If possible, there should be automatic information-sharing between previous trusts and schemes and the new awarding body;

j. There should be a monitoring and consultative body with representation from patient groups and infected/affected individuals which is responsible for overseeing the implementation of the new scheme and reporting on this to government.

Social and non-financial support

117. It is well-recognised that the UK benefits system can be hostile and byzantine to navigate. The awarding body responsible for delivering compensation should support applicants to access comprehensive welfare services, including housing, income support, and social care. This should encompass advocacy services in appropriate cases. That advocacy service should not be limited to public sector benefits but also should facilitate access to financial support from the private sector, including banks.

118. Some core participants have struggled to access benefits due to a lack of understanding of HCV on the part of officials working for the Department of Work and Pensions. Relevant healthcare assessors assisting in benefits decision-making should have a working understanding of HCV and of the support which IAP receive. A number of our core participants have faced difficulties in receiving the benefits to which they are entitled as officials within the DWP were not aware that the support from the Trusts and Schemes should not be off set against benefits. It is essential to ensure that adequate information is disseminated to decision makers.

119. We further invite the Inquiry to recommend that the UK emulate Ireland in providing access to life insurance, mortgage insurance and travel insurance by acting as an underwriter to allow IAP to access insurance on a '*level playing field*' with other customers.

120. We invite the Inquiry to recommend that the UK also follow the model of Ireland in making a number of further services available to infected individuals for free. Mr O'Mahoney explained that Irish victims of the infected blood scandal receive:

a. Free dentistry and optometry services;

b. Free hearing tests and hearing aids;

c. Free physiotherapy;

d. Free complementary therapies, including massage, reflexology, acupuncture and other services.

121. Ireland represents a clear case of best practice in supporting recipients of infected blood or blood products and their families. Mr O'Mahoney was clear about the success of the Irish programme and we consider it provides a strong model for the UK to emulate. One of the key aspects of the Irish scheme was the role of liaison officers, which Mr O'Mahoney described as "*crucial*".[1708] We consider that liaison officers should be created to support IAP in accessing the support and services to which they are entitled.

[1708] Transcript, 08/11/2022, p. 60, l. 2.

122. We invite the Inquiry to recommend that these services all be made freely available to IAP. We also consider that free prescriptions would be appropriate.

123. We invite the Inquiry to consider recommending a scheme similar to the 'Health Act Amendment Card' in Ireland, which would allow for the facilitation of joined-up care, and also to consider recommending that specific timed clinics be arranged for infected individuals, which would support greater focus on their unique needs.

124. We recommend that free domiciliary support and social care services be provided to those infected and recommend consideration of this being extended to the affected. Various means of providing such services could be arranged, whether by way of being "passported" in the continuing healthcare framework, by excluding someone's income from assessment under the Care Act 2014 and the Statutory Care and Support Guidance, or by the provision of services via the schemes/any compensation framework.

Recommendation 4: Social and non-financial compensation

a. All applicants for financial compensation should be offered comprehensive welfare rights advice and advocacy;

b. IAP should be supported to access life, travel, and mortgage insurance on a level playing field;

c. Adequate information should be supplied to DWP to ensure that IAP are not wrongly excluded from benefits;

d. Infected individuals should have free access to dentistry, optometry, hearing tests and aids, physiotherapy and complementary therapies;

e. Infected individuals should have free access to social care and domiciliary support. The Inquiry is also invited to consider extending this to affected individuals.

f. The Inquiry should consider whether to recommend the introduction of a scheme similar to the Irish Health Act Amendment Card, including facilitation of joined-up care and specific timed clinics for holders.

CHAPTER 8: GOVERNMENT

"Nothing like this should ever happen again. I would like the government to acknowledge the lives that have been ruined and to apologise"[1709]

Introduction

1. The infected blood scandal, and the totality of harm and suffering experienced by our CPs, was caused by a complex mix of actions and failures to act during the Relevant Period by various Governmental, NHS and other public bodies, as well as individual medical practitioners. These individual and systems failures are explored in other chapters in our submissions. Ultimately, however, it is central Government that is responsible for the health and safety of its citizens, and patients who use NHS services, and thus for the mass administering of infected blood and blood products ('infected blood in this chapter includes infected blood products). Its specific responsibility is explored in this chapter.

2. The Government response to the infected blood scandal can be described, in the words used in the Cumberledge Review, as *"disjointed, siloed, unresponsive and defensive."*[1710] In particular, we submit that the approach of central Government, including the Department of Health (as it then was) to the issue of infected blood showed institutional inertia; failure to critically examine and consider policies; decision making based on factual inaccuracy; lack of corporate memory; poor record keeping; unnecessary deference to clinicians; an obsession with legal liability; an unnecessary focus upon opening floodgates; and extreme defensiveness in decision making, policy design and implementation. This defensiveness led to there being no Government apology until 2015 and no public UK-wide Inquiry ordered until 2017. This tragedy has shown that the spirit of openness and transparency, enshrined in the seven Nolan principles of public life, are not always followed in practice.

3. We submit that the approach of Government to the issue of infected blood was characterised by the protection of its reputation rather than one which sought to

[1709] GRO-D

[1710] EXPG0000047_0046.

understand what happened and why, and how to improve the system. To that end, it significantly exacerbated any harm caused already by being infected. Even when stark evidence of the unfolding tragedy was put before Ministers and senior civil servants, the need to protect the group triumphed over the necessity of providing answers to those infected and affected (infected in this chapter includes affected). The Government, responsible for the NHS, failed in its duty to protect patients (and those affected as a consequence) and to maintain confidence in the healthcare system.

4. Other reports (e.g. The Mid Staffordshire NHS Foundation Trust Public Inquiry)[1711] have emphasised the need for leadership which recognises the reality of the care that is being provided to patients. There was inadequate leadership on the issue of infected blood throughout the health system, including within central Government. It was dealt with at a relatively junior civil service level[1712] but should have been allocated to a senior team tasked with resolving problems. These civil servants did not question or query received wisdom or seek to change the position to reflect circumstances as they emerged. Some former Ministers[1713] who gave evidence to the Inquiry and who recognised the tragic nature of the infected blood scandal, were often ineffective while in post. The approach of both civil servants and Ministers were demonstrative of failings of the culture of Government.

5. The female CPs we represent faced institutional sexism in their treatment and in the clinical responses throughout the NHS.[1714] This discrimination, we submit, was facilitated by the fact that there was little to no focus on the particular needs of women in the provision of health treatment throughout the Relevant Period.

6. As the Inquiry has recognised, whilst it has sought to hear from a range of voices of those from minoritised ethnic groups, it has received only limited evidence and has been unable to properly examine issues of structural racism in treatment and care. What evidence has been obtained suggests that there has not been a focus by the

[1711] RLIT0001757.
[1712] Rowena Jecock WITN0823; Transcript 13/07/2022, p2, l9 – p3, l17. Richard Gutowski WITN5292, Transcript 10/06/2022, p17, ll16-25.
[1713] For example Baroness Virginia Bottomley WITN5289001 Transcript 28/06/2022; Alan Milburn WITN6942001 Transcript 14/07/2022.
[1714] Explored in the chapter on the Role of Medical Practitioners in particular.

Government and the NHS upon the particular needs of those from minoritised ethnic groups, and a paucity of treatments for conditions that particularly impact these groups. For example, less money has historically been invested and research undertaken in relation to sickle cell disease.[1715] The Health Disparities Unit has a focus upon such inequalities, but its creation is recent. We submit that the Inquiry should ask for further research to be undertaken about blood and bleeding disorders and access to treatment on the grounds of ethnicity, to examine how and why historic disparities have arisen. It is disappointing that the Inquiry did not choose to instruct an expert in this area.

7. As has been explored in other chapters,[1716] we submit that the Government's failings included:

   a. The lack of focus by central Government on those infected with HCV via transfusion of blood and blood products has meant an absence of data collection, information, public education, awareness campaigns, and, crucially, thought given to their psychological and physical needs.

   b. There was a dearth of Ministerial awareness of non-A non-B hepatitis and later HCV during the 1980s and well into the 1990s. This should have been drawn to their attention by clinicians and civil servants who knew of the risks of transmission and the need for public health campaigns about this virus.

   c. The lack of priority given to HCV led to the Government failing to urge clinicians to make decisions quickly in respect of the introduction of HCV testing, which was delayed, as is explored in the chapter on Blood Services.[1717] Surrogate testing could and should have been introduced and the failure to discuss this with Ministers was wrong.[1718] There was an excessive focus upon damaging the donor base which overrode other considerations.[1719] Those who were in post at the relevant time did not consider that testing was delayed and have not altered their

[1715] Professor Dame Sally Davies, Transcript 03/03/2022, p40, l1 – p45, l21.
[1716] Please see the chapter on Impact.
[1717] Please see the chapter on the Role of Blood Services.
[1718] Dr Boulton was firm in his view about this, PRSE0001562; Dr Rejman in his oral evidence said that this letter provides "*no science*", Transcript 11/05/2022, p118, ll12-13.
[1719] For example, NHBT0000061_148.

view; for example, Dr Pickles was firm.[1720] It also appears that the CMO agreed to delay lookback over a longer period of time because treatment was not going to be practically available for everyone who was diagnosed.[1721] There has also been a failure, continuing to date, for central Government to undertake an exercise to identify those missed by lookback, in particular women who had blood transfusions during childbirth, and encourage them to take a test, or to provide testing as routine. A national strategy for HCV was only put in place in 2004, when it could have been implemented in the early 1990s.[1722]

d. For HBV, central Government failed to recognise that significant numbers of post transfusion cases occurred even after screening was introduced in the 1970's. This was despite it being well known by clinicians working in blood services that the screening often did not detect an active virus in a donation. Central Government failed to ensure that the most sensitive tests were widely available as they were developed, or to consider earlier if some form of general screening or vaccination of the public should be rolled out.[1723] HBV vaccination for the general population was only approved in 2017.

e. We rely upon the presentations made by Counsel to the Inquiry about the development of the knowledge of risk of HIV in the UK and upon the development of testing and screening facilities. However, as set out further in our chapter on haemophilia clinicians, in the early 1980s the Government did not take adequate steps to prevent the unfolding pandemic, despite knowing that the risk was palpable and significant. Whilst there is always a balance to be struck between causing public alarm and providing information, it is submitted that the public line presented was factually inaccurate and knowingly misleading. The Government did not follow the advice to withdraw blood products or to advise that alternatives should be offered, especially in cases where factor 8 was not considered to be

[1720] Dr Hilary Pickles stated that if public health principles were adopted when examining HCV tests in the early 1990s they would fall at the first hurdle as the cost/benefit analysis would not be made out as the *"tests were hopelessly unreliable"* and the decision was not *"finely balanced"*, Transcript 12/05/2022, p134, l19-24.
[1721] Sir Kenneth Calman WITN3430001, §§56.3 - 56.7
[1722] Caroline Flint, WITN5427001, §§5.4 – 5.5.
[1723] Sir Kenneth Calman WITN3430001 §12.41: This was not considered until 1996 when a new UK-wide National Screening Committee was set up to advise on new and existing screening programmes. In its first year it recommended, amongst others, screening antenatally for HBV susceptibility.

absolutely essential.[1724] Nor did the Government provide advice to clinicians as to the wisdom of continuing with the administration of imported and/or commercial blood products. The decision was left entirely to clinicians, who were dependent upon the UKHCDO's often misleading guidance. The Government could and should have made decisions about the use of blood products which reflected the precautionary principle. Even when Professor Rose during the course of the HIV litigation criticized the Department's failure to increase UK supplies of Factor 8, this was not accepted by the Department and his evidence was criticized as not carrying much weight because of his field of expertise.[1725]

f. There was unnecessary delay in the implementation of donor exclusionary measures, explored in more detail on our chapter on blood services.

g. There was undoubtedly a moral panic about HIV in the UK, much of which was led by bigoted attitudes present in society, and amongst government, at the time.[1726] The institutional distaste in some quarters to running effective and frank public health campaigns about HIV undoubtedly stemmed from homophobia and a stigma around injecting drug users. There is a variety of views amongst our CPs as to whether the 'Don't die of ignorance' campaign exacerbated the prejudice and hatred directed towards them within their communities. For some, the high-profile nature of this campaign led to greater understanding; for others it led to greater awareness but also to more hatred and discrimination. There was a tussle between those who favoured an open and honest approach, which included the CMO and some Ministers, such as the Secretary of State of Health, Norman Fowler,[1727] and others. Those wishing to present the clear and frank material did eventually succeed, but the institutional resistance to their approach delayed its rollout. The evidence given to this Inquiry by Ministers, officials, clinicians, and those working in public health was that the public health campaigns in the 1980s were effective and resulted in the spread of HIV in the United Kingdom being less disastrous than it could have been. Unfortunately, that was of little use to those

[1724] Letter from Nicol S Galbraith CBLA0000043_040.
[1725] Professor Rose report, MHRA0017604, p149,l12 - p150, l2.
[1726] Dr Pickles, Transcript 12/05/2022, pp66-67, ll10 – 15.
[1727] Transcript 22/09/2021, p14, l21- p15, l1.

upon whom this Inquiry is focussed where transmission, in the majority of cases, would have taken place before 1985.

h. There was delay in introducing screening of donations for HIV because of the need to ensure that GUM/STI clinics and other organisations could provide their own tests. This is explored in more detail in our submissions on the Role of Blood Services.

i. As set out in the chapter on Trusts and Schemes, despite an outcry by those infected, their families and friends, and a clear sense that something should be done to help those, whom as the statistics experts showed had exceptionally high rates of death (some 85% of all those infected with HIV with bleeding disorders have died from HIV),[1728] the Government had to be dragged to make any financial redress at all, and even then only relatively small ex gratia payments were made available. At every stage payments have been grudging and parsimonious to the point of miserliness, and the operation of the trusts and schemes was bedevilled by difficulties. The refusal of the Government to accept redress other than in cases of negligence was wrong. Payments to those infected with HCV were subject to intolerable delay and procrastination by officials and Ministers, based upon at best a misunderstanding of the factual picture or, at worst a stubborn refusal to accept the factual picture, as is explored in the Trusts and Schemes chapter.

8. As damaging to our CPs was the refusal to examine, interrogate or understand what went wrong, and why. That is inexcusable. A public Inquiry should have been initiated in the mid to late 1980s in respect of infected blood, or at the latest by the mid-1990s when it became clear that HCV was a significant and often debilitating illness. The Government had many opportunities to take this step, not least when the Archer and Penrose Inquiries were started, these could have been converted to a statutory public Inquiry or a UK wide Inquiry respectively. Our CPs rely upon the presentation by CTI which sets out the various documents and information which show the response in all four nations to calls for a public Inquiry.[1729] The failure to undertake a public Inquiry before 2017 demonstrates, in our submission, the need for a body independent of

[1728] EXPG0000049, p3.
[1729] Presentation not yet disclosed.

that potentially subject to criticism to make decisions on this issue, rather than a Department being judge in its own cause.

9. Our CPs submit that the successive Governmental failure to address the contaminated blood scandal by way of an independent public Inquiry was caused by the purposeful dismissal of the voices of those who had been infected and affected. Listening to those voices would have entailed a direct confrontation and acknowledgement of mistakes that had been made and pushed hard against the "*firmest of Government lines that had been established*"[1730] over a sustained period; that nothing had gone wrong, and that "*there were no more lessons to be learned*".[1731]

10. This chapter addresses:

    a. Why, in our submission, the Government's handling of those infected and its policy responses went wrong.

    b. The failures of decision-making on the part of DHSC, including a defensive culture (which is closely connected to the matters considered in a.);

    c. The ongoing need for candour in clinical settings; and

    d. Record keeping in central Government and the NHS.

Why did things go wrong?

11. Our CPs would suggest that the following underlying features contributed to decision making failures:

    a. Prioritising reorganisation above good policy.

    b. The lack of a national body with executive powers responsible for blood.

    c. An undue deference to clinicians' individual decision making rather than public health.

    d. The time committed and centrality given to societal sensitivities and prejudices led to a delay in implementing public health campaigns.

    e. The dysfunction within central Government, including a lack of long-term leadership; and

[1730] Andy Burnham, Transcript 15/07/2022, p119, ll5-6.
[1731] Ibid, p118, l13.

f. A failure to prioritise blood safety.

12. The public health and administration experts identify a number of current concerns and problems with the health system.[1732] Our CPs ask the Inquiry to concur with these conclusions as evidence of them has emerged in a number of instances within this Inquiry.

Reorganisation as the central political priority

13. The continual reorganisation of the NHS often took priority over policy decisions within central Government, and thus occupied the time and resources that could have been devoted to considering the issue of blood and blood policy or designing appropriate policies to manage the care and treatment of those who had received infected blood. Ministers and Secretaries of State who gave evidence identified the amount of time that these reforms took, in Parliamentary terms, thinking, policy making and development.[1733] At least one witness indicated that taking through these large pieces of legislation and being expert in the machinery of Government led to them being appointed Minister.[1734] In particular, the passage of the NHS and Community Care Act 1990 through Parliament, which created an internal market in the NHS, happened at the same time as HCV testing was being discussed. This was a very heavily contested piece of legislation and therefore took up a significant amount of time,[1735] which could and should have been devoted to considering issues surrounding HCV testing.

14. The changes in the organisation of the NHS have been significant: from local health authorities to regional hospital boards with family practitioner committees, to Regional Health Authorities, through to Primary Care Trusts, NHS Trusts and NHS Foundation Trusts, Clinical Commissioning Groups and now to Integrated Care Boards ("**ICB**"), the creation of NHS England and NHS Improvement. As a result, a vast amount of management time and resource throughout the Department of Health, the NHS

[1732] EXPG0000047, p21 – 23.
[1733] See for example Lord Kenneth Clarke, Transcript 29/07/2021, p5, ll12-15.
[1734] Baroness Gloria Hooper gave evidence that she was chosen to become a Minister because she had put through two previous large pieces of legislation in the House of Lords, Transcript 30/06/2022, p8, ll17-25.
[1735] Ibid, p12, ll23-25, p13, ll1-10.

Executive, NHS bodies and in each and every hospital, commissioning group, and GP surgery has been consumed without clear patient benefit or any discernible improvement in the NHS. Further, these ongoing changes in structures and processes has led to an absence of joined-up thinking. That some services are commissioned locally and some nationally, and mental health services commissioned separately to physical health services, has a direct impact on those infected accessing treatment and care via the NHS.[1736] By way of example of current failings, in England there is no commissioning of specialist mental health services for those infected, in contrast to Scotland, Wales and Northern Ireland, where these services are available.[1737] This is the direct failure of central Government. Central government inadequacy or inertia in this area was borne starkly from the evidence of NHSE's Dr Stewart on 11.11.2022.[1738] During this evidence the Inquiry heard that such specialist psychological support had still not been put in place in England, despite being accepted in principle as required in February 2020.[1739] NHS England identified that further research is being undertaken[1740] without seemingly having worked with the devolved nations or sought to learn from their services.

Lack of a national body responsible for blood

15. Until the formation of the National Blood Authority as a Special Health Authority in 1993, there was no national body which dealt with the donation of blood and its distribution for clinical use. In the chapters on Self-Sufficiency, Fractionation and Pharmaceutical Companies and the Role of Blood Services we identify how as a result of the fragmentation of services across nations of the United Kingdom, and the absence of any direction in statutory form, there was no way that regional transfusion services – or the national services in Northern Ireland, Scotland, South and Mid Wales - could be the subject of anything other than influence or exhortation by the NHS Executive and the Department of Health. This was a major oversight which led to a lack of co-ordination and an inability to effectively plan on a UK-wide basis.

[1736] See the Impact chapter.
[1737] Specialist Psychological Support Panel Transcript 11/11/ 2022, pp77-78.
[1738] Ibid, pp77-78, ll8-10.
[1739] WITN4688055.
[1740] Transcript 11/11/ 2022, pp135-136, ll11-4.

16. The absence of a national blood authority with executive powers until 1993, and of a statutory requirement on the Secretary of State for Health to organise and prepare blood and blood products on a national basis, led to a fragmented regional approach to the maintenance of the blood supply and the delivery of blood and blood products. There was no overarching direction and control of this supply by the systems steward, the Department of Health. Scotland and Northern Ireland made entirely their own arrangements. Different sums of money were spent by regional health authorities on the distribution of blood and blood products.

17. The absence of a national body meant that blood from Scotland, which would have been safer than the alternatives, was not used in England when it could have been. The production facilities in Scotland could have been scaled up to meet the shortfall whilst the BPL factory was being commissioned. The absence of central planning and oversight meant that patient safety was compromised.[1741]

Deference and clinical freedom

18. Like the rest of society, those working in central Government were deferential to clinicians until the twenty first century.[1742] We deal with deference to clinicians in the Role of Medical Practitioners and Haemophilia and Clinicians chapters, but this attitude was also true of those in central Government. This meant that there was insufficient interrogation of what was happening on the ground, in particular regarding patient consent to treatment. Furthermore, there was no central body until at least the 1990s tasked with providing oversight, audit, guidance, or to maintaining consistent standards across clinical settings, or even to providing intelligence on a systemic basis.

19. Clinical freedom was assumed by the Department of Health during the 1980s and 1990s. As was suggested by the oral evidence of Dr Pickles, a Principal Medical Officer in the 1980s, the NHS had no powers to limit the actions of clinicians other than to

[1741] See further the Self-Sufficiency, Fractionation and Pharmaceutical Companies chapter.
[1742] As confirmed by Lord Crisp who had worked in the NHS as a Chief Executive before joining the Department of Health, described a "*culture of deference to clinicians*" during his time working in the NHS; Lord Nigel Crisp Transcript 12/09/2022 p11, ll4-16.

restrict access to treatment by refusing to fund it.[1743] Ministers agreed that their view was that it was the right of clinicians to choose treatment.[1744] In fact, Sir Kenneth Calman described the Department as no more than a "*clearing house*" for decisions about treatment in the late 1980s.[1745] We submit that as the issues with infected blood became apparent, the continued laissez faire attitude demonstrated a trust in clinical judgment which could be considered to be, at the very least, naïve. As Dr Pickles said in evidence:

> "*Clinical freedom enabled advances to be made, but also enabled others to fail to keep up with best practice.*"[1746]

20. More fundamentally, the adherence to clinical freedom led to a reluctance to both promulgate advice on aspects of blood safety during the 1970s and 1980s, and also to disseminate any clinical guidelines prior to the institution of NICE in 1999. Our CPs would suggest that the absence of guidelines meant that there was an inability to promote good standards consistently. Furthermore, as can be seen in the Role of Blood Services and the Role of Medical Practitioners chapters, this lacuna meant that there was wide variation in practice without an ability to provide a baseline of what was appropriate. For the Royal Colleges, whilst the production of guidelines was undoubtedly important, the evidence to this Inquiry is that this work often took 3-4 years to be produced (in the case of the use of interferon the process started in June 1996 but the guidelines were not published until 1999)[1747] which is an excessive period of time given the urgent need for treatment.

21. There is no evidence that the CMO considered that it was their role to lead clinicians during the time in question, by identifying what treatments should or should not be provided or by defining appropriate professional standards. Their role was seemingly not to line manage doctors, with the only way to get them to change their practice

[1743] Transcript 12/05/2022, p44, ll18-21.
[1744] David Mellor Transcript 19/05/2022 p198, ll11-15.
[1745] MHRA0017634.
[1746] Transcript 12/5/2022, p51, ll16-17.
[1747] Sir Kenneth Calman WITN3430001, p62.

being by way of influence or funding.[1748] The evidence demonstrates that the idea of clinical freedom was widely considered to be essential and was an *"important and respected principle."*[1749] Sir Kenneth Calman identified that *"one of the most important functions of the CMO was to develop and maintain links with the medical profession."*[1750] It is submitted that the CMO should have taken a more active role in providing advice and guidance to doctors as part of the discharge of his function regarding health improvement and health protection, specifically in relation to HCV but also HIV .[1751] Dr Walford in her evidence identified that a "Dear Doctor" letter could and should have been written by Dr Acheson before 1985 to all clinicians . [1752]

22. It can fairly be said that there is still tension in the CMO role; Professor Sir Jonathan Van Tam identified that operational instructions to NHS bodies should have been communicated via NHS England, as he considered that it was not right for the CMO to intervene in terms of command and control within the NHS system.[1753]

23. The absence of national guidance in respect of policy regarding hepatitis and the use of blood meant that valuable opportunities were missed to disseminate information, reinforce good practice, and promote changes in culture. Dr Murphy described how vital the CMO was in ensuring that the BBT Initiative recommendations were escalated directly to senior management in Trusts and to leaders of national organisations, in order to give a profile to transfusion issues.[1754] We submit that this CMO intervention was effective and should have occurred at an earlier point in time.

[1748] Dr Hilary Pickles Transcript 12/05/2022 p44, ll18-23; Dr Acheson in the BSE inquiry MHRA0011433; INQY0000362, pp. 32; Kenneth Clarke WITN0758012, pp. 33- 36.

[1749] INQY0000362, §§32-34; Kenneth Clarke WITN0758012 §70.5; Lord Fowler WITN0771001 §8.19.

[1750] WITN3430001 §4.5.

[1751] David Mellor identified that *"The Chief Medical Officer wouldn't really play a part in [issuing guidance]. The Chief Medical Officer was available to deal with issues and, I increasingly thought, to deal with issues where public confidence turned on the authority of the person who was giving the advice. And I took the view that the more the CMO could do the better, because he was someone who automatically commanded respect and no one thought he had some ulterior political motive. So as far as actually managing the NHS, I mean, that was always going to be a subject of controversy, but he wouldn't have done a lot of that"* Transcript 19/05/2022, p. 200, l. 7-18. See also Sir Kenneth Calman WITN3430001, §§25.3; 42.15; 70.10.

[1752] https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Wednesday%2021%20July%202021%20%28Dr%20Diana%20Walford%20Continued%29_0.pdf p187, l1 – 188, l19.

[1753] Professor Sir Jonathan Van Tam Transcript 18/11/2022 p 20 l.25 – p21 l.15

[1754] Dr Murphy Transcript 24/02/2022, p142.

The relationship between doctors and Ministers – the CMO, the expert committees and the decision maker in central Government.

24. The issue of deference can also be seen in the relationship between Ministers, civil servants without medical qualifications, expert advisory groups and the CMO, especially during the Relevant Period. Ministers and civil servants typically have no clinical qualifications or expertise. They rely upon clinicians to give them advice on these areas.[1755] The role of the CMO was as principal Government medical adviser, and the head (until 1995) of the medical civil service. The role also required the provision of independent advice on public health issues, recommending policy changes, and providing information to the public on health issues of public concern.[1756]

25. The sheer scale and responsibility of the role of the CMO seems to have no equal in Whitehall. In the Whitehall hierarchy they are the equivalent to a permanent secretary. Diana Walford's evidence was that they could have access to Ministers whenever they required, and both civil servants and Ministers could communicate regularly with them[1757] (as continued during the Covid Pandemic).[1758] The CMO relied upon the Deputy Chief Medical Officers ("**DCMO**"). Professor Sir Kenneth Calman in his fourth witness statement, referred to an extract from his autobiography, in which he wrote that "*the CMO is effectively at the head of a medical intelligence operation and in theory should be relied upon to have his or her finger on the pulse of new developments. In practice, this isn't always possible.*"[1759] It appears from Professor Sir Calman's evidence and contemporaneous documentary material that Dr Metters, the

[1755] Lord Fowler WITN0771001, §0.30.
[1756] As described by Norman Fowler WITN0771001, pp8.14 – 8.15. It is also echoed in the BSE report MHRA0031996, p36, pp 4.18 – 4.19; INQY0000362; Sir Kenneth Calman WITN3430001.
[1757] WITN4461001, p15; The BSE report sets out the scale and responsibility of the role of CMO MHRA0031996 pp4.18 – 4.19; John Patten speaks of having coffee with Sir Donald Acheson Transcript 20/05/2022, p16, l. 15-20 and his "*openness*".
[1758] Professor Sir Jonathan Van Tam Transcript 18/11/2022 p13, l24 – p14, l11.
[1759] Professor Sir Kenneth Calman WITN3430001, §4.3.

DCMO, dealt with the vast majority of issues relating to infected blood during his time in office.

26. Both the CMO and DCMO were very heavily reliant on the expert advice they received on specific issues from various committees, for example the ACVSB, which from 1989 was seen as having the primary role of providing advice which would then be given to Ministers.[1760] The CMO and DCMO relied also on appointed advisers to the Department of Health with whom the medical officers could consult. Dr Gunson was the chosen specialist in respect of blood transfusion from the mid-1980s onwards according to Dr Pickles,[1761] but he was also on all the relevant advisory committees at that time. The Government should have sought a wider range of views, particularly in areas of emerging risk in order to avoid complacency and groupthink. Moreover, any committee should represent a range of views, especially where there is no consensus in the medical community on a given, evolving issue. The DCMOs and others did not seek input beyond their advisory bodies, to explore broader clinical or public health views.

27. Some Ministers and secretaries of state have indicated it would have been "*unthinkable for a politician to act against their [CMO's] medical advice*"[1762] in the 1980s and 1990s. Professor Sir Calman identified that Ministers were "*respectful of clinical advice and would follow it.*"[1763] It was therefore particularly important, it is submitted, for the CMO to have taken an active lead in respect of both HIV and non-A non-B hepatitis, HCV and HBV. Sir Donald Acheson wrote 3 Dear Doctor letters about HIV/AIDS. No such steps were taken by the CMO in respect of HIV/AIDS prior that time.[1764]

28. Ministers cannot be expected to have known of matters that they were not informed of by the CMO. Dr Pickles in her evidence explains that whether something went to the CMO was, prior to 1995, principally a decision for the DCMO or senior

[1760] Ibid, §28.4.
[1761] Transcript 12/05/2022, p42, l7-12.
[1762] Lord Fowler WITN0771001, §0.30.
[1763] Sir Kenneth Calman WITN3430001, §25.3
[1764] INQY0000362_0011 – 0012.

administrative civil servants.[1765] The evidence presented to the Inquiry paints a picture of Dr Yellowlees[1766] having limited interest in the Department generally and not having an active presence (at least in comparison to Sir Donald Acheson whose energy was remarked upon by all those who spoke of him in their evidence to this Inquiry). John Patten (then a Minister of health from 1983 – 1985) could not recall meeting Dr Yellowlees.[1767] Dr Pickles agreed with the evidence she had heard that Dr Yellowlees was a remote and disengaged figure.[1768] Indeed, the absence of documentation and information relating to his time in office in and of itself suggests that Dr Yellowlees was not as engaged as he should have been. Dr Acheson's focus upon HIV appears to have arisen only from late 1984.[1769] The reason for this apparent delay appears to have been addressed in Sir Donald Acheson's autobiography, namely, that once it was established that HIV was rapidly spreading in the heterosexual population[1770] and was therefore no longer confined to the homosexual population, it became a general public health risk. We submit that any such understanding would of course have been steeped in prejudice and naivety.[1771]

29. The absence of oversight from the CMO allowed the no conclusive proof line to be used[1772] in respect of AIDS being transmitted by blood, which was circulated in a key briefing to Ministers, crucially without the caveat drafted by Dr Walford.[1773] In evidence several Ministers and officials have agreed this was poor drafting, if not actively misleading.[1774] Lack of oversight also led to the failure in May 1983 to communicate to either the CMO or to Ministers the advice from Dr Galbraith, who was a very senior figure in public health at the time, to withdraw all products which could have been made with blood donated by US patients since 1978.[1775] The

[1765] WITN6965001, §12.2 – 12.3.
[1766] Accurately summarised in the presentation to the Inquiry at INQY0000362_0028.
[1767] John Patten Transcript 20/05/2022, p37, l22.
[1768] Transcript 12/05/2022, p40, l12-16.
[1769] INQY0000362, pp104 onwards.
[1770] Sir Donald Acheson *One Doctor's Odyssey The Social Lesion* WITN0771088, pp183 – 184.
[1771] Ibid and as cited in the Inquiry presentation INQY0000362_0038.
[1772] DHSC0001651.
[1773] DHSC0002229_019.
[1774] Lord Fowler, Transcript 21/09/2021, p148, ll7-20; p149, ll10-25. Diana Walford, Transcript 21/07/2021, pp157-158, ll7-10.
[1775] DHSC0002227_021; CBLA0000043_040.

Secretary of State, Norman Fowler, made it clear that he would have expected such a letter to have been discussed with the CMO and to be raised with Ministers.[1776] Lord John Patten identified that had this letter been seen, the Ministers would have "*pressed the panic button*".[1777] It was clearly a significant error for Dr Galbraith's letter to have gone unnoticed.

30. In addition, Ministers were not given information from relevant advisory committees in 1983 by the CMO or his team, which could have made a significant difference to the approach to blood at that time.[1778]

31. In respect of non-A non-B hepatitis/ HCV, there seems to have been a view in the department that all clinicians knew and would have provided information about the risks of non-A non-B/HCV to patients before or during treatment.[1779] Second, clinicians and officials were of the view that this virus did not necessarily have long term consequences.[1780] There was little or no attempt by the ACVSB or by officials to raise with Ministers a discussion of the introduction of surrogate testing, and the evidence given (albeit given from a long distance of time and based upon reconstruction from the documents) suggested that Ministers were not told of the international position in respect of HCV testing in any significant detail. The issue certainly does not seem to have been "*underlined*".[1781] The slippage of the date for rolling out HCV testing from July 1991 to September 1991 was also not brought to Ministerial attention.[1782]

32. Having information about the debate and discussions which led to their decision making would have been helpful for Ministers to understand why they were being advised to choose certain option over others. This is particularly important in considerations around public health. Whilst Ministers are not technical experts, part of their responsibility is to be accountable to the public for the decisions taken. To

[1776] Lord Fowler Transcript 21/09/2021, p158.
[1777] Sir John Patten evidence, Transcript 20/05/2022, p89, l19-25.
[1778] DHSC0002227_021; CBLA0000043_040; Lord Fowler Transcript 21/09/2021, p158; Lord Patten Transcript 20/05/2022, p23; PRSE0000372 R(83)8 – Committees of Ministers 23 June 1983; Lord Glenarthur Transcript 22/07/2021 p8.
[1779] Lord Horam Transcript 29/06/2022, pp101-108.
[1780] DHSC0006348_055.
[1781] Lady Hooper Transcript 30/06/2022, p91, l3-4.
[1782] Lady Hooper Transcript 30/06/2022, pp113 - 118, although she was told that the Newcastle RTC had started anti HCV testing NHBT0000062_053.

that extent, it is suggested that issues about the implementation of HCV testing in particular should have been the subject of discussions between Ministers and their officials.

33. While Professor Sir Jonathan Van Tam identified that the role of the CMO would not necessarily have been to talk to particular cohorts of patients about risk,[1783] in our submission, inadequate steps were taken by successive CMOs to identify and inform the public about the risks of transfusions, blood products, and the availability of testing. These issues are set out in more detail in the Role of Medical Practitioners and the Role of Blood Services chapters.

Public health, stigma and shame

34. There is no need to rehearse the bigotry, discrimination and unkindness meted out to those infected with HIV/AIDS, HCV and HBV by society, as is set out in greater detail in the Impact chapter. Elected politicians and officials reflected the views of broader society, which was riddled with institutional homophobia and with a less open attitude towards sex and sex education. There was a widespread fear of how AIDS could be contracted, and a moral panic about homosexuality. NANB hepatitis and HCV were not as well known by the general public and therefore by politicians, and if known, seem largely to have been associated with injecting drug users.

35. Attitudes towards HIV and AIDS amongst Ministers varied. Lord Fowler, as described both in his evidence and the evidence given by others, was progressive, but some Ministers held regressive attitudes and wanted to detain infected people, withhold clean needles, and engaged in "*empty moralising*".[1784] Evidence from those in Ministerial positions at the time identifies that Mrs. Thatcher, the then Prime Minister, wanted to have some form of "*moral indignation about AIDS*" and would "*harrumph*" about this, but the Secretaries of State and Ministers in post at the time could "*handle her*".[1785]

[1783] Professor Sir Jonathan Van Tam Transcript 18/11/2022, p22, l15 – p23, l2.
[1784] David Mellor Transcript 19/05/2022, p40, l18; Dr Pickles Transcript 12/05/2022 p67, ll16-24.
[1785] David Mellor Transcript 19/05/2022 p 31, ll9-22.

36. There is no doubt that Government campaigns which spoke about sex between men, drug use, and wearing condoms was something that was challenging to some people within Government (the last public health campaign of a similar nature was during the Second World War to avoid large scale syphilis and gonorrhoea outbreaks). These health campaigns were therefore subject to greater scrutiny and oversight by Ministers than others would have been.[1786] Lord Patten in his evidence[1787] identified that between 1983 – 1985 the sensitivity of the issues meant that leaflets sent out to potential blood donors had to be examined by Ministers, which caused a significant and unnecessary delay in their publication.

Ministers, civil servants and the making and execution of policy

37. The complex mechanics of Government decision making contributed to the delay and inertia in addressing a number of issues related to infected blood.

Blood and its importance as a political priority

38. The blood team was headed by a mid-ranking civil servant (Grade 7), who reported to either the CMO or the DCMO, depending on the period in question and to a director in the administrative hierarchy. The team was too small for the issues it had to deal with, and this also led to delays in returning correspondence.[1788]

39. Whilst there were periods of time when the Secretary of State and Permanent Secretary were copied in or directly involved in decision making (usually concerning funding for *ex gratia* payments or litigation) they were not routinely consulted about blood policy issues.[1789] For example, the Secretary of State was not consulted in relation to decisions about the introduction of HCV testing;[1790] that decision was made

[1786] This is also likely given that homosexuality was only decriminalised in Scotland in February 1981 and in Northern Ireland in 1982.
[1787] Transcript 20/05/2022, p60, l13-25. Transcript 20/05/2022, p60, l13-25
[1788] Charles Lister WITN4505002 §1.7; Gutowski Transcript 10/06/2022, p16, l8 – p17, l6; Mr Canavan Transcript 22/09/2022, p13, l13 – p15, l1.
[1789] For example Lord Crisp did not get much material copied to him for example about whether to hold a public inquiry because of the nature of his role, Transcript 12/09/2022, p21, l1-15.
[1790] Lord Waldegrave Transcript 06/07/2022 , p39, l9 – p40, l14.

by Lady Hooper, the junior Minister.[1791] Lady Hooper was not told about the slippage in the introduction of testing between July 1991 and September 1991 and was not provided with information about how funding for the testing would be delivered.[1792]

40. Those infected and their families were often active campaigners, yet the issue was not seen as a political priority in comparison to others such as cancer and waiting times.[1793] The relative scarcity of material copied to the Prime Minister's office in relation to infected blood demonstrates that the issue was not one which occupied a significant amount of their time.

Churn of Ministers

41. Throughout the period under consideration by the Inquiry, the churn of Ministers was not helpful to ensuring expeditious, consistent, or effective decision making. Whilst the Secretary of State for Health usually remained in post for a longer period, junior Ministers regularly changed every 18 months to two years. And even if the Ministers themselves did not change, often the policy brief would. Very few of the politicians had any background in health or social care policy. Lady Bottomley[1794] was the only former Secretary of State who gave evidence to this Inquiry and had direct experience of these matters. Baroness Jay had worked for a health charity and Baroness Cumberledge and Lord Darzi had worked in the NHS.[1795] Many others were like Lord Reid who said *"I knew nothing at all about health…. before I went into it."*[1796] They were generalists without expertise in underlying health systems, policies, and practices. They were therefore very much led by the advice given to them by the CMO, the expert committees advising them and their civil servants. Many of them commented upon their lack of experience and that they did not have time to master their portfolio. In particular in respect of (a) record-keeping, (b) the decision to hold a public Inquiry, and (c) questions around the range and scope of redress, the churn in

[1791] Lady Hooper Transcript 30/06/2022, p32, l22 – p33, l3.
[1792] Lady Hooper Transcript 30/06/2022, p32, l5-16.
[1793] See for an example Lord Reid's evidence Transcript 21/07/2022, p83, l6-17; WITN4131001 witness statement of Sir Robin Butler.
[1794] Virginia Bottomley Transcript 28/06/2022, p6, l8-18.
[1795] Ibid, p8, l24 – p9, l6.
[1796] Lord Reid Transcript 21/07/2022, p5, l5-7.

Ministers impeded good decision making. It appears to be a reasonable delineation that unless they came into office after a general election, they did not receive briefings or handover notes.[1797]

42. The churn also meant that they did not develop sufficient expertise to challenge those advising them on the department's received wisdom. We heard from many Ministers and Secretaries of State who indicated that, unless they were asked to consider a change of approach, they did not seek it out themselves. This was despite the fact that it was the Minister who was responsible for changing the line. As Andy Burnham said "[y]*ou don't defend the policy, you don't defend the line, you are the only person in that Department who can change the line. The only person.*"[1798] Ministers did not have access to all the background papers or to dissenting views when making decisions, they had only a summary which made it much more difficult to provide an effective critique of a current policy.[1799] This Inquiry has heard evidence that only the consensus view was presented to Ministers on the majority of occasions.[1800] Lord Bichard when giving evidence identified that only being provided with a consensus view was a "*big problem*" and was "*tantamount to misleading a Minister.*"[1801] He identified that it was "*absolutely*" important for Ministers to know dissenting views and "*good Ministers want to know.*"[1802]

43. Former Secretaries of State remarked in their evidence that having Ministers in post who had expertise and experience in the department could bring a "*valuable source of continuity and experience on a whole range of issues.*"[1803]

44. The level of Ministerial churn was inimical to good administration and policy making. Ministerial positions are used as part of prime Ministerial patronage in many cases, rather than to appoint someone with enthusiasm, expertise, or ability to perform the role.[1804] If Ministers are doing a good job, they should stay there to develop rapport,

[1797] Dawn Primarolo Transcript 23/09/2022, p125, l7-18
[1798] Andy Burnham, Transcript 15/07/2022, p18, ll7-10.
[1799] Baroness Dawn Primarolo Transcript 23/09/2022.
[1800] For example, in respect of the Galbraith letter (Lord FowlerTranscript 21/09/2021, p158).
[1801] Transcript, 03/10/2022, pp52-53, ll9 – 12.
[1802] Ibid, p171, ll13-14.
[1803] Lord Reid Transcript 21/07/2022, p7, l20 – p20, l2.
[1804] Expert evidence, public health and administration Transcript 04/10/2022, p6-13.

expertise and deep policy knowledge and understanding. The turnover of Ministers caused problems for the delivery of long-term projects. Lord Bichard explained that appointing Ministers without understanding their lack of experience in their area could often mean that officials would be "*running the show.*"[1805]

45. Ministers during this period were largely reactive rather than proactive to the infected blood scandal. This led to preservation of the status quo rather than an examination of whether change was appropriate. This Inquiry has heard a wealth of evidence about the lines to take and has seen the majority, if not all, of such lines operated between the late 1980s – 2017 on the question of infected blood. It is clear that there was stasis in the approach to this issue, despite frequent parliamentary, public and press concern. It is submitted that this was due, at least in part, to the turnover of Ministers who did not remain in post for a sufficient period to understand or notice the continuing nature of the concerns. As Lord Reid remarked *"...I would much rather have spent a prolonged period of time in more departments."*[1806] Charles Lister, a civil servant responsible for blood policy, agreed with the question posed by Counsel to the Inquiry that when there was a turnover of Ministers, civil servants would have to "*start again*", with a "*stretched team.*"[1807] Ministers were also moved before they had a chance to make a change. This churn also incentivised the types of unnecessary administrative change identified above, as ministers were more preoccupied with making their mark along political lines during their short tenure rather than improving on service delivery and so would prioritise reorganisations.

46. All Ministers remarked upon the heavy Ministerial workload. The Inquiry has seen hundreds of submissions to Ministers, most of which would be put into red boxes and read overnight. This could not have been the basis for reflective decision making and learning.

47. The consensus view was that Ministers were informed of issues relating to changes of policy, significant spending commitments or matters of media attention which

[1805] Ibid p12.
[1806] Lord Reid, Transcript 21/07/2022, p4, l16-23.
[1807] Charles Lister Transcript 08/06/2022, p20, l12 – p21, l11.

required their intervention. Civil servants were sometimes said to have a *nose* for this and asked for input from Ministers *"when it was considered that there were issues which needed their attention."*[1808] This winnowing of information means that much material copied to a Minister's office or even to the Minister themselves would never have been seen by them (for example, the letter from Dr Galbraith). Therefore, longstanding policies would not routinely go to Ministers for review or reflection unless something significant had changed, as assessed by officials.

48. Ministers did not receive minutes of advisory committees[1809] or the background papers and technical underlying documentation which were sent to civil servants.[1810] These went to the CMO, or DCMO and other officials, who then decided what would be forwarded to Ministers.[1811] On a number of occasions this meant that information crucial to decision making was not presented to a Minister, much of which they considered (with the benefit of hindsight) should have been presented to them.

Lack of training for Ministers

49. Unless appointed after a general election (when a book is prepared briefing on major topics),[1812] the majority of Ministers have no briefings, handover notes or any other information before they begin in office. This is a missed opportunity. Many Ministers told the Inquiry that they would have welcomed both training and handover notes. Being thrown in at the deep end is not appropriate when you are making decisions about the future of the country, and in particular the workings of the health system. The oral evidence of the Public Health Administration expert group recommended such training.[1813]

Allocation of Ministerial portfolios

50. The allocation of Ministerial responsibilities seemed to be, at least in part, random and a question of balancing portfolios between issues which would require legislative

[1808] Sir Kenneth Calman WITN3430001, pp23.2.
[1809] John Canavan Transcript 22/09/2022, p29, l25.
[1810] Transcript 23/09/2022, p103, l1.
[1811] John Canavan Transcript 22/09/2022, p29, l17-22
[1812] William Waldegrave, Transcript 06/07/2021, pp3-4, ll.23-18.
[1813] Transcript 04/10/2022, p151.

change and broader policy areas. We submit that the issue of infected blood and blood policy should have been dealt with by the Minister and officials who also had responsibility for HIV/AIDS and infectious diseases given the overlap between the two areas. This team was made up of many individuals who acquired the relevant expertise, having worked on these issues on a full-time basis during the late 1980s and early 1990s.[1814] It is suggested that, had this team also covered infected blood, the development of policy, in particular around redress, may well have been more aligned with an in depth understanding of the difficulties faced by those infected with HIV/AIDS or HCV. Further, it would have led to contact with patient organisations and charitable groups who, particularly prior to the advent of retroviral treatment, provided support, advice and practical help to those infected with HIV/AIDS. These groups would have been able to provide very detailed input into the discussion of the extent of financial, domiciliary, psychological and social assistance required by those infected and their families.

Recommendation 1: Ministerial training and working arrangements

a. When they are appointed to office, all Ministers should receive an induction pack outlining the current policies and priorities and be required to speak with relevant policy leads to identify the background to the issues, the length of time that the policy has been in place, and to have a handover with the previous Minister.

b. All Ministers should receive training on the nature of their function, the Ministerial code, the Nolan Principles and the values expected of them. They should also receive training on decision making and the factors that need to be considered (it would appear that such training is now offered in Scotland and may be offered in England, but the position is not entirely clear).[1815] Ministers should recognise the requirement to query or question received wisdom and interrogate policies which seem to reflect stale thinking.

c. Facilitated time should be given to allow Ministers to master their briefs. Ministers should be moved only if they are not performing, not as part of political patronage.

[1814] Dr Pickles Transcript 12/05/2022, p17, l14 – 25.
[1815] WITN7351001, §7.6.

d. There should be time for reflection, discussion and debate built into Ministerial working days.

The DHSC: systems steward, candour and defensiveness

51. The Administration expert group identified that the Department of Health is the only body with oversight of the whole English health landscape and acts as systems steward to (i) ensure that the parts work well, (ii) that they talk to each other, and (iii) that policies, guidance and legislation are made to reflect priorities set nationally.[1816] The evidence from the devolved administrations is that, as smaller nations, they have more direct control over their NHS bodies than would be the case in England.[1817]

52. Despite acting as systems steward, the DHSC has failed in several key respects. First, it has failed to make policy effectively. The Administration expert group made a number of criticisms of how policy is made within central Government, including the absence of evaluation of the programmes from the start and how success of a policy is measured. The experts commented that there is limited accountability to ensure that policy being made is of a *"high quality."*[1818] They also spoke of a lack of resources to review and revise extant policies.[1819]

Inertia and groupthink in respect of blood policy

53. It is submitted that there was an absence of review of blood policy over a very long period of time, and in particular in relation to the approach towards redress. This was in large part caused by inertia and groupthink. As Charles Lister said there was a *"collective mindset"* and *"that's what everyone believed and I didn't challenge it. If enough people believed something, it becomes something."*[1820] The most egregious examples of this are the lines to take outlined above. The civil servants who gave

[1816] Transcript 04/10/2022, p145, ll1-180.
[1817] Public Health Group expert report p146, l21 – p147, l14.
[1818] RLIT0001753, p9.
[1819] Expert advisory group on public administration and health, day one, 2 October 2022, pp148– 160.
[1820] Transcript 08/06/2022, p24, l.6-9, p78.

evidence did not question the lines to take or seek to interrogate them and neither did the majority of Ministers.[1821]

54. There needs to be a system of sufficient scrutiny and review which understands the full context of a policy.[1822] As Yvette Cooper explained:[1823]

> *"When there are long running policy issues that have been considered by successive teams of officials and successive Ministers, it is possible for each Minister or group of officials to assume that each of their predecessors have probed all the issues in considerable detail and it is possible as a result for assumptions to be built into both the civil service advice that is given, and the Ministerial decisions that are taken. I also recognise that it is impractical for Ministers to continually re-open every decision their predecessors have made, particularly when there is a churn of junior Ministers covering an issue as there was during the period I have discussed. I accept that it is therefore possible for views to become taken for granted that may not have been properly justified at the beginning. However, all these risks are why it is so important that Ministers must continually answer to parliament and also why Departments and officials must take seriously their Parliamentary accountability, as there is a responsibility on both Ministers and civil servants to continually question received or inherited wisdom when issues are raised by MPs on behalf of constituents because problems remain."* [1824]

55. Lady Primarolo suggested that this issue could be remedied by a committee or an examination of the *"lines to take."*[1825] This may well avoid the problem identified by a number of Ministers that they did not have access to, and were not permitted to see, advice given to or decisions taken by their predecessors.[1826] Some Ministers pushed quite hard for such material (an example being Lady Primarolo in 2009).[1827]

[1821] See e.g. Charles Lister Transcript 08/06/2022, p22, l14-22.
[1822] Transcript 03/10/2022, p161, l3 – p162, l25.
[1823] WITN7187001, p44, pp4.36.
[1824] WITN7187001, p44, pp4.36.
[1825] Transcript 23/09/2022, p18-19.
[1826] Transcript 03/10/2022, p24, l10-21.
[1827] Transcript 23/09/2022, p115-116, ll5-11.

56. The convention that civil servants do not tell Ministers the views of the previous Minister in post, other than what was noted on the previous parliamentary record, was seen as appropriate by former senior civil servants.[1828] However, in the circumstances involving infected blood (and given the Ministerial churn identified above), this convention meant that Ministers may well have been echoing disquiet voiced by a number of previous Ministers, but they would not have known. There was a collective blindness to what had gone before.

Failure to listen to or take account of those infected and affected

57. The Administration expert group discussed the importance of public input into policy. However, despite an overwhelming volume of correspondence identifying flaws in policy making related to infected blood,[1829] this public input made no difference. That was partly because Ministers did not frequently personally respond to such correspondence. Those responses were instead being drafted by officials who abided by the line to take. There was no review, discussion, reflection, or debate as to whether or not the correspondents were correct. We suggest that the culture of allegiance to the official line, which was taken by Ministers as well, reflected the Government's fear of being criticized.[1830]

Lack of long-term planning and funding

58. The expert report and oral evidence from the public health and administration expert group, and the evidence from some witnesses who had been in senior Government positions identified that central Government can struggle to think, plan and deliver in the long term. The focus is often on immediate political priorities and political attention. Our CPs consider that the issue of self-sufficiency and the redevelopment of BPL was not seen as a political priority during most of the 1970s and early 1980s. The budget for the NHS was frozen from the mid-1970s because of general economic turmoil. It is all too easy in that situation to use money meant for long term projects

[1828] Transcript 03/10/2022, p28, l3-25, p29, l1-2.
[1829] Richard Gutowski (Transcript 10/06/2022, p78, l22-25) identified that the level of correspondence was very high even for the Department of Health.
[1830] Andy Burnham (Transcript 15/07/2022, pp32-34, ll22-19; pp147-148, ll18-19).

to plug short term gaps. As Ms. Salters identifies for the health service to flourish and thrive, officials and politicians have to plan over a 30 to 50-year horizon.[1831]

59. Whilst this Inquiry is only concerned with NHS policy related to infected blood and its consequences, it is suggested that the difficulties with long term funding, particularly of matters which will take many cycles of parliament to come to fruition, reflect general problems with policy making in a system which reflects a 3-5-year electoral cycle.[1832] As was identified by Jeremy Hunt in evidence,[1833] and with the introduction of the 10-year plan by the NHS, the idea of long term planning has been initiated but the vagaries of spending reviews (which happen at least biannually) mean that the system for such planning remains fragile.

60. Allied to a lack of planning, was, according to Professor Pollock, a failure to build a system of adequate public health surveillance which would have spotted concerns, but also created a system of support for haematologists and clinicians. The Public Health Administration group report identified that during the 1970s the introduction of new treatments and a comprehensive system of vaccinations for many infectious diseases led to a degree of complacency in relation to surveillance of and public health protection from infectious diseases.[1834] Professor Pollock stated that instead of there being regional epidemiological posts, it was left to Dr Galbraith to mobilise support throughout the country for surveillance, and that this was not adequate.[1835] Professor Pollock's view was that if more *"attention had been paid for the need for good surveillance […] much of this Inquiry would never have been necessary."*[1836]

61. Every Secretary of State for Health, and the one former Prime Minister who gave evidence described their period in the Department of Health as a time of budgetary constraint or a very difficult period for public finances.[1837] Over the past decade, the UK has had a lower level of capital investment in healthcare compared with the EU, in

[1831] Transcript 03/10/2022, p176, ll7-19; Transcript 04/10/2022, p6, ll11-13.
[1832] Transcript 03/10/2022, p176, ll7-19.
[1833] Transcript 27/07/2022, pp30-31, ll2-10.
[1834] EXPG0000047 p. 23.
[1835] Transcript, 03/10/2022, p84, ll1-24.
[1836] Ibid, ll10-13.
[1837] For example, William Waldegrave, Transcript 05/07/2022, p11, l12 - p12, l10.

respect of the 14 countries for which data is available.[1838] The UK spends around the median for members of the Organisation for Economic Co-operation and Development (broadly countries with similar development profiles as the UK).[1839]

62. That is a question of choice for the Government of the day. Extensive evidence was provided to the Inquiry from those working in the Treasury and individuals who went into bat with them when seeking monies for the spending review, where monies are allocated to each Department in Government for a set period of time or are sought for additional funding. Some described the discussions as a *'dance'*[1840] others as more like *"armed combat."*[1841] There is no doubt that the Treasury holds the purse strings and has to be convinced of the need to spend money before it is allocated. During the Relevant Period the Treasury was involved not only in determining whether monies should be paid, but also if a budget was to be changed from a course that had already been agreed in the spending review.[1842] It would appear that Ministries responsible for spending Government money, like the Department of Health, were not always trusted by the Treasury as reliable indicators of when money was required on the basis of the widely-held belief that *"spending Ministers are like the elephants: they come down to the waterhole in the evening, and you drive them off, but the following morning they are back."*[1843]

63. The lack of flexibility in budgets and the relatively limited room for manoeuvre caused by the imposition of Treasury diktat led to considerable difficulties when setting up trusts and schemes or providing additional treatments or services to IAP's.

64. During that time there did not appear to be money available to the Department of Health to spend on projects which appeared on the political agenda after the spending round or to use for objectives which may not have been obvious when the budgets

[1838] The Health Foundation, '*How does UK health spending compare across Europe?*' https://www.health.org.uk/news-and-comment/charts-and-infographics/how-does-uk-health-spending-compare-across-europe-over-the-past-decade

[1839] Office for National Statistics, *How does UK healthcare spending compare with other countries?* https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/articles/howdoesukhealthcarespendingcomparewithothercountries/2019-08-29

[1840] RLIT0001628_0003.

[1841] Lady Bottomley, Transcript 28/06/2022, p78, l21.

[1842] Transcript 05/07/2022, p13, l14-21.

[1843] In his evidence David Mellor highlights that Sir Eric Roll stated this Transcript 19/05/2022, p129, ll12-18.

were set. The requirement for stringent oversight and accountability for spending is understandable, however the evidence has shown that there is little scope for and often great difficulty in obtaining even small sums of money (in Government spending terms) to spend on specific health issues.

65. The money found for additional health spending during the Covid 19 pandemic does show that, where seen as necessary, additional sums can be found. However, many have argued that had there been adequate long-term investment in the system, there would not have been the need for such an increased level of spending and the NHS would have been more able to withstand pandemic pressures.[1844]

Recommendation 2: Departmental funding

a. It is suggested that there should be a mechanism for departments such as health to have access to flexible pots of money, to cover unexpected or unanticipated costs. In the alternative we suggest that such departments should be able to use "*unspent money*" from a financial year providing of course that there is sufficient justification for its use.

Organisation of the civil service

66. A March 2022 report from the Institute of Government reflects the concerns of our CPs about the role of the civil service.[1845] This Inquiry provides a reflection of the concerns expressed by the authors of this report, that the civil service has a lack of "*clear identity*" and "*defined responsibilities*"[1846] which it considers to be an obstacle to effective Government. We consider that the infected blood Inquiry shows all the problems set out below.:

[1844] *NHS funding data analysis*, BMA https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/funding/nhs-funding-data-analysis

[1845] *Reinforcing ethical standards in government,* Institute for Government https://www.instituteforgovernment.org.uk/sites/default/files/publications/reinforcing-ethical-standards.pdf

[1846] *A new statutory role for the civil service,* Institute for Government https://www.instituteforgovernment.org.uk/sites/default/files/publications/new-statutory-role-civil-service.pdf, p5.

"Nobody, including the prime minister or the head of the civil service, has the necessary authority and available time required to lead and manage the civil service. Instead, often conflicting responsibilities are distributed between ministers, senior civil servants at the centre of Government and departmental permanent secretaries. Policy co-ordination and implementation suffer because of inconsistencies between departments. The Cabinet Office and Treasury cannot accurately track the delivery of key priorities. The long-term capability and resources of the state are not well managed and the constitution is poorly interpreted. Risk management is poor with personal responsibilities for owning risks too diffuse. And ill-defined accountability within the civil service, and between ministers and officials, leads to unnecessary mistakes followed by blame games, preventing important lessons from being learned." [1847]

Project management and delivery

67. The Public health and administration expert's evidence recognises that civil servants are often moved in the middle of a project as career advancement in the civil service is dependent on acquiring skills and experience at different levels, within different teams and departments.[1848] As is recognised by the experts, and acknowledged by several current senior civil servants in their oral evidence, this often means that working on long term projects is not attractive to those seeking to advance their careers.[1849] The experts identified the need to incentivise long term projects to make them attractive to undertake as part of a civil service career.[1850]

Recommendation 3: Civil service careers

a. Civil servants should be encouraged, and a career pathway found, to ensure advancement even if individuals choose to work on long term projects to develop their experience and expertise.

[1847] Ibid.
[1848] Transcript 04/10/2022, p2-4, ll18 - 6; EXPG0000047_0029-0030.
[1849] Ibid, p11, ll6-9.
[1850] Ibid, p10, ll13-25.

The hierarchy of the civil service

68. The civil service is a very hierarchical institution. This Inquiry has heard that the civil service officials leading on blood policy would not have spoken to a Minister or the CMO about an issue directly, even if they were in the same room. Matters were passed up the chain in accordance with seniority, but often to individuals with less expertise and knowledge of the issues in hand. For example, the permanent secretary was often involved in briefing the Minister or the Secretary of State, but they in fact had far less knowledge of the detail than the civil servant who prepared the original submission. Some witnesses did indicate that there were occasions where a junior civil servant could test what was said by those who were more senior, if there were good grounds, but that it was very much dependent on personalities and the process for this does not appear to have been built into the system.[1851]

The need for "the whole truth"

69. Candour is essential in all jobs involving public service. The Ministerial Code[1852] (which is a mixture of ethics, values, and practical advice)[1853] identifies that:

> *"It is of paramount importance that Ministers give accurate and truthful information to Parliament, correcting any inadvertent error at the earliest opportunity…"* [1854]
>
> and
>
> *"Ministers should similarly require civil servants who give evidence before Parliamentary Committees on their behalf and under their direction to be as helpful as possible in providing accurate, truthful and full information in accordance with the duties and responsibilities of civil servants as set out in the Civil Service Code…"*[1855]

[1851] Transcript 22/09/2022, p14, ll6—16.
[1852] RLIT0001738.
[1853] Transcript 09/11/2022, p18, l23-25, p19, l1-11.
[1854] RLIT0001738_0006, pp1.3, IIC.
[1855] RLIT0001738, p1-2, pp1.3, IIE.

70. In this case, the lines to take presented to Parliament on numerous occasions, were not only factually inaccurate but also dangerously misleading. To give one example: despite there being a high court judgment[1856] which identified that testing for HCV was not introduced as soon as was reasonably practicable, the line to take in answers to questions put in Parliament and in written Ministerial statements post-dating the judgment was that testing **had** been introduced as soon as reasonably practicable. Whilst it had not been published at this point, the essence of the information in the code has always been part of the responsibility of Ministers.[1857] It should be noted that even when Ministers questioned the consistency of this line with decisions of the High Court, it was not altered save where Ministers expressly requested it.[1858]

71. This emphasis upon candour is also central to the Civil Service Code.[1859] Again, whilst only put on a statutory footing in 2010, it reflects long held principles, codified in 1992 following the Committee on Standards in Public Life.[1860] The Nolan report identified that "*more needed to be done to ensure that all civil servants remain aware of the standards of conduct required in the public sector*"[1861] and the principles emerging from these standards were seen as long underpinning the spirit of public service.[1862] The Civil Service Code relies upon the principles of integrity, honesty, impartiality and objectivity.[1863] These are reflected in the current (as at March 2015) and previous versions of the Code, and would have been enshrined at least informally throughout the relevant period.[1864] The Code requires that civil servants act in a way which is professional and that "*deserves and retains the confidence of all those with whom you have dealings"* and to "*deal with the public and their affairs fairly, efficiently, promptly, effectively and sensitively, to the best of their ability."*[1865] The evidence before this

[1856] *A & Ors v National Blood Authority & Ors* [2001] EWHC QB 446 (26th March 2001)
[1857] Transcript 03/10/2022, p15, l10-21.
[1858] WITN7187001, pp. 2.21-2.27.
[1859] Constitutional Reform and Governance Act 2010.
[1860] RLIT0001795, p.9, pp. 19-20.
[1861] RLIT0001795, p9, pp27.
[1862] RLIT0001741; EXPG0000047_0010.
[1863] RLIT0001796, p47; Transcript 03/10/2022, p48, l8-15.
[1864] https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code; Public Health & Administration Expert Group – Transcript 03/10/2022, pp43 – 53.
[1865] Civil Service Code, available at: https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code

Inquiry clearly indicates that these principles and professional standards were repeatedly not followed.

72. We suggest that part of this problem is that there is currently limited civil service accountability. We consider that the Institute for Government report of March 2022 [1866]reflects the difficulties with accountability and lack of candour emerging from it which are identified throughout the evidence given to this Inquiry:

> *"One secretary of state, or even a group of half a dozen ministers, cannot fairly be responsible to parliament for all the actions of a sprawling department. That is especially so as the responsibilities and services of government have become more complex, departments have become bigger and the line between policy and implementation is ever more difficult to identify. As civil service responsibilities for managing and leading parts of the state that run things have grown, so too has the need to hold officials to account. But the system of oversight has not kept pace with the evolution of civil servants' roles. Another point of tension is that ministers are – technically at least, given the requirements of impartiality and permanence of the civil service – restricted in holding officials directly to account through hiring and firing decisions, which are mostly the responsibility of civil servants.*
>
> *We are left with an unresolved compromise between the accountability of ministers and that of civil servants. It remains unresolved partly because it is more comfortable for politicians and officials for their responsibilities to be blurred. That does not mean that people are deliberately evading their responsibilities, but that the system incentivises diffuse accountability for decision making at the expense of more effective government in the long term. Too often the question of accountability for failures is left publicly unanswered and ambiguous. One recent example would be NHS Test and Trace (as it was at the time) and its poor co-ordination with local authorities in the early stages of the pandemic, including the mistaken May 2020 decision to set up a centralised test and trace programme.*

[1866] https://www.instituteforgovernment.org.uk/sites/default/files/publications/new-statutory-role-civil-service.pdf, pages 10 – 15, quotation from page 12.

Despite numerous parliamentary inquiries into the matter it remains unclear where responsibility should sit between ministers, Baroness Harding, then head of NHS Test and Trace, and permanent civil servants. "

73. Linked to this is the need for civil servants and Ministers to acknowledge when things have gone wrong. The Code of Ministerial Conduct identifies that "*Ministers should be as open as possible with Parliament and the public, refusing to provide information only when disclosure would not be in the public interest…*"[1867]

74. The Government often closed ranks and behaved with defensiveness rather than candour in response to the infected blood scandal. This defensiveness arose out of concern for either collective professional reputations or individual clinical reputations which seemingly outweighed the needs of the infected and affected. It is submitted that decision making which places concern for the reputation of an institution or individuals above public health is unethical and inimical to the Nolan principles. In particular, this defensiveness was seen in the Government's response to litigation, to the need for a public Inquiry, and to calls for transparency into its actions and policy positions. We submit that this response has caused additional, palpable harm to those infected and affected, and amplified feelings of mistrust.

75. Part of the role of the civil service is to provide advice on reputational risk, to minimise that risk and advance departmental priorities. This is particularly evident in Government press releases and other documentation prepared by communications departments. This is the information most accessible to the public: it is not neutral but is designed to be eye catching and to put the Government in a favourable light. For example, in September 1991, in the course of preparing a press release about the introduction of HCV testing, the Department of Health wanted to make changes to defend their position, in order to avoid implicit criticism of the delay in the roll out of the screening.[1868] Whilst we accept that Dr Rejman considered that HCV screening took place as soon as possible, this was obviously not the universal view given the

[1867] Ministerial Code, RLIT0001738_0006.
[1868] WITN4486065; Transcript 11/05/2022, p146, l20 – p152, l13

discussion about the need to defend the position.[1869] We submit that the briefing lacked nuance and was in places positively misleading. For example, blanket statements were made that all patients had been given the best treatment, which was demonstrably untrue.[1870]

76. A corollary of candour is transparency and openness, which was often lacking. The minutes of expert advisory committees were not published in the 1980s and early 1990s.[1871] Those involved in public health today have assured us that they insist "*on certain standards and [insist] upon responsibility and accountability*", and that this is supported by the Freedom of Information Act 2000.[1872]

77. Strikingly, transparency is not one of the four principles set out in the Civil Service Code, albeit that under integrity the Code identifies that information should be handled *as openly as possible within the legal framework*" and that "*official information should not be disclosed without authority.*" [1873] There appears to still be a tension inherent in central Government and public sector decision making between wanting to be open, but also requiring briefings which are full and frank which will not then be circulated within the public domain for fear of adverse political consequences.

78. The approach of the civil service to the Archer Inquiry and its refusal to put forward oral witnesses shows that there was, at least during the first decade of the twenty first century, a continued reluctance to disclose information and concerns about embarrassment if mistakes had been made.[1874] For example, Mr Connon in March 2007 in a minute about the Archer Inquiry, identified that there is "*considerable scope for embarrassment for the department if officials are asked to appear before the Inquiry*" (because of the loss and destruction of files).[1875] This reflects an institutional caution and an inclination to keep material confidential where possible.[1876]

[1869] Transcript 11/05/2022, p149, ll12-17.
[1870] Lord John Horam Transcript 29/06/2022, p21, pp14-15.
[1871] Dr Rejman Transcript 11/05/2022, p62,l117 - p66, l11.
[1872] Professor Sir Jonathan Van Tam Transcript 18/11/2022 p66, l22 – p67 l19.
[1873] As above, https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code.
[1874] Judith Willets WITN4736001 and the Solicitor to the Inquiry Vijay Mehan WITN5599001.
[1875] DHSC0041193_054.
[1876] Judith Willets and Vijay Mehan (*supra*) are deeply critical of the Department of Health'sapproach, describing it as very defensive.

Absence of a public Inquiry – part of the lack of candour

79. The first mention of a public inquiry in the evidence before this Inquiry, is in 1988/89 when it was raised during the course of the HIV litigation as a *"passing thought."*[1877] For example, Charles Lister, who was responsible for the blood policy team between 1998 – 2003, *"does not recall Ministers voicing concern that there should be a public Inquiry."*[1878] When the issue was considered as the Inquiry has seen a from a number of submissions to various Ministers the recommendation was that a public Inquiry was not necessary and could be *"embarrassing for previous ministers and officials."*[1879] The reasons given for not commissioning a public Inquiry were at best factually inaccurate and at worst deliberately misleading and did not change over time, despite the emergence of evidence refuting them.[1880] The reasons given were:

a. **There was no evidence of wrongdoing by the Government or the NHS.** This was not an accurate statement. It implied that there was no legal wrongdoing in the form of a claim in negligence, ignoring the breaches of the Consumer Protection Act 1987 identified in *A & Ors v National Blood Authority & Ors* in the delay in implementing HCV testing in the UK.[1881] It also failed to recognise that wrongdoing should encompass more than just legal liability; it did not take into account the criticisms levied in Professor Rose's report regarding the failure to more vigorously and efficiently increase UK blood supplies or to increase production or use the resource from Scotland;[1882] issues pertaining to patient consent, and the absence of oversight of the actions of clinicians.

   i. The conclusion that no wrongdoing had occurred meant that Ministers, officials, CMOs and others did not consider that an investigation was needed. For example, Lord Waldegrave identified that *"the press of continuing events mean[s] that there's a limited capacity to go back and review all the time*

[1877] Dr Rejman WITN4486040; Transcript 10/05/2022, p115, l9-23. A chronology relating to the issue of a public inquiry is due to be published by the Inquiry which will undoubtedly provide further detail about this issue.
[1878] WITN4505389 p66.
[1879] DHSC0041193_054.
[1880] Charles Lister WITN4505389 p64 §4.60; DHSC0020742_093; DHSC0020742_093; DHSC0020742_093; DHSC0042461_064.
[1881] *A & Ors v National Blood Authority & Ors* [2001] EWHC QB 446.
[1882] Report of Professor Rose: MHRA0017604.

previous decisions, unless weighty voices had been saying that there was a serious mistake earlier…But no such voices were heard by me at least". This became a self-reinforcing narrative: no mistakes have been made and therefore there is no need to investigate whether any mistakes have been made.[1883]

b. **There was nothing of fundamental significance not already known, and all relevant facts were in the public domain.** This is clearly misleading as this Inquiry has heard evidence about documents that were lost or mistakenly destroyed by an unnamed junior member of staff. This was known at the time that the above statement was being made and had been set out in the *'Burgin'* review about self-sufficiency.[1884]

c. **There was no evidence that Parliament had been misled.** The analysis in this chapter shows that claim to be, at best, highly debateable and at worst knowingly incorrect.

d. **This was a problem linked to the state of science and technology at the time, it was not an isolated UK problem and so any Inquiry would be unlikely to provide the infected and affected with satisfactory answers.** Whilst all countries were responding to the emergence of HIV, and HCV was only identified in the late 1980s, it is not accurate to say that the problem was linked to the science and technology of the time. As explored in other chapters, the problem was linked to, *inter alia*, the lack of self-sufficiency, the use of blood in UK hospitals, management and oversight of blood policy, the issue of consent, and the money allocated to blood services. Furthermore, most other Western European countries had introduced some form of testing at least a year in advance of the UK. There appears to have been an active reluctance to consider if those infected with HIV may also have been infected with non-A non-B hepatitis, or that they understood the potential seriousness of HCV. Dr Rejman's evidence was that no steps were taken by the Department of Health to ascertain the state of knowledge

[1883] Lord Waldegrave, Transcript 06/07/2022, p43, ll18-25.
[1884] DHSC0006612_002.

of those who had to sign the wavier in the HIV litigation either as to their infection or if they understood how serious HCV was.[1885]

e. **An Inquiry would not prevent future transmission of blood borne viruses**. This fails to identify that the issues explored by a public Inquiry can help to shape policy and practice in the future, and public health decisions more widely.

f. **A public Inquiry would raise the profile of no-fault compensation at a time when litigation in the NHS was an increasing problem.** This suggests that the concern of cost is greater than remedying wrongdoings. Further, it incorrectly conflates negligence claims with the possibility of compensation for a discrete group of seriously wronged individuals.

80. The Government[1886] failed to critically examine the basis upon which its conclusions were reached. We suggest that continuing to rely on these conclusions without any examination was a breach of the Civil Service Code's commitment to objectivity. The Code stresses that people must not "*ignore inconvenient facts or relevant considerations when providing advice or making decisions,*"[1887] which happened here. Because the problems were not identified, they were not corrected. As Lord Evans said, "*accountability is pretty meaningless…. if the facts are not known.*"[1888] Lord Evans identified the need for a more robust system of compliance than is currently present within the civil service. The team in the Cabinet Office working on propriety and ethics is small and public service does not have the compliance layer that other organisations and bodies have.[1889]

81. We consider that linked to this are the blurred lines of accountability for the civil service (as explored above). The civil service does not have a clear statement of its purpose, governance and permanence and this leads to confusion and obfuscation.

[1885] Transcript 11/05/2022, p211, ll16-25.

[1886] Whilst the references here are largely to evidence given by witnesses in the UK government, we submit that these briefings and advice from civil servants were as misleading in Scotland, and lead to ministers reaching decisions based upon partial information – see Andy Kerr who was Minister of Health from 2004–2007: WITN5753003 at paragraphs 56 and 71.

[1887] Civil Service Code, set out in oral evidence Transcript 03/10/2022, pp49 – 51.

[1888] Lord Evans Transcript 09/11/2022, p14, l8, p15, l6.

[1889] Report on the Committee on Standards in Public Life 2021 RLIT0001838 p13, recommendation 1 and oral evidence of Lord Evans Transcript 09/11/2022, p16. l19, p17, l23.

Ministers and civil servants need to be accountable to learn lessons, and to be able to explain and justify their decisions. Because the relationships between ministers and civil servants are ambiguous, and because of the vast areas of policy implementation over which ministers sit, people can pass the buck back and forth – leading to either no accountability, or scapegoating. This can be seen here in stark relief. Ministers end up being accountable for decisions for which they are not responsible (because they have not seen the information for whatever reason).

82. Furthermore, there is weak governance and an absence of effective oversight of the civil service. The Cabinet Office does not really "lead" other departments – this was evidenced during the Relevant Period even where decisions were made at prime ministerial level, it was not then co-ordinated there. The absence of oversight of the civil service damages its legitimacy.

83. Lady Primarolo in her evidence[1890] spoke of engaging with the Cabinet Office/ another department that is not the subject of the allegations as a separate body which would make decisions about an Inquiry under the Inquiries Act 2005. Our CPs suggest that this responsibility could lie with the Healthcare Safety investigation branch and/or another Government department that is not subject to the allegations which give rise to the need for a public Inquiry. The level of external scrutiny could vary depending upon the nature of the issues, and the speed with which they need to be decided. This would create some kind of coherence to what seems (currently) to be idiosyncratic and one-off decisions made about whether a particular issue does or does not need external investigation.

84. To give an analogy, the Department of Education currently operates a Child Safeguarding Review Panel[1891] which oversees, allocates, audits and reviews independent reviews where children have died or been seriously injured within the child protection system. The review panel is independent of the Government and appointed for its expertise in child protection. The Patient Safety Investigation team

[1890] Transcript 23/09/2022.
[1891] UK Government, *Child Safeguarding Practice Review Panel* <https://www.gov.uk/government/organisations/child-safeguarding-practice-review-panel>

may well perform a similar role, but it would seem appropriate for there to be systemization of the nature of external reviews, and when they should occur.

85. There had not been an independent review of internal departmental decision making. We submit that neither the Burgin review[1892] nor the subsequent chronology of documentation commissioned in or around 2006/7 comprehensively sought to discover what had happened and why. The internal HCV audit carried out in around 2000 was not carried out by an internal auditor, for example, from the Government Internal Audit Authority, and did not involve auditors working to a particular standard of audit for investigation.[1893]

86. The arguments seen in the multiple written submissions to Ministers over several years are consistent and have hardly varied at all over a 40-year period. [1894]They are based upon two broad assumptions that (i) the Government and the public know enough about infected blood and (ii) there was little or no wrongdoing. Given the sheer volume of correspondence, parliamentary questions, concerns, and campaigning, it is not clear how either of those positions were realistically maintained, other than through obduracy and inertia. Every time another concern came to light, the automatic, and often knee jerk, response was that either it did not matter or that it could be dealt with internally. This institutional will held despite eminent individuals within Government (for example, Lord Owen, Lord Jenkin, Lord Morris) raising concerns.

87. It is suggested that the failure to hold a public Inquiry was a combination of:

    a. Self-satisfaction: the evidence across many witnesses was that they genuinely considered that everything that could have been done had been done, and that they did not look behind that. Yvette Cooper, who was Minister of state for health in 2002 said: "*it had become the established Departmental view, repeated often*

[1892] Self Sufficiency in Blood products in England & Wales: A Chronology from 1973 to 1991 DHSC0200111.
[1893] WITN6955001, §6 and standards for investigation at RLIT0000847 and implementation guidance set out at §18.
[1894] For example, the witness statement of Patricia Hewitt, WITN7420001, at paragraphs 3.7 and 3.10 where, even in 2006, long after it was found that the technology had not been implementedproperly when that line was still taken.

in advice to Ministers that all the facts were known, established and well-rehearsed. However, that was simply not the case. Neither Ministers nor officials had the full facts about what happened in the 1970s and 1980s, and in key areas internal departmental judgments had been made about what was reasonable or an appropriate balance of risk at the time that had not been independently reviewed".[1895]

b. Inertia: the assumption that times had moved on and that this was a historic issue.

c. Fear of spending money: every Governmental witness who gave evidence about considering a public Inquiry raised this as being a major concern.

d. Defensiveness and concern about risk to reputation of the department, and the system.

e. Fear that the evidence of at best a lack of candour or at worst cover up would come to light

88. The Inquiry should also conclude that the failure to engage with the Archer Inquiry on anything other than the most perfunctory basis, and the failure to have a UK wide Inquiry when the Penrose Inquiry was commissioned by the Scottish Parliament were both errors of judgement caused primarily by a defensive approach to previous decisions.

89. We submit that the rationale for a public Inquiry is made most clearly by Nicola Sturgeon in her witness statement.[1896] Initiating an internal investigation, rather than a public Inquiry does not command confidence, but instead, whether rightly or wrongly, fuels suspicion that certain acts or findings are being withheld from public scrutiny. Those affected lacked confidence in the independence, transparency or robustness of internal investigations into infected blood, which led to a deep suspicion that the truth had been covered up.

90. Even after Lord Archer reported and identified a number of concerns with the previous position of Governments, there was no change of view by civil servants in the

[1895] WITN7187001, §4.30.
[1896] WITN7299001_0003, §12-15.

submissions that they made to Ministers.[1897] The lines to take were maintained: that the Government had acted in good faith and any benefit to be gained from lessons being learnt was minimal. For example, this was the position conveyed to Alan Johnson, Dawn Primarolo and Andy Burnham when they came into office.[1898] When Ministers pushed the issue,[1899] they were repeatedly told that there was no point implementing the Archer recommendations.

91. Under the principle of Ministerial responsibility,[1900] the Inquiry is invited to find that a succession of Ministers and Secretaries of State are accountable for the failures of the Department of Health in respect of infected blood. The problems identified here were not the fault of one individual, Minister or Secretary of State. They are systemic failures, to a system which failed to abide by its own principles and codes.

Recommendation 4: Candour and transparency

a. Lines to take should be the subject of regular scrutiny if they are long standing policies. For historical policies, adequate records must be kept of (a) the basis upon which the line to take was first adopted, and (b) what facts have subsequently emerged or could be examined. This examination could be by a commissioner or tsar, select committees, or a body which did not participate in the original decision making. If it is necessary for the advice given to or the decisions made by Ministers in previous administrations to be examined as part this process, there should be a mechanism to ensure that this can happen.

b. A duty of candour should be introduced on a statutory footing for all public servants, including Ministers. It is accepted that whilst candour is set out in the civil service code, which itself is on a statutory footing, evidence heard by this Inquiry demonstrates that this has not been effective. Whilst the current heads of the English, Welsh Scottish and Northern Irish civil service did not favour such,[1901] it is submitted that the need for

[1897] For example, DHSC5034285, a submission from April 2009, and Alan Johnson's witness statement at §§4.18 – 4.21.
[1898] DHSC5011228; WITN7197001 p50, §4.21 & p56, §4.33.
[1899] Transcript 23/09/2022; WITN5494001.
[1900] RLIT0001738, p1 §1.3; RLIT0001737, p8; Transcript 03/10/2022, p14, l23–25 & p41, l3-10.
[1901] Transcript 14/11/2022, pp63-68, ll14– 16.

codification is overwhelming given the many instances where an absence of officials communicating the whole truth has been evidenced. This was not by one or two individuals over a short period of time, but by countless teams of civil servants across several administrations.

c. This Inquiry shows the necessity to have stronger accountability for the civil service and a governance structure which creates legitimacy. It is suggested that this Inquiry recommends the reforms suggested in the Institute of Government report: the Statutory Role of the Civil Service and creates a civil service board to whom civil servants are accountable.[1902]

d. In cases of gross failures or clear dishonesty with the public, consideration should be given to implementing the Law Commission reforms in respect of the offence of misconduct in public office, so that those who breach the duty to prevent death or serious injury and are reckless about doing so can be exposed to criminal liability.[1903] In this case, our CPs agree with Andy Burnham[1904] that the nature of failings requires careful consideration by prosecutorial authorities.

e. The Ministerial Code in England, Wales and Scotland does not have any statutory underpinning and its enforcement is at the discretion of the Prime Minister alone.[1905] The Independent Advisor on Ministerial standards is not a statutory post. This role should be put into statute[1906] and be given the power to initiate inquiries and determine breaches of the Code.[1907]

f. There should be implementation of the 2021 report from the Committee on Standards in Public Life to provide for and to put into effect a robust compliance system across all departments in Government.

[1902] https://www.instituteforgovernment.org.uk/sites/default/files/publications/new-statutory-role-civil-service.pdf, pages 27-45.

[1903] Whilst there is the offence of misconduct in public office, the Law Commission has identified concerns with it and recommends that it is significantly reformed and placed on the statute book – Law Commission paper: Law Commission final report on misconduct in public office published 4 December 2020. Law Commission, www.lawcom.gov.uk

[1904] Andy Burnham, Transcript 15/07/2022, P132, LL12-14.

[1905] Transcript 03/10/2022, p24-37; EXPG0000047_0008; The Northern Irish Code does have statutory underpinning and operates differently given the contentions set out in the Belfast, Agreement, the Northern Ireland Act 1998, and the St. Andrews Agreement and the NI Act 2006.

[1906] RLIT0001838.

[1907] RLIT0001838; Transcript 14/11/2022.

g. The civil service should use reflective learning as a mechanism for improvement as a matter of routine, and this should be endorsed throughout the culture of the organisation.

h. Central Government and the devolved Governments need to implement an effective system of continuous improvement training focussing upon the need for candour and transparency, as well as innovation. Public servants should be measured in their performance against the upholding of those values.[1908]

i. The culture of the civil service needs to encompass discussion and debate of the values set out in the Code. Recruitment, promotion, and advancement should examine the personal values and ethics of the candidates and promote those who can demonstrate the values of the Code. The Inquiry should carefully examine the report of the Committee on Standards in Public Life due to be published in January 2023.

j. There must be some kind of objective system for examining if a public Inquiry should take place, particularly in respect of healthcare and patient safety. Such a system should be led by individuals who are independent of the actions concerned and ensure that the procedures which are then in place are structured, transparent and put those affected at the centre of the process. As to when a public Inquiry should be ordered, under the Public Inquiries Act 2005 this can only be ordered by a Minister (s1 of the Act). It is suggested that whilst this decision may still need to remain one for a Minister (in order to ensure accountability to Parliament), it could and should be informed by advice from the bodies described above.

k. At present, the recommendations of public inquiries do not need to be implemented by Governments. Successive academics and others have identified this as a major gap. This Inquiry should recommend that an independent body lead oversight and monitoring of Inquiry recommendations.[1909]

l. As part of reflective learning, the Government should continue to ensure that the minutes of relevant expert committees and the scientific advice provided to Government is given to Ministers directly, and any facts upon which a policy are made are published

[1908] Transcript 14/11/2022, p11, l14.

[1909] Sir Robert Owen, 'When Things Go Wrong, The response of the justice system, A report by JUSTICE', <https://files.justice.org.uk/wp-content/uploads/2020/08/06165913/When-Things-Go-Wrong.pdf> d

in order to ensure openness and transparency.[1910] As Professor Sir Jonathan Van Tam identified in his evidence, if there is disagreement, the fact of such disagreement and the broad nature of the disagreement should appear on the face of the minutes.[1911]

Devolution

92. There was very little evidence of proactive engagement and discussion in respect of blood and blood related matters between central Government and Ministers in Wales and Northern Ireland. The presentations on Welsh and Northern Irish decision making showed a paucity of information.[1912] Whilst Welsh and Northern Irish officials seem to be copied in on a number of documents, they were often not invited to meetings at which representatives from central Government and the Scottish Executive were present. Most officials who gave evidence described a position whereby Wales and Northern Ireland usually adopted the UK position on a given issue. There does appear to have been regular communication between the various CMOs in post at various times.

93. In respect of Scotland, prior to the establishment of the Scottish Parliament in 1999, powers had been devolved to an administrative Government for many years. This meant that Scotland had its own cadre of officials. The evidence indicates that there was more engagement and discussion with Scotland during the Relevant Period, but limited discussions between the Secretaries of State for Scotland, Ministers, senior civil servants and their counterparts in England about infected blood. Scottish policy was often distinct from that in force in the rest of the UK, and the presence of the SNBTS and the fact that they produced their own blood products meant that they ran their own systems. There does, however, seem to have been limited discussions and the UK Government about these issues.

94. The size of the Scottish administration (and that of Wales and Northern Ireland) meant that civil servants had to cover policy issues across a wide range of subjects pre-

[1910] Lord William Waldegrave, Transcript 05/07/2022 and Transcript 06/07/2022.
[1911] Transcript 18/11/2022.
[1912] INQY0000364, §§18-27; INQY0000363, §§19-39.

devolution, and so there was not a dedicated blood or blood policy team in these territories. Despite this, it would appear that Scottish civil servants were aware of the issues related to infected blood and made decisions about them. Most health civil servants were based in Edinburgh and not in London which meant that they were near to the organisations which provided health but were not particularly engaged on a day-to-day basis with Ministers acting on behalf of Scotland from Westminster.

95. The Inquiry may wish to consider those aspects of devolved organisation or decision making which seemed to work well. In Scotland, as a country with a smaller population and where the centre of health administration was Scotland's central belt, organisations were physically proximate to each other and knew each other well. Even before devolution, the Scottish Office had a hands-on approach to management of the NHS. Having one official who dealt with a number of interrelated policy areas could also be effective as it should mean that this person has a knowledge and understanding of how the system works as a whole, rather than operating in a small silo.

96. The systems of health provision in the four nations were distinctive to that of the UK Government post devolution. The relationship, and arguably the differences, between the UK Government and the Scottish Government, is demonstrated in the decision making around the HCV trusts and schemes from 1999 – 2006. It is submitted that the Inquiry could conclude that without the Ross report and the system of petitions available in Scotland, alongside the findings of the Health Committee and the wishes of Scottish Ministers, the HCV *ex gratia* payment scheme for those who had blood transfusions would not have been set up. In his evidence, Alan Milburn explained that he did not wish to change position in respect of such a scheme and Scottish Ministers were told to tough it out rather than give in to the advice of the Health Committee.[1913] When Lord Reid became Secretary of State for Health, the position changed in a week. The political pressure from Scotland was, it is submitted, a compelling factor. Our CPs also submit that where there was political comity between the UK and Scottish

[1913] Transcript 14/07/2022, pp145-155.

Governments, one can see the political impetus to have a consistent party line, albeit not on health policy more generally.

97. The Scottish Government's decision to hold a public Inquiry happened, partly because of litigation but largely because there was political impetus to resolve the issue. The UK Government should have made the Inquiry UK wide at that time: the rationale given for the implementation of the Inquiry in Scotland only, because of Article 2 of the European Convention on Human Rights ("**ECHR**"), was a convenient fig leaf for the UK Government to hide behind.

98. The report of the public health and administration experts indicates that at a Ministerial level there was little communication in respect of health on a formal level given the lack of meetings of the Joint Ministerial Committee.[1914]

99. The landscape of current regulation and oversight in healthcare varies depending upon the issue in question. In respect of blood, the NBTS and Medicines and Healthcare products Regulatory Agency ("**MHRA**") are both UK wide bodies as is the United Kingdom Health Security Agency ("**UKHSA**"). Other forms of audit and oversight are, however, different depending upon the country. So NICE guidelines apply in England, Wales, and Northern Ireland but in Scotland there is a different system called Scottish Intercollegiate Guidelines Network ("**SIGN**"). The regulator for hospital settings is separate in all four nations.

100. Devolution does mean that there will be differences in the healthcare and other services offered between the four nations. As can be seen, this includes the financial provision paid to those who qualify for the UK *ex gratia* schemes (until recently) and the psychological support services available to them (currently). There are also differences in access to specialist services for care and treatment. There is inevitable asymmetry in resources and personnel given the different sizes of the countries. This will include differences in regulatory and oversight bodies with different powers. However, it is suggested that as far as possible, even if those systems are distinct, they should co-operate and work with each other on issues of patient safety by devising

[1914] EXPG0000047, p35.

common standards, guidance, and advice where possible. We note the Public Health Protection and Health Security Common Framework, [1915] which is designed to strengthen strategic co-operation between all four UK governments and national public health organisations. We recognise that this includes UK level coordination of health protection including policy development and expert committees, as well as research data and intelligence.[1916]

101. We note that different governments are at different stages of embedding the statutory duty of candour in respect of clinicians, which we consider should be in statute in all four nations and consistently embedded and implemented (and extended to include ministers and public servants). We note that the Scottish government duty of candour has been subject to a review of its operation which may well be helpful to inform development in all four nations. [1917]

Recommendation 5: Patient safety

a. There should be a shared analytical resource that all four administrations could draw upon to inform policy development, operating via the UK Health Protection Committee.[1918]

b. There should be patient safety commissioners appointed in all four nations who are required on a statutory basis to co-operate with each other and whose role is, as far as possible, identical in all four nations. The Scottish Patient Safety Commissioner Bill was published in October 2022[1919] and provides that the Scottish commissioner will bring together patient feedback and safety data from all healthcare providers to identify concerns and recommend actions. They will also hold healthcare providers to account in their responsibility to listen to patients.

c. The duty of candour should be implemented in all four nations with consistent and identical understanding of when and how it should operate.

[1915] WITN7458008
[1916] WITN7458001, Witness evidence of Caroline Lamb, paragraph 5.44 - 5.46.
[1917] WITN7458009, and paragraph 6.5 of WITN7458001, witness statement of Caroline Lamb
[1918] WITN7458001, p16, para 5.46
[1919] Scottish Government, *Patient Safety Commissioner Bill published* <https://www.gov.scot/news/patient-safety-commissioner-bill-published/>

d. Consideration should be given to each country's legislation implementing a four nations policy which requires co-operation between the devolved nations on health, and co-operation between the various national regulatory bodies to seek to promote similar guidelines and standards in respect of patient safety. Whilst the Public Health Protection and Health Security Common Framework[1920] does provide some arrangements for co-operation, it is yet to be seen if it is suitably comprehensive.

e. Consideration should be given to permitting and/or ensuring that the Health Care Safety Investigation Branch can investigate failings UK wide, not just in England.

f. For those with infected blood, there should be a four nations group made up of representatives from each administration which seeks to provide, as far as possible, identical support structures and systems of compensation. Consideration should be given to the establishment of specialist centres or at least a specialist centre for the IAP of this Inquiry in respect of HBV, HCV and HIV treatment, to provide support to deal with the particular issues that emerge for these individuals.

Lack of patient involvement and engagement

102. Until very recently, neither the Department, hospitals, clinicians, or others routinely involved patients in decision making about policy or about how to implement decisions.[1921] Whilst there is now a patient charter, an NHS Constitution, and statutory duties to consult with and engage with patients, there is still much work to be done.

103. As identified above, the Department was often too willing to listen to what clinicians had to say about whether or not to introduce a treatment or the extent of the information that should be provided to patients, rather than to find out what patients themselves wanted. For example, it was assumed by the Department that patients would agree with the ethical stance taken by clinicians that individuals would not want to know that they may have been infected with HCV in the absence of treatment.[1922]

[1920] WITN7458008

[1921] Lord Bichard in evidence said that the "instinctive response of government and Civil service is not to involve people". Transcript 03/10/2022, p136, ll11-15.

[1922] PRSE0001236; NHBT0005855; WITN3430001 p51, §37.5.

Of course, this ignores the potential improvement to long term liver health that lifestyle changes would or could have brought about. It is striking that on this and many other occasions the Department of Health did not seek to investigate patients' wishes, assuming that clinicians knew best. In particular, this approach seems to be incongruent with the emphasis upon lifestyle as an influence on physical and mental health which was being emphasised by the CMO at the time, and by Ministers as part of the State of the Nation campaigns.[1923]

104. The public health and administration expert group identifies[1924] that patients should be involved in the formulation of new policy. There is now a statutory duty to involve patients in the design of services at the local level and by NHS England.[1925] But the expert group identifies that it is very hard to know how effective NHS bodies are in involving patients in a fundamental way to shape the policy concerned. There were bodies which used to work with patient user groups to identify service gaps but they were abolished in 2012.[1926]

105. In the case of infected blood, there was no patient involvement in investigations of safety issues and adverse events. Research and the findings of other inquiries[1927] identify that the system did not listen to patient concerns. The same applies here, with as much force. Organisations were slow to intervene and did not understand the extent and degree of failure. Patient groups were ignored, as were individuals, even though they were organised, had considerable "*social capital, professional expertise, financial resources and motivation*".[1928] At least in respect of formal investigations, the new national guidance on involving and engaging patients in investigations of safety issues, is a step forward but needs to be systemized and embedded on a consistent basis.[1929]

[1923] WITN3430001; WITN5289001; Bottomley – Transcript 28/06/2022.
[1924] EXPG0000047_0044-0047; Transcript 03/10/2022.
[1925] Health and Social Care Act 2012.
[1926] Transcript 03/10/2022, p69-70 & p72-75.
[1927] EXPG0000044_0046.
[1928] EXPG0000047_0046.
[1929] EXPG0000047_0045; Transcript 04/10/2022, p76-77.

106. Furthermore, as the impact chapter shows, the failure of the NHS (and central Government bodies) to react sensitively has compounded and exacerbated the trauma experienced by infected and affected people.[1930]

107. Despite the creation of frameworks to support patient involvement, the expert report identifies the barriers to individuals coming forward to speak of the harm caused to them, barriers which reflect the asymmetry of power between an individual and the NHS as an organisation.[1931] Although there is now a multiplicity of organisations and agencies providing oversight on some parts of the system, if things go wrong, the complaints and redress procedure is still opaque, complex and difficult to manage. Though there are options; the Patient Advice and Liaison Service ("**PALS**"), the NHS complaints system, the Ombudsman, or legal action, it is widely perceived that the PALS system is toothless[1932] and that accountability under the NHS complaints system can be limited. Neither provide easy or swift routes to address concerns. Legal cases and cases before the Ombudsman can be lengthy and cause significant emotional trauma.

Candour in clinical settings

108. Whilst there is now a statutory duty of candour for those undertaking regulated activities (which includes most healthcare and also personal care) in England, the criteria for engaging with the duty varies between the nations[1933] and is not underpinned by statute in Northern Ireland. The duty is new in Wales (to be implemented in 2023) and was only implemented in 2020 in Scotland. Such duties need to be embedded via widespread training; through the provision of mechanisms for audit and accountability both for individual hospitals and other clinical settings, but also for ICB and health boards in Scotland, Wales and Northern Ireland.

[1930] RLIT0001760; Transcript 04/10/2022, p79-80.
[1931] Transcript 04/10/2022, p82-84; EXPG0000047_0047-0048.
[1932] Transcript 04/10/2022, p24-25.
[1933] EXPG0000047 _0057.

109. Having a duty of candour is meaningless if it is not used, and if clinicians feel frightened to admit mistakes for fear of being blamed, losing their jobs or being made a scapegoat. The expert report references the Professional Standards Authority report of 2019[1934] which identified the difficulties of achieving candour throughout the profession. In order to ensure that candour does happen, significant cultural change needs to occur within healthcare organisations. That needs to be led by central Government setting the tone and ensuring that there is the space, time, and resources for this work to undertaken. Having a tick box approach to candour is inimical to achieving these aims. We support the recommendations of the expert report that change is required within every healthcare organisation with a focus on skills, behaviours, processes, and culture. This will need to involve a collaborative approach between all those involved in healthcare and patient safety.[1935]

110. We consider that it is essential that leaders – from the Secretary of State for Health and Social Care, through to board members of every ICB and hospital trust, chief executives, and medical and clinical directors - encourage candour, openness, and transparency and a just culture. This by necessity involves moving away from a culture of blame. If people are scared to lose their jobs, or their professional reputations, they will not admit mistakes. Part of this change involves patients, as consumers of the healthcare system, understanding that mistakes will be made, and although their concerns should be acknowledged, what is most important is that lessons are learnt. Our CPs have demonstrated this understanding during the course of this Inquiry. Having a just culture does not mean that there is no accountability for individual failures. The expert group report and oral evidence reflects the great difficulty in achieving this sort of cultural change in practice but points out what has worked in some organisations.[1936] Overcoming fear of retribution can happen when there is psychological safety i.e. people know that they can speak up or admit a mistake and will be given support and training. There is much research work on this, which it is suggested, should be adopted, and used by the DHSC.

[1934] EXPG0000047_0059.
[1935] EXPG0000047_0049.
[1936] EXPG0000047_0066-0067.

Reflective learning

111. From the expert evidence presented, it seems clear that using *"reflective learning"*[1937] assists in securing better outcomes for patients and enables staff to feel more confident and less stressed. The Inquiry should assert the need for this to be imbued within all cultures dealing with healthcare.

Approval of blood as a medicine and reform with the MHRA

112. The MHRA is the latest incarnation of a body which has existed in different forms during the period examined by this Inquiry to regulate medicines, including blood and blood products.[1938] All were responsible for ensuring that blood components met the standards of safety, quality and efficacy (a test in place during the entire period in question and that the distribution and supply was also safe.[1939] Indeed, the current role of the MHRA is to inform the public and healthcare professionals about the risks and benefits of such components and contribute to the development of regulations for medical products to ensure they are effective and safe.

113. Our CPs have identified the dependence that the MHRA (and its predecessors) have upon pharmaceutical companies. There is and has been a reliance upon pharmaceutical companies to carry out the research in advance of an application and to provide, along with other sources, safety updates on a rolling basis. Whilst some steps are put in place to avoid conflicts of interest, our CPs consider that this close interrelationship mean that such conflicts will always exist and suggest that there needs to be a layer of independent scrutiny and vigilance. This is particularly the case given the flow of expertise between academics, clinicians and the pharmaceutical companies who often fund their research. As is recommended in chapter concerning pharmaceutical suppliers, all licensing applications and safety reviews should be

[1937] EXPG0000047_0054-0056.
[1938] The Medicines Division of the Department of Health, followed by the Medicines Control Agency, the Medical Devices Agency and then the MHRA in 2003, which merged with the National Institute for Biological Standards and control in 2013.
[1939] Sir Michael Rawlins - Transcript 07/06/2022, p15 & 23-24; Sir Michael Rawlins - WITN6406001 p12-20; Dame June Raine WITN7135001, p6, §3.3

candid and subject to such a duty. Dame June Raine identified that following the *Cumberledge* review the MHRA re-examined the issue of conflicts of interest[1940] but it is still not clear that even with the requirement to provide more detailed information, there can be confidence in the independence of the system. Broader oversight could be given to Ministers and the Department of Health to check conflicts and ensure that they do not compromise the provision of the entire facts as to the potential safety of medicines. A very high degree of scrutiny should be encouraged, taking into account both the lessons learned from the *Cumberledge* Review and the experience in the US in respect of the nexus between pharmaceutical organisations and their regulators and how this enabled the inadequate reporting of adverse effects.

114. In respect of blood, there are three different ways in which adverse effects can be reported: Serious Adverse Blood Reactions and Events ("**SABRE**"), SHOT, and the yellow card scheme. The evidence of the MHRA is that the yellow card scheme is likely to be the scheme to which most delayed adverse impacts will be reported, as it allows any user of medicine (not just doctors, but individuals as well) to report concerns. The Yellow Card scheme in its pre- internet form involved sending off a physical card. As many witnesses to the Inquiry have identified, this system led to significant under reporting.[1941] This scheme should have been the way in which the post transfusion adverse effects of those infected were picked up, but there is little to no evidence that this system did identify or alert individuals, or their clinicians, to there being a problem. Despite it being recognised that the mechanisms for reporting are now easier using technology, Dame June Raine identified that they still have not *"quite cracked making it a systemic role of a health professional"*[1942] to report. The Cumberledge review describes a gross under reporting by the yellow card system.[1943] A similar position appears to exist in respect of professionals looking at the "*Drug Safety update.*"[1944]

[1940] Transcript 14/11/2022, p134-135.
[1941] Sir Michael Rawlins - Transcript 07/06/2022; Sir Michael Rawlins - WITN6406001; Transcript 14/11/2022, p141, ll1-14.
[1942] Transcript 14/11/2022, p144, ll1-9.
[1943] Transcript 14/11/2022, p161-163.
[1944] Transcript 14/11/2022, p153.

115. Furthermore, at present there is no legal obligation on healthcare organisations, or individual clinicians, to report adverse effects to the MHRA within a designated time period. Within the Cumberledge Report it is identified that this should happen.[1945] The MHRA's evidence suggests that this is still at discussion stage.

116. One can see that until recently, the National Reporting and Learning System could not easily talk to the Yellow Card system so that adverse effects in hospitals were not always collated with what was being reported by way of yellow cards.[1946]

Confidentiality and expert committees

117. The Committee on the Safety of Medicines, and the Medicines Division of the Department of Health were not transparent and gave little information out to members of the public about licensing and safety procedures, citing the need for confidentiality. Such confidentiality was mistaken. The MHRA now does provide minutes of the Commission on Human Medicines and provides public assessment reports for new products or major safety decisions which would include some information about risk/benefit. These, however, are limited to new drugs so a formulation of an already licensed product would not be the subject of a public assessment report.[1947]

118. There are still gaps. There is no one stop shop for patients to learn about a particular drug in the way that a doctor can look at the British National Formulary. Given the increasing sophistication of the medical consumer, it is suggested that this is a project worth undertaking. There is no oversight of drugs prescribed on a named patient basis. The Inquiry is asked to consider that whilst named patient prescriptions may not be a significant problem in many areas of medicine, in others it could be a practice which happens more often, for example in paediatrics or obstetrics. It is concerning that the MHRA does not know how often it happens, and with what types of medicines are involved, in what situations. Without this information, it cannot be known if named

[1945] WITN7328002 §1.42.
[1946] Transcript 14/11/2022, p143, ll3-17.
[1947] Transcript 14/11/2022, p148-149.

patient prescriptions are a widespread difficulty and what the consequent problems may be.[1948]

119. We submit that the findings and recommendations of the *Cumberlege* review[1949] are just as applicable to this Inquiry. It would appear at present that whilst some of the recommendations are being put into practice, others are still at a very early stage of consideration.[1950] The Inquiry should reinforce the need for the implementation of all those recommendations which aim to improve patient safety across the board.

The Precautionary principle

120. Professor Farrell[1951] identifies the "precautionary principle" as a mechanism to evaluate and assess risk in respect of public health[1952]. The principle requires that "proactive action be taken to prevent or minimise threats to human health or the environment, notwithstanding the absence of full scientific certainty about the nature and scope of such threats".[1953] The key elements are:
    a. To take preventative action in the face of scientific uncertainty; [1954]
    b. To shift the burden of proof to the proponents of a particular activity to show that it is not harmful;[1955]
    c. The exploration of a wide range of alternatives to possibly harmful actions;[1956]
    d. The need to increase public participation in decision making about the use of the precautionary principle.[1957]

121. As is identified in these submissions, the "precautionary principle" as described above was not an analysis much used by clinicians and those working in public health concerning blood safety in the 1970s and 1980s (although as the expert group on Public Health and Administration identified, the letter from Dr Galbraith was an

[1948] Transcript 14/11/2022, p157-159.
[1949] WITN7328002.
[1950] Transcript 14/11/2022, p160-180.
[1951] In her book The Politics of Blood, Ethics, Innovation and the Regulation of risk, p168.
[1952] Transcript 03/10/2022, p127, l18 – p135, l18.
[1953] Transcript 03/10/2022, p121, l16 - p122, l16.
[1954] EXPG0000047, p.1.
[1955] Ibid.
[1956] Ibid.
[1957] Ibid

articulation of the concept)[1958] . Rather, emphasis was given to a form of "evidence based medicine"[1959] which required more data and information, and subsequently and necessarily led to delays, for example, in the introduction of screening tests (explored earlier in these submissions).

122. Despite more widespread acceptance of the precautionary principle in respect of blood safety, we submit that the approach taken by the government in funding and adopting new technologies as seen with vCJD still shows an element of reluctance.[1960]

123. To give an example, Professor Collinge highlighted the change in the government's attitude from 1997 when ministers were generally accepting of his advice on a precautionary basis, to decision making based on cost / benefit analysis.[1961] He recalled being told by one Department of Health official that the Department of Health would be unlikely to do anything "unless, you know, it really happens" in respect of the prion decontamination work he was undertaking.[1962]

124. He also stated that this view has led to the delay in research regarding the effectiveness of his clinic's DDA test,[1963] the development of which was firstly commissioned by the Department of Health. The Department of Health subsequently rejected the National Prion Clinic's applications for funding to carry out a requisite prevalence study, despite the Clinic being able to produce Direct Detection Assay ("**DDA**") test results of 100% specificity. Professor Collinge remains perplexed as to why the Clinic was not able to take forward the publicly funded research that they were initially asked to do.

[1958] Transcript 03/10/2022, p.135, l. 2-12

[1959] This was discussed by Professor Farrell in relation to an article dealing with the application of the principle to transfusion safety, Transcript 03/10/2022, p.137, l.1 – p.140, l.18. It is accepted that there is not necessarily a contradiction between evidence-based medicine and the precautionary principle, but as Professor Vincent indicates, there were debates about what would be "evidence" from different specialities.

[1960] Lord Bichard in his oral evidence to the Inquiry identified that when he was in government he found that civil servants were very reluctant to involve themselves in decisions about contingency planning, and there is an instinctive reluctance within the civil service to involve people (precis of his evidence), Transcript 03/10/2022, p. 136, l.2-l.16.

[1961] Transcript 13/05/2022, p. 75, l.5 -p. 77, l.25.

[1962] Ibid, p.76, l.8-11.

[1963] Transcript 13/05/2022, p.115, l.4 - 11 – p.117, l.19.

125. Professor Ironside described the Protein Misfolding Cyclic Amplification ("**PMCA**") technique which he helped to develop, and which has the potential to become a blood assay for blood services. He said he viewed this assay and Professor Collinge's DDA test as complementary; one as a screening tool and the other as confirmatory. He was unable to advise the Inquiry as to whether the PMCA technique had been progressed at all since his retirement. He described the technology and science in relation to DDA and PMCA being developed as a test for blood services as having great promise, and the failure to progress this further is 'a matter of considerable regret'.[1964]

126. We submit that the government should adopt the precautionary principle when examining other current and potential blood borne viruses. This should include further research work on the transmission of HPV and the other blood borne viruses mentioned in the supplementary virology report, including conditions that are associated with transmission by blood, such as primary biliary cirrhosis.[1965] We also suggest that the need for good public health surveillance will require continuing research into blood borne pathogens, and that proactive steps are taken in line with the principles set out by Professor Farrell.

Recommendation 6: For Government implementation of UK wide healthcare improvements [1966]

a. Create a one stop shop for patients to raise concerns with the NHS, which has clearly defined outcomes and involves the system engaging with the patient.[1967]
b. Every clinical organisation should have someone who has responsibility and accountability to the Board of that organisation (or its management structure) to identify ways in which they have sought out, identified and addressed patient safety issues.
c. Focus groups and patient feedback should be sought on an in-depth basis.
d. Co-production frameworks should be used in policy, treatment, and improvement across the whole of the NHS (not just locally but also nationally).

[1964] Ibid, p. 118, l.3-11.
[1965] EXPG0000047.
[1966] Transcript 14/11/2022, p137-138.
[1967] Transcript 04/10/2022, p177.

e. The Patient Safety Commissioner should consider not just the safety of medicines and medical devices but also work with the various patient safety bodies in the UK and the devolved administrations to examine patient safety as a whole and provide benchmarks and standards for engaging with patients.

f. The Scottish Patient Safety Commissioner Bill was published in October 2022[1968] and provides that the Scottish commissioner will bring together patient feedback and safety data from all healthcare providers to identify concerns and recommend actions. They will also hold healthcare providers to account in their responsibility to listen to patients. In as much as the English patient safety commissioner does not do this, her remit should be extended to ensure that these actions are included.

g. Consideration should be given to a Health and Social Care Safety Commissioner who advises on addressing patient risk and has responsibility for the collation and aggregation of data; and monitoring safety information to identify emerging concerns. This must take place alongside a system to plan and track safety information at all levels of the NHS and in all bodies who provide health or social care. This should be a UK wide appointment.[1969]

h. The statutory duty of candour currently enacted for healthcare officials should be identical between the four nations and should provide clear requirements to (a) identify when the duty is triggered (b) ensure that understanding of the duty is embedded through training of all staff (c) audit the duty working in practice, with accountability to the board/management of every clinical organisation, and (d) ensure that breaches of the duty result in disciplinary action, acknowledging that the body that enforces this may differ between countries.

i. The DHSC, and the departments of health of the devolved administrations, should implement a wholesale programme of cultural reform, starting at leadership level, to implement just cultures within healthcare, and to assess the implementation of such a culture. The implementation of a health and psychologically safe culture should be communicated to all those working within or for the NHS, and in all private healthcare services in the UK.

[1968] Scottish Government, *Patient Safety Commissioner Bill published* <https://www.gov.scot/news/patient-safety-commissioner-bill-published/>

[1969] RLIT0001736; Transcript 04/10/2022, p92-94.

j. All insurance companies, professional indemnifiers, Royal Colleges and professional organisations, patient groups, charities, health, and social care regulators should undertake a collaborative programme of work to identify and provide a 10-year programme to embed a culture of learning and candour within the system.

k. Those recruiting, promoting or performance managing practitioners in the healthcare system should assess their competence in and management of candour, and their implementation of learning cultures and their values and ethics as central features of any review, recruitment, or audit (just as with civil servants and Ministers above).

l. Research should be undertaken into how to encourage clinicians and all those working in health to report adverse effects using the Yellow Card system.

m. The MHRA should publish a dip sample of licensing decisions – not just new drugs - by way of public assessment reports on an annual basis, to encourage transparency and openness as routine in the licensing of medicines.

n. The MHRA, working with others, should endeavour to commission or produce a patient version of the British National Formulary available for patients to understand and be provided with accessible information about the drug and its risks.

o. The UK and devolved Governments should compel practitioners to note and send to the MHRA any prescriptions they give off licence and a body should be set up to research and examine this.

Gender Inequality in approach to blood policy, and in healthcare

127. The disproportionate impact of malpractice in blood transfusion on women, particularly in the field of obstetrics and gynaecology, and the possible reasons for it are explored in detail in our chapter on the Role of Medical Practitioners. The same chapter explores the failures of practitioners to diagnose our female CPs' TTIs.

128. The Government has also played a role by failing to consider the gender inequalities in responding to this treatment disaster. The institutionally sexist response to women when they sought treatment and the refusal at times to treat them compassionately or with kindness, was something that the Department of Health as the systems steward should have tackled. The culture of the NHS is often patronising and

dismissive towards women. In 2021, in advance of a House of Lords debate on women's health outcomes, the Lords Library produced a research paper which provides information about the gender health gap.[1970]

129. This report identified that the UK has the largest female health gap in the G20 and the 12th largest globally. The experiences of women who received infected blood during obstetric and gynaecological treatment show the hallmarks of the same flaws in the system as those exposed in these reports – namely not being listened to, a lack of compassion, and women's pain and suffering being diminished or perceived as something which was normal for them to endure. The experience of our CPs and their family members reflects general research that there is bias in the treatment of women's pain.[1971] The experience of women from minoritized ethnic communities, according to the Birthrights report [1972] is that they are far less likely to be believed when they report pain or symptoms. There are no statistics about race in respect of this Inquiry but the Inquiry should, in the absence of data which suggests otherwise, make reasonable assumptions that treatment and care would have been impacted both by someone's gender and their ethnicity, race or nationality. We suggest that the Inquiry views the treatment of women in this scandal as another manifestation of the inadequate healthcare provision given to women in the UK, in particular in respect of maternity and gynaecological care.

130. The first ever Women's Health Strategy for England was published by the DHSC in August 2022.[1973] There is now a Women's Ambassador for Healthcare, Professor Dame Lesley Regan, whose background is in gynaecology and maternity services. In order to highlight and ensure that lessons are learnt from this Inquiry, it is recommended that:

[1970] UK Parliament House of Lord Library, *Women's health outcomes: Is there a gender gap?* https://lordslibrary.parliament.uk/womens-health-outcomes-is-there-a-gender-gap/

[1971] Digital Commons at UM Carey Law, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain* https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1144&context=fac_pubs

[1972] https://www.birthrights.org.uk/wp-content/uploads/2022/05/Birthrights-inquiry-systemic-racism_exec-summary_May-22-web.

[1973] GOV.UK Department of Health and Social Care, *Women's Health Strategy for England* https://www.gov.uk/government/publications/womens-health-strategy-for-england/womens-health-strategy-for-england

Recommendation 7: Gender inequality

a. The Women's Health Strategy should consider the use of blood transfusions during pregnancy and postnatally as part of its approach to pregnancy and post-natal support and should seek to ensure that clinicians comply with guidelines in place about minimal use of blood transfusions during this period, and the use of tranexamic acid.[1974]

b. The experience of many women heard by this Inquiry of patronising, rude and belittling care immediately post-partum should be fed into the Women's Health strategy; there should be mandatory education and training for health and care professionals on this issue and on the impact it has upon women not just at the time, but for the rest of their lives. Many of our CPs continue to relive experiences which happened 40 or 50 years ago, the vivid impression it has left upon them and the trauma and distress it has caused them is lifelong.

c. The Hepatitis C Trust and British Liver Trust are encouraged to work with the Women's Health Ambassador to examine disparities in treatment and outcomes for women with chronic liver disease resulting from HCV infection.

d. The Health Ambassador should look at the experiences of women infected with HBV and HIV and ensure that diagnosis and treatment of such conditions has similar outcomes to those of men.

e. Training of clinicians should recognise the bias in diagnosis and treatment of women's pain and ill health, as is understood by this this Inquiry and in the others mentioned above, there can no longer be a view that women should just put up with it.

Health Inequalities on the basis of race, ethnicity or nationality.

131. Our CPs include those who, or whose relatives, were infected as a result of transfusions made necessary because of sickle cell anaemia or thalassaemia. Those with sickle cell anaemia will, most likely be of African or African Caribbean/American

[1974] Professor Ian Roberts, Transcript 10/11/2022.

diaspora or South Asian or Middle Eastern heritage.[1975] Those with thalassaemia will, most likely be of Mediterranean, Middle Eastern or South Asian heritage.

132. The Inquiry has identified that it has received relatively few applications for core participant status or indeed information from those with these medical conditions despite putting a call out for these witnesses on a number of occasions. It has heard evidence, albeit limited, from the infected and affected about the impact that ethnicity had upon their individual experience.[1976] It also heard evidence in writing and orally from Professor Dame Sally Davies[1977] who was a consultant specialising in sickle cell disease in the 1980s and early 1990s prior to her move into public health administration.[1978] The chapter on medical practitioners deals with these issues in some detail.

133. The impact chapter's analysis of stigma and shame identifies the particular issues associated with having HIV and/or HCV and/or HBV and being from a minoritized ethnic community, which are real and palpable. There is the shame felt by parents of those with the underlying conditions that can lead to blood transfusion, alongside the prejudice shown to those with these conditions within their community, leaving aside the issue of HIV and HCV. Then there are those who received transfusions during routine or emergency treatment not linked to a genetic disorder. As has been identified in the evidence to the Inquiry, having a condition which is perceived as being caused by sex or drug use, in communities which are often socially conservative, has had a significant impact on those infected and their families. People may be ostracised: their families may be seen to be tainted. This intersectionality should be recognised by the Inquiry.

134. The Government now has an Office for Health Improvement and Disparities, whose job is in part to gather expert evidence and research about inequalities and to advise

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[1975] Professor Dame Sally Davies, Davies, Transcript 03/03/2022, p10: '*...that explains why this gene has reached quite high levels in Sub-Saharan Africa, Nigeria, Ghana and places. It is also present in the Middle East and India and wherever those populations have migrated to.*'

[1976] NICE, *How common is sickle cell disease?* https://cks.nice.org.uk/topics/sickle-cell-disease/background-information/prevalence/ ; see also Transcript 30/09/2022.

[1977] Transcript 03/03/2022; WITN6929001

[1978] Transcript 03/03/2022, p1-2.

on how these can be addressed. As a public body it is under an obligation to take proactive steps under section 149 of the Equality Act 2020 to reduce inequalities and to identify and set plans for how this will happen. What appears clear, however, is that the treatment and care of those with blood disorders has not been at a standard that it could and should have been, and that this may have been a reason why HCV, in particular, may not have been identified in some patients.

135. This Inquiry may speculate, tentatively, that those with these forms of anaemia would not necessarily have lived long enough to develop liver complaints allied to HCV and, in respect of sickle cell, the much truncated life expectancy caused in part by limited or poor treatment options for their underlying condition, meant that this experience has been hidden and shall remain hidden.

Recommendation 8: Inequalities on the basis of race, ethnicity or nationality

a. The Inquiry should identify to the Office for Health Improvement the information that it has uncovered indicating that poor treatment and outcomes for conditions such as sickle cell and thalassemia are likely to have masked issues around infected blood.

b. The Government should recognise that those from some minoritised ethnic backgrounds have been discriminated against by their communities because of their infection status, as well as being treated in a manner which is discriminatory and derogatory by healthcare providers. As with other areas of healthcare practice, the Office for Health Disparities should examine the discrimination experienced by those from a minoritized ethnic background who are infected with HIV, HBV or HCV and identify ways in which their treatment, care or experience could be improved.

c. The Government should consider initiating a public inquiry into health inequalities.

Government record keeping

136. Government record keeping around the issue of infected blood shows significant failings in adhering to reasonable practice, and a slapdash and haphazard approach that meant documents were mislaid or lost. There is an expectation from the public that central Government records will be kept meticulously because of their

significance both in the present but also for future historians. The Public Records Acts 1958 requires that records are kept which can show how policies were made, decided upon and executed.

137. The Inquiry's exploration of the various records which disappeared in the 1980s and 1990's has been exhaustive. Had the Government carried out a similar exercise thirty years ago, the suspicion of a cover up and deliberate destruction of records would not have arisen. It took far too long for the Government to examine what records went missing and why. When internal reviews took place, they took an interminable time to be published and did not really answer the questions which campaigners had asked.

138. Had material been put into the public domain at an earlier stage, or had it been accepted by the Government that there was not a clear account of decisions taken during the 1970s and early 1980s, then it would not have been necessary for the campaigners to have continually identified the same omissions and absences. As campaigners were constantly stonewalled or told that there was nothing to see, it is wholly unsurprising that fears of a cover up emerged, especially as they held information which contradicted the official view.

139. There was guidance in place at least from 1971 about managing records,[1979] with key guidance being published in 1994.[1980] Experts on the public health and central Government administration group who had worked in central Government[1981] and officials who gave evidence to the Inquiry, either did not remember with any clarity if any training was given about record keeping at all or reported that such training as was given was limited. Officials in post before 1994 could not remember any training being given but some were emphatic that they knew that (a) they had to file relevant material and (b) such material had to place on the appropriate file and the mechanism

[1979] WITN0001013 – 'A Guide for Departmental Records Officers' 1971: WITN0001004– 'Managing Registered Files' 1989. WITN0001003 = 'Guidance for File Sections' 1989.
[1980] WITN0001002.
[1981] Transcript 04/10/2022, p151, ll5-25.

to do so.[1982] Thus, better record keeping systems could and should have been in place well before 1994.

140. The For the Record guidance issued in 1994[1983] was poorly remembered by those working at the time,[1984] and it is unclear whether there was a compulsory training programme for all staff following its introduction.

141. Officials also described guidance as to what should be kept as very limited[1985] beyond that on how to record Cabinet committee and Cabinet discussions. Furthermore, those who were deciding if records were kept in the file in the first place and/or should be retained upon a review were executive officers or their equivalent, and would not necessarily have had an adequate working knowledge of particular policies in order to make these decisions.[1986] As Lord Bichard said, "*decisions need to be taken by someone who understands why you need to keep something and someone who may well have been doing that work for a very long time.*"[1987] That did not happen to the records examined by this Inquiry.

142. This Inquiry has heard evidence that records that should have been kept were destroyed. It seems clear therefore that there was insufficient guidance given to individuals as to which records may be significant in the future, and further that there was insufficient emphasis on the importance of record keeping on a day-to-day basis.[1988]

143. Leaving aside what was not kept, it was also the case that information did not always make its way to registered files.[1989] In the case of the ACVSB papers from May 1989 – February 1992, Dr Troop could not explain why Dr Metters had the only copy of the

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[1982] Dr Andrzej Rejman, Transcript 10/05/2022, p.24, l.7; Charles Lister Transcript 08/06/2022, p126-127; David Burrage – WITN7149001, §6.1-6.4.
[1983] **WITN0001002**
[1984] Charles Lister Transcript 08/06/2022, p126-127; John Rutherford WITN7224001 p9.
[1985] Transcript 04/10/2022, p151, ll18-21.
[1986] WITN0001013.
[1987] Transcript 04/10/2022, p152, ll19-22.
[1988] Transcript 04/10/2022, p51-154.
[1989] Transcript 08/06/2022, p128, ll5-7 & ll19-20. The evidence of Charles Lister was that "*busy people neglected to do what should have been done a lot of the time*" and that records of phone conversations were not always made.

ACVSB papers when they should have been retained on registered files (but appear not to have been, or if they were, then those volumes were destroyed). [1990]

144. The destruction of the ACVSB papers was arbitrary and unjustifiable, as the internal report indicates.[1991] There is some evidence that, as DCMOs and those who were recruited as medical specialists were not traditional civil servants, they may not have kept files in the same way leading to material not being transferred to registered files when it should have been.[1992]

145. Even though the expert group identified that the importance of record keeping at the top of the office, for example in relation to Ministerial and cabinet papers, was emphasised, this Inquiry has shown that even these records have been left incomplete or been thrown away. Briefing notes to Ministers from the 1970s and 1980 – 1985 on parliamentary questions and debates are missing.[1993] None of the key submissions to Ministers about self-sufficiency from the early 1970s /early 1980s had survived by 2003.[1994]

146. Incorrect information was given out by the Department to former Ministers as to what had happened to their private papers. Lord Owen was told that his had been thrown away as a matter of routine after 10 years which was not a rule in place at the time or subsequently.[1995] What Lord Owen should have been told is that all registered files were meant to include copies of Ministerial submissions, but that there was no repository for other Ministerial papers. It should also be noted that the Department of Health had recognised in 1999[1996] that its processes for keeping papers within private offices was deficient, but this was not then communicated to Dr Owen or others when discussing the absence of his or other private papers.

147. Records were thrown away in circumstances which still cannot be explained convincingly; there is supposition by some individuals as to why this happened but no

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[1990] WITN7169001.
[1991] **WITN6955015** §§3.1, 4.5.
[1992] Laurence George, WITN6963001, p13, §3.24; WITN6955051.
[1993] William Vineall and Lorraine Jackson, WITN7193052.
[1994] **DHSC0020720_081**
[1995] **DHSC0020720_081**, p17, §60.
[1996] WITN0001015, §§35 – 40.

absolute clarity.[1997] Various excuses have been provided such as the retirement of Dr Rejman and the HEO or staffing and location changes. However, these still do not adequately explain why it happened. Furthermore, in 1996 when papers were requested for the purposes of HCV potential litigation, there was no comprehensive study undertaken of what was missing or what was retained.[1998]

148. As Mr Sheehy indicated, documents were found in 2008 concerning Lord Owen which were not found during the course of the HIV litigation. There has never been a satisfactory explanation as to why some files that included materials to be disclosed during the course of the HIV litigation in 1989/1990 were permanently lost after the litigation ended. It is submitted that the evidence of Ms James does not assist the Inquiry.[1999] She did not know what happened to the files. As Dr Rejman and others had been clear that the materials gathered in the HIV litigation were likely to be needed in future litigation in relation to HCV,[2000] and in any event contained important materials, we would submit that losing these files was careless and inexcusable. Likewise, the fact that the signed undertaking made in 1991 – 1992 relating to the waivers made in respect of the HIV litigation were destroyed in a number of cases again was unacceptably careless.[2001] It would appear that the record keeping of the litigation team of the Department of Health was inadequate at this time. Mr Sheehy could not tell the Inquiry how such waivers were stored. Given that this was extremely high-profile litigation, which was extensively discussed both by Ministers and the Cabinet, it is extraordinary that essential documents were lost and reflects a system which did not have sufficient safeguards in place to avoid destruction.

149. The evidence to this Inquiry has shown that records also appear randomly at different times. In 2006 47 lever arch files were found including documents which may be

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[1997] William Vineall and Lorraine Jackson, WITN7193052, p13, §1.22; Laurence George WITN6963001, p33-34, §3.67.
[1998] William Vineall and Lorraine Jackson, WITN7193052, p12, §1.21.
[1999] Transcript 13/09/2022, p34-35.
[2000] On the basis that (a) the issue of HCV was raised in the HIV litigation and (b) the fact that many of those with HIV were also infected with HCV and this was known about from the mid 1980s onwards- WITN4486025 at §§25 -30 and §§15 – 20 which set out various documents which make it clear that the issue of hepatitis was discussed during the settlement of the HIV claims, leading to the "waiver".
[2001] WITN0001015, §1.84.

relevant to the issues of infected blood. These were released into the public domain in 2007. However, there were then another 41 folders of documents found in July 2008, which were not registered files but were documents organised for disclosure during the HIV litigation.[2002] Records were also found in February 2019 which appear to have been with the DWP until that point in time.[2003]

150. Even when a report was commissioned to look at why documents were lost, this investigation took place on an internal basis only.[2004] But not all staff were interviewed (e.g. Dr Metters was not interviewed; neither was Dr Rejman). It was not if the team interviewed or even found the person who signed the destruction authorisation. This remains a mystery.[2005]

151. It is suggested that the Department of Health was defensive on this issue just as it had been to other factors in relation to infected blood. Whilst it internally admitted that things had gone badly wrong with keeping of records, this was not communicated publicly. This obviously and understandably led individuals outside of Government to reach the conclusion that things had been destroyed deliberately.

152. There were also significant structural issues related to the keeping of records. First, it would appear that reorganisations of departments caused papers to disappear either because they were physically not moved when the department moved or were not kept where they could be easily found.[2006] Second, the transfer of records to a private company in 1996 led to the destruction of original card index slips which resulted in difficulties in tracing papers or confirming whether certain papers ever existed from before 1996.[2007] Third, there have been two different electronic records systems in place since 2003 which will cause confusion. Fourth, paper records are stored in four

[2002] WITN7193052, §§1.60. 1.82.
[2003] WITN7193001, §3.3.
[2004] WITN6955001, §6 and 18, RLIT0000847.
[2005] WITN6955015, Internal Audit Review Hepatitis C Litigation Final Report; by the Department of Health; WITN6955026, Terms of Reference for the Internal Audit Review - Hepatitis C Litigation
[2006] Brendan Sheehy WITN0001001, p4, §10-13. Identifies that there was a separate file store set up in 1987 so documents were moved to Lancashire from London and in 1994 the DH moved its papers again to separate premises for the DHSS. In 1996 the papers were transferred to a private company.
[2007] Brendan Sheehy WITN0001001, p4, §13.

different places and the sheer number of files is enormous.[2008] Fifth, the transfer of files between the department of health litigation team and back to the department appears to be haphazard on occasions. Sixth, once the physical records have transferred to the National Archives, a copy is not kept by the DHSC.

153. Records are now kept electronically but, as has been identified, that brings its own problems as it means that there is far more information and documentation, and further that information can easily disappear as it is kept by way of e-mail files and attachments. If an individual leaves the civil service, their email inbox can disappear and information which should be kept in a shared management system can be kept on personal drives. Official business is also conducted via SMS text and WhatsApp messages, and there is little evidence of formal minutes of meetings with Ministers now being recorded as file notes. This Inquiry has identified that it has been difficult to effectively interrogate electronic systems in some cases.

DHSC and records of health organisations.

154. The DHSC has records formerly kept by primary care trusts and strategic health authorities, which includes some 489,000 boxes of material stored at 80 different locations and a large number of electronic records. This information can be relevant to decision making by such bodies, for example, about record keeping and treatment decisions. The reorganisation of the NHS on multiple occasions therefore can orphan records so that (a) successor organisations do not have copies of previous records of organisations, which could be relevant both for policy development and to find out what happened in the past and (b) finding documents to assist individuals to make claims for financial assistance from the trusts and schemes can be exceptionally difficult.

155. There are 100,000 organisations which at some point would have been within the overall responsibility of the DHSC.[2009] Other records such as the records of local health

[2008] Brendan Sheehy WITN0001001, p6-7, §23. There are 9,827 archive boxes, 427,0000 files and 30 million electronic records.
[2009] WITN0001001

boards, go to local archives. The huge number of bodies responsible for providing healthcare and the reorganisations which have taken place will inevitably lead to accidental loss or destruction of documents.[2010] Whilst guidance was issued to the health service by way of circulars,[2011] and there has been codification of records management,[2012] that does not always lead to records being kept.

Recommendation 9: Government records

a. Training should be given to all staff at all levels of seniority on a regular basis about the importance of keeping records and of maintaining adequate filing arrangements.
b. Decisions as to which documents are kept on registered files or the equivalent should be made by individuals who are familiar with the policy background and issues raised by the documents. There should be an assumption that material should be kept unless it looks obviously ephemeral.
c. All read outs from Ministerial discussions or civil service meetings should be preserved and archived as they provide the current day manner in which decisions are recorded.
d. Where records have gone missing, this should be acknowledged and communicated publicly.
e. Where internal investigations need to take place, these should follow the relevant GIAA policies.

156. Our CPs have a number of recommendations which relate to the actions to be taken by central Government and which reflect the need to acknowledge the wrongs which have been caused. We submit that the following recommendations should be made:

[2010] The witness statement of Mr. Sheehy on behalf of the DHSC shows that there have been numerous changes of oversight on local and regional and national levels. WITN0001001, §39 – 47.
[2011] For example, HSC (89) 20 WITN0001014.
[2012] NHS Code of Practice on Records management 2005, and again in 2016 available on the NHS website– §62 of WITN0001001, Brendan Sheehey.

Recommendation 10: General Recommendations in relation to central Government

a. An official apology should be issued by the UK Government. Such an apology must be given by appropriately senior members of the Government. We would recommend that the Prime Minister, Health Secretary, regional Health Ministers, and NHS leaders participate in the apology.
    i. It should be given in primary languages recorded as being spoken by the infected and affected, as well as in British Sign Language and braille where appropriate.
    ii. It should acknowledge the pain, suffering, and long-term trauma which the infected and affected have experienced. As the Inquiry has sought to do throughout, the experiences of the infected and affected must be foregrounded.
b. As the NHS is a revered and trusted public institution, there must be recognition of the suffering caused by the repeated refusals by the NHS and Government to acknowledge wrongdoing over a period of decades. The psychological impact upon the infected and affected of being expected to rely upon the institution which has failed them undermines their trust in authority and has serious consequences for the rest of their lives. That must be recognised and reflected in any apology.
c. The UK Government should candidly accept any findings the Inquiry may make about Government wrongdoing and specifically identify what steps it intends to take alongside health officials to (i) support the infected and affected immediately and on an ongoing basis and (ii) prevent the reoccurrence of such a failure.
d. A number of our CPs have expressed appreciation of the memorial at the Inquiry hearing centre. We recommend that an official memorial be arranged, with input from the infected and affected, after the Inquiry reports. While we would not wish to be prescriptive about the form of any memorial at this stage, we consider that an oral history project, featuring video and written accounts from infected and affected people, made available online and curated as part of the National Archives would be one possible option.
e. Victims should be assisted by a public advocate, funded by the public purse, to act for victims of major tragedies (where they are not already entitled to representation as core participants, as has been done successfully in this Inquiry).

Coronial procedures

157. The Inquiry has heard evidence relating to death certification. Some individuals wanted HIV/HCV listed on the death certificate to prove that their loved one died as a result of receiving infected blood and blood products. Others did not want it listed due to stigma.

158. Other inquires, such as the Shipman Inquiry, demonstrated the flaws within the coronial system. Although, much has been put right many still have concerns that that true cause of their death or the death of an infected loved one will not be recorded accurately. Even though this Inquiry has shown a spotlight onto what happened, it is clear there are still individuals within the medical and coronial systems that are not aware of this tragedy. Therefore, in order to assist individuals, navigate the coronial process and to ensure an accurate cause of death is recorded on the death certificate we submit the Inquiry should recommend

Recommendation 11: Recommendations in respect of Coroners' powers and procedure

a. Review of current Medical & Coronial Registration and Death Certificate Conclusions, with amendment to the notes to Schedule Form 2 of the Coroners (Inquests) Rules 2013, to add a new Short Form Conclusion of: 'Death from infectious illness HCV HIV, Variant Creutzfeldt-Jakob disease ("**vCJD**"), liver carcinoma or other arising from the provision of contaminated blood products/ blood.

ANNEX 1: RECOMMENDATIONS

CHAPTER 3: THE ROLE OF MEDICAL PRACTITIONERS AND THE MEDICAL SYSTEM IN THE UK

Recommendation 1: Research regarding behavioural and cultural change in the NHS

a. The Inquiry should recommend research is conducted on how to initiate cultural change in the NHS with regards to compliance with guidelines.[2013]

Recommendation 2: Placing Montgomery on a statutory footing

a. The *Montgomery* duty in relation to patient consent should be placed on a statutory footing, which will encourage compliance and/or heighten awareness of the duty among both medical professionals and patients. This could be a similar mechanism to the statutory duty of candour, which is now seen as a crucial, underpinning aspect of a safe, open, and transparent culture in medicine. We suggest that there may be an added benefit in formalising the *Montgomery* duty in the same way.[2014]

Recommendation 3: Patient-focused consent campaign and questionnaires

a. There should be a consent campaign aimed at doctors and patients, similar to the "*choose wisely*" campaign, referred to by Dr Murphy, which encourages patients to ask their doctors five important questions, to avoid unnecessary medical intervention where not supported by evidence.[2015]

b. Patient surveys should ask questions to determine whether patients gave informed consent to treatment or procedures, for example by asking whether anyone spoke to them about giving consent, or whether the risks, side effects, and alternative treatments (including no treatment at all) were discussed with them. This information

[2013] There is significant overlap with this recommendation and our recommendation in the chapter on the Role of Other NHS Bodies on creating a national guidance repository, which we hope will in and of itself create cultural change. However, the Chair may consider that it is worth making a separate recommendation on research into cultural change, given the widespread non-compliance with critical evidence-based guidelines demonstrated by evidence to this Inquiry.

[2014] Which was also the view of Dr Susan Hopkins: see Transcript 15/11/2022, p59.

[2015] WITN7001029.

should be proactively audited to determine if there are issues with particular practitioners or departments.

Recommendation 4: Obstetric consent

a. Proactive discussions regarding transfusion should take place with all pregnant women and those with gynaecological conditions which may require surgery to ensure that they understand the risks associated with blood transfusion and that the clinical team understand their attitude to transfusion. Patients must be given written information setting out the risks discussed for consideration in their own time. The issues of obtaining effective and informed consent discussed above are particularly important for this group and should be emphasised throughout medical education and information literature in this area. As this is a time when ongoing conversations take place with midwives and obstetricians during ante natal care it would be possible to obtain informed written consent to transfusion (or not) well in advance of labour in the vast majority of cases following discussion and dialogue.

b. Practitioners should ensure that where a patient is of a minoritised ethnic group, biases are actively acknowledged, and full information is obtained from the patient (especially where this may be material to care and treatment choices) and provided by the practitioner in a bespoke and sensitive manner.

Recommendation 5: Post-operative consent under the Mental Capacity Act 2005 Code of Practice

a. The Mental Capacity Act Code of Practice[2016] stipulates that professionals should support individuals to plan ahead for the possibility that they might lack capacity in the future but does not discuss situations where decisions have been made on a best interests basis in the past.

b. We therefore recommend that, in addition to the existing guidance in the Mental Capacity Act Code of Practice, there should be a requirement for medical professionals who make best interests decisions for their patients, such as a blood transfusion while

2016 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/921428/Mental-capacity-act-code-of-practice.pdf

they are unconscious, to disclose those decisions in full and discuss the risks involved. Such guidance must stipulate which healthcare professional is responsible for having these conversations with patients. The Royal Colleges, NICE and other relevant bodies such as the GMC should be requested to amend their guidance in the same terms.

Recommendation 6: HCV monitoring

a. All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

b. Those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with specialist interest in hepatitis.

c. Those who have fibrosis should receive the same care.

d. Where there is any uncertainty about whether a patient has fibrosis, they should receive the same care.

e. Fibroscan technology should be used for liver imaging, rather than inferior ultrasound technology, or other alternative tests such as advanced LFTs.

f. This care should be delivered throughout the United Kingdom on a consistent basis as geographically close to the patient as possible.

g. There should be the possibility of additional ad hoc appointments, just as with other areas where there is an elevated risk of cancer. This group should not be in a different position to other groups at higher risk of serious disease.

h. In Ireland dedicated times / days have been set aside for treatment, follow up and appointments of those who fell ill as a result of receiving infected blood. This has the advantage of facilitating more effective, informed care. We invite the Inquiry to consider the viability of such a recommendation.

Recommendation 7: Patients lost to the system

a. There should be conscious efforts (the most effective means for which we invite the Inquiry to consider and/or recommend further study into) to recall patients who were "*lost to the system*" and thus have not benefited from any monitoring (who may still have cirrhosis or be at risk of HCC) or other treatment services they may be entitled to. There should be a particular focus on those who received early interferon and/or ribavirin treatment.

Recommendation 8: MDT care for HCV as a multi-systemic disorder

The Inquiry should recommend:

a. Regional HCV "hubs" for commissioning care and ensuring joined-up working between practitioners; at present, the elimination programme operated by NHS England has led to the creation of these "*hubs*" (or Operational Delivery Networks "**ODN**"), and these systems should continue after the elimination programme has ended (in 2030).

b. Integrated care by an MDT model with effective communication between practitioners.

c. Oversight and management of each individual's care by a specialist HCV nurse.

d. Opportunities for patient involvement in decisions relating to their care and treatment, for example at MDT meetings or by some other bespoke means.

e. Psychosocial support as described below.

f. Regular and consistent follow-up for those not currently under active clinical care as described above.

g. Involvement of specialist HCV nurses to bridge the gap between hepatology and palliative care, and between primary and secondary care.[2017]

Recommendation 9: Psychological care and treatment

a. Specialist psychological input should be offered as routine upon diagnosis with HBV and HCV (and available after diagnosis as well) as a result of receiving infected blood or blood products. This should be funded and not limited to the usual NHS offer of 12

[2017] EXPG0000043, pp15-16, 18-19.

sessions of CBT in the first instance. It could also include support groups or where appropriate family therapy, considered on a case-by-case basis. Family members of those infected should be offered psychological support, as has been done successfully in Ireland.

b. As Samantha May and many of our CPs have explained in their evidence to the Inquiry,[2018] psychological support and/or counselling for those infected with viral hepatitis from infected blood should be targeted towards the needs of this group. It is essential that professionals providing psychological support and/or counselling for this group understand the history of NHS infected blood and therefore the nature of the trauma, sense of injustice, or lack of trust in the NHS and medical professionals that may be experienced by those infected by this route.[2019] We understand that there is specialist counselling available in Wales, Scotland, and Northern Ireland, but not in England. We recommend centralised commissioning through NHS England and delivery via the regional HCV/ODN hubs in England.

c. Treatment should not be viewed as the end-point of psycho-social difficulties for those suffering with HCV. Access to HCV support should not be time-limited and should be provided on the basis of need, without unnecessary access hurdles.

d. Alongside psychological support, there is a need for day-to-day support via support groups, help and information lines to assist people manage the impact of living with infection. This should be commissioned in addition to any psychosocial service – there is a great need to help people access relevant clinical care, and psychosocial care – particularly given the lack of trust that the infection has engendered in NHS services. The Hepatitis C Trust identifies that they provide a great deal of support through their information lines without any form of government support at present, something which may not be sustainable in the long term. The Inquiry may wish to consider if such services should be funded through an NHS grant.

[2018] See WITN0912001, §209. The psychosocial expert report also identified this need, as above.
[2019] This was referred to by Dr Ben Hudson and Dr Fiona Finlay (of the Palliative Care in Advanced Liver Disease Expert Group) in their evidence to the Inquiry on 4 March 2022: Transcript 04/03/2022, pp128-129.

e. Patients from minoritised ethnic groups, who have sickle cell disease and thalassaemia, have faced stigma, inequality in care, and discrimination on grounds of their race and ethnicity.[2020] They therefore should be provided with specialist psychosocial support that acknowledges and is informed by the unique obstacles they have faced.

f. Where appropriate, this support should be provided as part of properly commissioned palliative care pathway (see below).

Recommendation 10: Palliative care

Palliative care for those infected by NHS blood and blood products should:

a. Be provided at an earlier stage (Dr Hudson said at the point of diagnosis and/or at the pre-cirrhotic stage) and as part of a MDT.

b. Be expressly commissioned as part of HCV/hepatitis pathway (Dr Hudson).

c. Be included within speciality-specific training curricula and treatment guidelines; this should promote care planning and improve the standard and consistency of care.

d. These guidelines must be properly disseminated and emphasised as part of continuing professional development. This should be done by mandating that hepatologists gain accreditation under the Royal College of Physicians' IQILS (Improving Quality in Liver Services) programme and are funded to do so.[2021] There are currently only four accredited services in the UK.

e. Use the CQUIN (Commissioning for Quality and Innovation) payment framework to incentivise multi-disciplinary working and integration of palliative care.

f. Include funding of high-quality, large-scale research studies into best practice in palliative care.

[2020] See evidence of Professor Dame Sally Davies.
[2021] https://www.iqils.org/

g. Involve specialist hepatitis nurses to support palliative care, as part of the HCV hub model we recommend above and ensure integrated working with palliative care best practice.

h. Facilitate patient-led advocacy by:

   i. Using a diversity of information sources and media to convey information about patients' health, prognosis and treatment/care options;

   ii. Incorporating healthcare advocates into care planning, both by including carers where patients ask for this and employing independent advocates to support patients who struggle to advocate for themselves.

CHAPTER 4: HAEMOPHILIA CENTRES, CLINICIANS, THE UKHCDO, AND THE HAEMOPHILIA SOCIETY

Recommendation 1: Haemophilia Centres, Clinicians, the UKHCDO, and the Haemophilia Society

a. The UKHCDO and government offer an apology for their failures to prioritise patient safety, in particular for the dilatory actions in responding to the unfolding HIV/AIDS pandemic. They should also take responsibility for encouraging patients to remain on life-threatening treatment without proper information on risk; and

b. The Haemophilia Society offer a fuller apology for its actions, which recognises its serious errors in disclosing privileged legal advice and takes responsibility for its failure to provide accurate advice to protect its members' health.

CHAPTER 5: THE ROLE OF OTHER NHS BODIES

Recommendation 1: NHSBT's responsibility for improving blood transfusion practice and education

a. Transfusion 2024 should be amended to make clear that NHSBT has a statutory function to promote appropriate use of blood.

b. NHSBT should revise its education increase target of 20% to a more ambitious level, given the serious issues of non-compliance with NICE quality standards.

c. NHSBT should be required to report each year to the Secretary of State and to the public on its progress in promoting the appropriate use of blood and development of educational activities to achieve this.

d. The issue of patient consent for transfusion should be explicitly mentioned in NHSBT's 5-year Service Strategy and within the context of clinician education. It should include the scenario where a patient has been given a transfusion while incapacitated and the need to post-operatively engage in a dialogue with the patient about the transfusion and its material significance in terms of risks.

e. The NHS Blood and Transplant (England) Directions 2005 should be amended to define "*appropriate use of blood*" as including "*that patients have given informed consent to a blood transfusion where possible*".

f. NHSBT should work with all relevant stakeholder bodies to develop an effective system for auditing whether patients have given informed consent to transfusion, for example, by the use of patient questionnaires and surveys to determine whether patients are aware of the risks of transfusion.

g. NHSBT should conduct research to determine why there is such poor compliance with the most important NICE Quality Guidelines (as per its 2021 audit) and how cultural change could be established around blood transfusion.

h. NHSBT should spearhead an educational campaign for all doctors for whom blood transfusion practice is a relevant part of their practice, using a mantra such as "*the safest blood is the blood that is not given*".[2022] It should work with all relevant stakeholder bodies, such as education providers and regulators such as the GMC, to ensure this is adequately transposed into clinicians' knowledge. This campaign should stress the vital importance of informed consent, as well as recording blood transfusions and including relevant details in discharge letters to GPs and other relevant clinicians.

[2022] The mantra of Dr George Galea. Transcript 07/12/2021, p25, ll11-12.

It should stress the alternatives to transfusion and means of minimising blood use, including specifically the use of tranexamic acid. This campaign should use the infected blood scandal as a case study for learning.

k. NHSBT should work with all relevant stakeholder bodies to develop an effective system for auditing whether blood transfusions have been appropriately recorded in a patient's records and in discharge letters.

l. NHSBT should work with other stakeholders to collect data on the number of transfusions on an annual basis and ensure there is adequate information to allow for traceability. Analysis of transfusions should also take account of age, gender and ethnicity (to identify if there is any disparity or differential use of transfusion).[2023]

Recommendation 2: Statutory requirement for Hospital Trusts to fulfil important transfusion and laboratory roles

a. All Hospital Trusts and Foundation Trusts must have a named individual, who must specialise in transfusion medicine, whose role is to report, monitor and audit adverse incidents from blood transfusion.

b. There should be a statutory requirement that this role is always filled.

c. This role must be adequately resourced depending on individual hospital circumstances.

d. This individual should report to the Trust's Patient Safety Officer under the Patient Safety Incident Response Framework when that comes into force.

e. Trusts should be legally mandated, via this individual, to report adverse incidents to SHOT in accordance with SHOT's.

[2023] Confidentiality should not have primacy, providing that data can be suitably anonymised and subject to trusted research environment criteria as identified by the Goldacre review.

Recommendation 3: A truly interoperable and accessible patient record

a. NHS England and Improvement and/or NHS Digital (and/or any other NHS body or agency charged with the reform and digitisation of NHS patient records) should prioritise the development and roll out of a digital patient record.[2024]

b. This digital patient record should be truly "*interoperable*" between different health care providers and settings to allow for effective multi-disciplinary care and treatment – it should include records from secondary care, primary care, as well as other health and social care settings, such as hospices, mental and community health services, and even clinical research organisations.[2025]

c. With this in mind, it should contain a repository of all medications a patient is on, or has been on recently, so that a clinician managing a patient with multiple morbidities has the information to make a judgment on drug interactions.

d. It should provide means for easy and quick digital communication between different clinicians and providers.

e. Any digital infrastructure required to support this digital patient record should be prioritised for investment and development by the NHS and Government.

f. Patients should have unfettered access to this record, and it should be available as an app, like the existing NHS App (which currently only includes primary care records and some other test results where there has been a referral from a GP).[2026]

g. Significant opportunities for patient involvement and interaction through this digital record should be grasped and explored, with a particular view to improving the quality of the patient consent process. This would also assist doctors in fulfilling the subjective element of their *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 duty of care.

[2024] This is completely consistent with the NHS Long Term Plan: https://www.longtermplan.nhs.uk/areas-of-work/digital-transformation/ [accessed: 01/11/2022]

[2025] Subject to strict confidentiality and consent processes. Please note the evidence of Professor Mark Bellamy, who highlighted the benefits of an interoperable system in terms of passing transfusion records onto GPs, and also in the case of "*shared care*" for patients with conditions such as sickle cell disease: at §58 of his witness statement: WITN7312001_0018.

[2026] The ALD/Palliative Care Experts extolled the virtues of patient "*ownership*" of their records. They described this as a "*hugely important step*" that would be "*empowering*" and "*a good way for patients to advocate for themselves*": Transcript 04/03/2022, pp121-124.

For example, we invite the Inquiry to consider recommending that the app should allow for:

i. An area to write notes after or before a consultation, as an aide-memoire for the patient, which could also be visible to practitioners if the patient elected;

ii. A means of answering a pre-consultation questionnaire, or posing questions to a clinician in advance of a consultation;

iii. A feature allowing a patient to input some basic details about themselves. This could be by way of prompts such as "*Who am I?*", "*What is my job or occupation*", "*How do I like to spend my free time*", "*What are my religious beliefs or other cultural or spiritual values?*", "*What is my ethnic and cultural heritage and how does this impact on my choices around care and treatment*", "*What is my personal pain threshold*", "*What particularly concerns me about my care and treatment*", or "*What is important to me in life?*". This would allow doctors to gain a snapshot of a patient's lifestyle, values and preferences in a manner that is consistent with *Montgomery* as well as GMC guidance on informed consent[2027] and is potentially a solution to the fact that clinicians have very little time to conduct these conversations in person during appointments, which may be further exacerbated when a patient requires any form of adjustments because they have a disability, or if English is not their spoken language.

iv. Opportunities for advanced planning of palliative and end of life care.

v. Opportunities for advanced planning before surgery, for example by indicating preferences around transfusion.

vi. The digital record should allow for a tickbox for the medical practitioner to say whether a patient has had a blood transfusion, which should trigger access to a link within the app to information about the risks of blood transfusion.

[2027] See: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/the-dialogue-leading-to-a-decision#paragraph-16 [accessed 01/11/2022].

Recommendation 4: Lifelong hospital records for all patients

a. Secondary care records should no longer be kept for eight years after the last treatment. They should be brought in line with primary care records and should be retained for ten years after the patient's death. This should be ensured by way of legislation.

b. This has been made possible by the progression towards full digitalisation and there is no longer any justification for more premature destruction when modern medical practices demand MDT working and integrated care and treatment, nor where there is increasing treatment for chronic disorders and interrelated morbidities. A failure to retain records could lead to vital missed opportunities to "*join up the dots*" in patient symptoms, which has occurred for our CPs with viral hepatitis.[2028]

c. Further or alternatively, there should be a process by which a patient is notified and given the chance to object to and/or receive a digital or paper copy of their records in the event that a Hospital Trust intends to destroy them.

Recommendation 5: Retention of hospital policies (on record keeping)

a. Trusts should be statutorily required to retain copies of their policies on record keeping, retention and destruction for fifty years.

Recommendation 6: Flagging blood transfusions on patient record

a. GP records should include a "*flag*" or some form of mechanism to alert the GP that a patient has had (or is suspected of having had) a blood transfusion.

b. To the extent that that this system is being trialled and/or developed in pilot studies coordinated by NHS England, this system should be fully implemented across the United Kingdom after lessons have been learnt from the trial results.

c. However, it should also be a mandatory requirement that every patient is asked when they join a surgery if they have or suspect that they have had a blood transfusion at any time in the past and an affirmative answer should translate into a "*flag*" on the system.

[2028] See the discussion in the chapter on the Role of Medical Practitioners chapter regarding "*constellations*" of symptoms.

d. Many records omit details of transfusions (even in the present day). The absence of any such record should not be seen as conclusive proof that a transfusion has not taken place, particularly prior to the 21st century.[2029]

Recommendation 7: Infected blood record task force

a. NHS England and/or NHS Digital should create a targeted infected blood record task force, with a brief to find historic records of blood transfusions and add them to patient records.[2030]

b. Such work would complement the GP "*flagging*" system discussed above, because it would identify "*missing*" patients who do not know they are infected.

c. It would be of value to CPs whose records of a transfusion are missing, both because of the trusts and schemes' approach to documentary evidence (which is still ongoing in the case of EIBSS etc)[2031] and because of the likelihood that an individual will be advantaged in any future compensation scheme if they have records of their transfusion.

d. It would also have a cathartic function for patients whose doctors did not believe that their hepatitis was caused by a TTI and who have faced the trauma of finding that there was a gap in their records with regards to transfusion history.

e. Particular attention should be paid to examining hospital blood bank records[2032] for this missing information and correlating with patient records.

f. This task force should also identify as far as possible where records have been destroyed, and by whom, when and for what purpose, or in what circumstances.

[2029] Indeed, the evidence of Professors Neuberger and Bellamy demonstrates that thisoccurs even in the present day.

[2030] We note Dr Hewitt's similar recommendation that, if practicable, a database should be compiled of all those who had received blood transfusions and those listed on it should be notified of their right to be tested: transcript 10/12/2021, p140.

[2031] Such approach is the subject of criticism and discussion in our chapter on Trusts and Schemes.

[2032] Which, as far as we are aware, are a separate system of records to patient medical records.

Recommendation 8: National guidance system

a. NHS England, NICE, the CMO or another appropriate body should be charged with creating a national guideline system, available digitally, for all doctors. This system should:

   i. Act as a central repository for all relevant guidelines;

   ii. Allow practitioners to easily access, view and understand the significance of guidelines in other areas of practice (for example by way of "*important flags*" or summaries);

   iii. Crucially, include guidance statements of best practice relevant to blood transfusion medicine, and these should be flagged for all specialities of medicine, but particularly those where surgery is more likely;

   iv. Should cross-refer between relevant guidelines.

b. This system should be tied to the GMC-regulated revalidation and appraisal process for all doctors. This could be by way of some kind of test, which utilises information in the national guidance system, or through a declaration by an individual doctor when confirming that they have complied with their CPD requirements.[2033]

c. There should be consideration of integrating this guidance system with a national system for electronic prescribing, to ensure that prescriptions are based on best practice and evidence-based guidelines.[2034]

d. Dr Finlay, consultant in palliative medicine, made a recommendation, which we endorse, that high level guidance should be disseminated not only to clinicians but also to charities and other advocacy groups (we suggest, like the Hepatitis C Trust).[2035]

[2033] As well as the IMMDSR, this was also suggested as potential mechanism for improvement by the ALD/Palliative Care Experts: Transcript 04/03/2022, pp104-105, ll18-11. We consider that the existence of a national system, which makes guidelines easily accessible, makes the IMMDSR Action for Improvement fairer and more workable for doctors.

[2034] See, for example, the suggestion of Professor Neuberger at transcript 16/11/2022, p170.

[2035] Transcript 04/03/2022, pp101-102, ll22-1.

Recommendation 9: HCV medical education generally

a. Even against the backdrop of aiming for elimination by 2030, HCV should be re-emphasised within the current medical curriculum alongside other TTIs.

b. All specialists whose practice involves (i) blood transfusion, (ii) obstetrics and gynaecology, (iii) anaesthetics, and (iv) surgery should be required to undertake CPD on the topic of HCV and other viral and non-viral risks associated with blood transfusion. This should be assessed as part of their revalidation/appraisal process.

Recommendation 10: Accuracy around the risk period for receiving a transfusion in clinical information and education

a. We consider that there should be no temporal limitation within the NICE Guidance. The Guidance should recommend testing for HCV and HBV (not currently included) for: *"All people who have received blood transfusions. People who received blood transfusions before* [any more reasonable longstop date to be determined by the Inquiry based on accurate evidence about when testing was no longer fallible] *in the UK may be at particular risk"*.

b. The information on testing on the NHS website should be amended in the same manner. Furthermore, the risk of transmission related to blood transfusions should be included on the first page – known as the "landing" page – on the Hepatitis C and Hepatitis B websites, and not solely on the page specifically related to risk factors.

c. The UKHSA Hepatitis in England 2022 Report refers to the same risk period and this report, and associated UKHSA risk assessments for the purposes of the elimination campaign, should be amended similarly.

Recommendation 11: GP education

a. An education and awareness campaign (involving, if required, the issuing of CMO letters/guidance to all clinicians following the conclusion of the Inquiry) should be run to remind GPs about the signs and symptoms of viral hepatitis, its prevalence in groups outside the "at risk" groups identified above, and the need to investigate whether a

patient *may* have a history of blood transfusion (noting that some patients may not be aware that they have received blood or blood products).[2036]

b. The ideal outcome would be for each GP to undertake a course of learning such as the RCGP Hepatitis B & C course,[2037] however, this should be alongside bespoke information about the risks attributable to infected blood. NHS England, or another appropriate body, should ensure that all GPs have access to this course and to bespoke training.

c. Any GP educational or training resource should:

   i. include guidance on using clear, simple language to explain both the disease, the treatment available, and what tests involve. This should be supported by clear and accessible guidance provided in leaflets/online.

   ii. ensure GPs ask questions to identify those infected through blood transfusion. Doctor-facing guidance should include a "tick box" or similar feature reminding GPs to explore histories of blood transfusion. This could be done, for example, at the NHS health check currently offered to all 44-year-olds, or any other form of routine discussion (for example when registering with a new surgery).

   iii. include training on how to communicate an HCV diagnosis to patients, signpost patients to support schemes, and to ensure their cases are appropriately followed-up.

d. There should be at least one GP in every large practice and/or several GPs in every commissioning area with this expertise and with a particular knowledge of the history of infected blood. This could be ensured by way of a contractual mechanism (supported by a financial incentive), which may require legislative change.

[2036] Such training must emphasise that even where there is no record of a bloodtransfusion, where an individual has had obstetrics or gynaecological interventions, or surgery before (for example) 1995 and presents with symptoms of HCV, they must be offered a test. The onus must be shifted onto the service provider to proactively explore and exclude the diagnosis of TTI from blood transfusion, rather than leaving patients to selfadvocate.

[2037] Available here. We endorse the UKHSA's recommendation that *"All stakeholders should work to improve awareness of HCV and national guidance on testing for HCV among health care professionals, for example by encouraging participation in, and audit of RCGP e-learning*" but it must be made freely available.

i. This GP or practice should link with the current HCV "*hub*" (ODNs)[2038] to facilitate the creation of a clinical pathway from GPs to appropriate HCV care for each patient within the hub.

ii. GPs must be made aware of the specialist lead HCV nurse in their area and be able to refer patients on to the hub easily.

e. The Inquiry should consider that any GP database or sources of information promulgated or required to be accessed by GPs should provide information about the position of those infected by way of blood or blood products, the payment schemes, and any future compensation framework.

f. We endorse the current Public Health England Guidance: "*Whenever a liver function test is returned with unexplained raised transaminase levels, consider testing for HCV as part of further investigation, even when there are no overt risk factors*".[2039] However, the experience of our CPs suggests that this is often overlooked in practice and should be re-emphasised as part of GP education.

g. The NHS HCV pages[2040] should contain a link to the Hepatitis C Trust in a similar way that organisations are linked which help and provide support for patients diagnosed with other conditions (such as HIV).

h. All medical training and GP education should focus on the up-to-date clinical understanding of HCV as a multi-system disease and not simply a disease affecting the liver. This should include an emphasis of the disease's extrahepatic manifestations, including rheumatoid arthritis, thyroid problems and type 2 diabetes, autoimmune disorders, musculoskeletal problems and mental health problems (as set out in the Inquiry's Hepatitis Expert Group Report, pp58-61). This should be for the purposes of testing (namely identifying symptoms) and ongoing management of the condition.

[2038] Please see the recommendation on HCV commissioning in the chapter on the Role of Medical Practitioners.
[2039] NB – this guidance is still promulgated under PHE name, notwithstanding its dissolution and replacement with UKHSA and OHID: *Hepatitis C: information for GPs*, updated 25 November 2020 (accessed 10 November 2022).
[2040] In particular this page.

i. GPs should be "*spot-checked*" for HCV CPD and for compliance with national guidelines on HCV, as part of any routine inspection process. The Inquiry should consider whether this should be part of a GPs' contractual requirements and/or their appraisal and re-validation.

j. NHS England should consider how they might incentivise GPs to ensure that adequate HCV treatment and follow up is undertaken. This must be maintained beyond the current elimination programme end date (2030). This could be by way of the Quality and Outcomes Framework.[2041]

Recommendation 12: Public information campaign

a. A targeted public education campaign[2042] is necessary to enable infected but undiagnosed people to identify themselves and come forward.

b. The campaign should highlight the variety of symptoms associated with viral hepatitis and emphasise the possibility of contracting HBV or HCV as a result of a transfusion.

c. We recommend undertaking a one-off publicity exercise in a range of media, including social media, with a focus on addressing those aged 50 and over.

d. Patient representatives, such the Hepatitis C Trust, should be invited to advise on the most effective and value for money means of targeting the cohort of people most likely to be affected by infected blood.[2043] If the Inquiry considers that it is more appropriate for an organisation like the Hepatitis C Trust to run such a campaign, it is essential that it is fully funded by NHS England or by the Government.

e. Leaflets and information posters regarding HBV and HCV, encouraging patients to ask their doctor for a test, should be prominently displayed at GP surgeries or in material used by patients to access appointments and the doctor (such as patient access apps/the NHS app).

[2041] As Dr Mary Ramsay from the UKHSA suggests in her written evidence: WITN7375001, §2.10(d).
[2042] Consistent with the evidence of the experts on HCV elimination.
[2043] See Dr Ramsay: WITN7375001, §2.17, who suggests that any media campaign would likely be co-developed with input from The Hepatitis C Trust and other target audience patient representative groups to ensure appropriate and impactful messaging and channels were used.

f. Issues with lost records and inadequate reporting from hospitals to GPs also means that GPs are often unaware that their patients have had a blood transfusion. Given this, any awareness campaign (and associated materials) should alert individuals that their GP may well not know this and will need to be told about this in order to be able to consider the issue of transmission of infection by blood.

Recommendation 13: Finding undiagnosed patients - testing[2044]

a. All those who meet the amended (as per our recommendation above) guidance for testing for patients who have previously received blood or blood products should be offered HCV and HBV tests.[2045]

b. Moreover, all those with potential HCV symptoms (including chronic extrahepatic symptoms) should be offered an HCV test.

c. The non-specific symptoms of HCV (for example, fatigue, digestive problems, joint pain and brain fog) can easily be dismissed or misdiagnosed, particularly given the ageing nature of the infected population, menopause and more recently the rise of long Covid. HCV testing should be part of the standard battery of tests for patients presenting with these symptoms. We are aware that some of the NICE guidance does recognise this, but not all of it.

d. In the USA, all adults born between 1945 - 1965 have a chance to have "*one off HCV testing*" because of the higher rates of transmission in that group. The Inquiry should carefully consider if this type of screening programme would be beneficial to ensure that all those who may possibly have HCV are identified and can access treatment upon diagnosis.[2046]

e. If our primary recommendation is not practicable, we recommend that all women aged 45 or older who have given birth before the longstop date/a date to be determined by the Inquiry, should be offered a test.

[2044] Please note this is additional to our endorsement of the existing NHS England algorithmic flagging pilot, and our recommendation that it is fully rolled out.

[2045] This also intends to build on the recommendation of the Penrose Inquiry, which has not been satisfactorily implemented and which does not fully address the position of those who continued to receive infected blood after September 1991, including some CPs.

[2046] Hepatitis Expert Group Report, p21.

f. We understand that NHS England has tendered for the development of a "*web portal*" so that individuals can order a test online in a discreet and private manner. We understand that this is due to be implemented /come into force at some point in 2023.[2047] We consider that this may well provide a quick and easy mechanism to ensure or roll out widespread testing: and that the experience of Covid has made the population more willing to access and use online mechanisms for the ordering of tests.

g. This testing programme should be publicised through the media campaign discussed above.

CHAPTER 6: SELF-SUFFICIENCY, FRACTIONATION AND PHARMACEUTICAL COMPANIES

Recommendation 1: Self-Sufficiency, Fractionation and Pharmaceutical Companies

a. That the corporate successors to the pharmaceutical companies who supplied blood products to the UK in the 1960s-1990s offer an apology to the IAP communities and recognise the role of their predecessors in contributing to the infected blood tragedy;

b. The government should consider whether it is appropriate to seek compensation from the corporate successors of relevant pharmaceutical companies;

c. The UK should allocate proper resources to its licensing system, ensuring that it has the precautionary principle at its heart;

d. The UK should mirror or exceed all relevant EU regulations for safety in blood products, including future regulations; and

e. Pharmaceutical companies should be subject to a duty of candour in licensing applications.

[2047] https://www.contractfinder.service.gov.uk/Notice/348b567-ebef-4122-b8f6-005bdc8b2031.

CHAPTER 7: "FORCED TO BEG FOR SCRAPS OFF THE TABLE": TRUSTS AND SCHEMES

Recommendation 1: Structure of a Future Compensation Scheme

a. HBV should be included;
b. There should be no cut-off date for infections;
c. It should have open-ended funding and provide life-long financial support on the basis of need (unless applicants choose to receive 'lump sum' payments);
d. Back payments should be paid to those wrongly refused by previous schemes; those who suffered loss as a result of the support schemes' discriminatory policies; and those who missed out on regular payments as a result of poor publication of the schemes when they were established;
e. Bereavement awards should be paid to the estates of those who have died and should be set at the statutory level;
f. Compensation should include parents of eligible infected persons (i) whose eligibility started in childhood, (ii) at a time when they were still living with their parents, or (iii) who returned to live with their parents after infection for care and support;
g. Affected individuals should be able to apply for a financial loss award;
h. Compensation should include members of the family, or friends of an eligible infected person, whose relationship with them was so close that it can properly be compared to the other relationships in this category;
i. Partners whose relationship broke down less than one year after infection should be included.

Recommendation 2: Level of Compensation

a. Any of those who become eligible for financial support under the future scheme should receive £100,000 to achieve parity with those who have received interim payments. A similar award should be paid to the estates of bereaved individuals;

b. Levels of compensation must be set in consultation with IAP;

c. There should be individualised assessment of past and future damages, including financial losses and caring costs;

d. Compensation should be tax free, not offset against any previous awards under the trusts and schemes, and disregarded in assessment of means tested benefits;

e. Awards should not be subject to 'clawback' or later deduction but applicants should be able to apply for further financial support if it becomes clear that greater damage has been sustained than that covered by an initial award;

f. Social impact awards should not be fixed according to the severity of the disease;

g. There should be a fixed sum to reflect the moral harm which IAP have suffered.

h. Individuals who have participated in and/ or received an award of compensation via previous litigation related to infected blood must not be prevented from applying the scheme. Their previous involvement in litigation should not remove their right to challenge through the courts an award decision made by the scheme or by a tribunal on appeal.

Recommendation 3: Form of Awarding Body

a. It should be an independent ALB, created in collaboration with IAP. The approach to compensation should similarly be co-produced.

b. Awarding panels should include legal, medical and infected/affected representation;

c. Applications should be simple, with the lowest possible evidential burden placed on them. The production of medical records must not be a precondition to eligibility. The ALB should be able to obtain evidence independently from third parties.

d. There should be a right of appeal to an independent Tribunal sitting within HMCTS;

e. There must be free legal representation and advice throughout the process;

f. The scheme should avoid being adversarial and the lower standard of proof should be applied;

g. The scheme should be UK-wide;

h. The ALB and / or Tribunal should have access to expert evidence but applicants should not bear the cost of this;

i. If possible, there should be automatic information-sharing between previous trusts and schemes and the new awarding body;

j. There should be a monitoring and consultative body with representation from patient groups and infected/affected individuals which is responsible for overseeing the implementation of the new scheme and reporting on this to government.

Recommendation 4: Social and non-financial compensation

a. All applicants for financial compensation should be offered comprehensive welfare rights advice and advocacy;

b. IAP should be supported to access life, travel, and mortgage insurance on a level playing field;

c. Adequate information should be supplied to DWP to ensure that IAP are not wrongly excluded from benefits;

d. Infected individuals should have free access to dentistry, optometry, hearing tests and aids, physiotherapy and complementary therapies;

e. Infected individuals should have free access to social care and domiciliary support. The Inquiry is also invited to consider extending this to affected individuals.

f. The Inquiry should consider whether to recommend the introduction of a scheme similar to the Irish Health Act Amendment Card, including facilitation of joined-up care and specific timed clinics for holders.

CHAPTER 8: GOVERNMENT

Recommendation 1: Ministerial training and working arrangements

a. When they are appointed to office, all Ministers should receive an induction pack outlining the current policies and priorities and be required to speak with relevant

policy leads to identify the background to the issues, the length of time that the policy has been in place, and to have a handover with the previous Minister.

b. All Ministers should receive training on the nature of their function, the Ministerial code, the Nolan Principles and the values expected of them. They should also receive training on decision making and the factors that need to be considered (it would appear that such training is now offered in Scotland and may be offered in England, but the position is not entirely clear).[2048] Ministers should recognise the requirement to query or question received wisdom and interrogate policies which seem to reflect stale thinking.

c. Facilitated time should be given to allow Ministers to master their briefs. Ministers should be moved only if they are not performing, not as part of political patronage.

d. There should be time for reflection, discussion and debate built into Ministerial working days.

Recommendation 2: Departmental funding

a. It is suggested that there should be a mechanism for departments such as health to have access to flexible pots of money, to cover unexpected or unanticipated costs. In the alternative we suggest that such departments should be able to use "*unspent money*" from a financial year providing of course that there is sufficient justification for its use.

Recommendation 3: Civil service careers

a. Civil servants should be encouraged, and a career pathway found, to ensure advancement even if individuals choose to work on long term projects to develop their experience and expertise.

Recommendation 4: Candour and transparency

a. Lines to take should be the subject of regular scrutiny if they are long standing policies. For historical policies, adequate records must be kept of (a) the basis upon which the line to take was first adopted, and (b) what facts have subsequently emerged or could be examined. This examination could be by a commissioner or tsar, select committees,

[2048] WITN7351001, §7.6.

or a body which did not participate in the original decision making. If it is necessary for the advice given to or the decisions made by Ministers in previous administrations to be examined as part this process, there should be a mechanism to ensure that this can happen.

b. A duty of candour should be introduced on a statutory footing for all public servants, including Ministers. It is accepted that whilst candour is set out in the civil service code, which itself is on a statutory footing, evidence heard by this Inquiry demonstrates that this has not been effective. Whilst the current heads of the English, Welsh Scottish and Northern Irish civil service did not favour such,[2049] it is submitted that the need for codification is overwhelming given the many instances where an absence of officials communicating the whole truth has been evidenced. This was not by one or two individuals over a short period of time, but by countless teams of civil servants across several administrations.

c. This Inquiry shows the necessity to have stronger accountability for the civil service and a governance structure which creates legitimacy. It is suggested that this Inquiry recommends the reforms suggested in the Institute of Government report: the Statutory Role of the Civil Service and creates a civil service board to whom civil servants are accountable.[2050]

d. In cases of gross failures or clear dishonesty with the public, consideration should be given to implementing the Law Commission reforms in respect of the offence of misconduct in public office, so that those who breach the duty to prevent death or serious injury and are reckless about doing so can be exposed to criminal liability.[2051] In this case, our CPs agree with Andy Burnham[2052] that the nature of failings requires careful consideration by prosecutorial authorities.

[2049] Transcript 14/11/2022, pp63-68, ll14– 16.

[2050] https://www.instituteforgovernment.org.uk/sites/default/files/publications/new-statutory-role-civil-service.pdf, pages 27-45.

[2051] Whilst there is the offence of misconduct in public office, the Law Commission has identified concerns with it and recommends that it is significantly reformed and placed on the statute book – Law Commission paper: Law Commission final report on misconduct in public office published 4 December 2020. Law Commission, www.lawcom.gov.uk

[2052] Andy Burnham, Transcript 15/07/2022, P132, LL12-14.

e. The Ministerial Code in England, Wales and Scotland does not have any statutory underpinning and its enforcement is at the discretion of the Prime Minister alone.[2053] The Independent Advisor on Ministerial standards is not a statutory post. This role should be put into statute[2054] and be given the power to initiate inquiries and determine breaches of the Code.[2055]

f. There should be implementation of the 2021 report from the Committee on Standards in Public Life to provide for and to put into effect a robust compliance system across all departments in Government.

g. The civil service should use reflective learning as a mechanism for improvement as a matter of routine, and this should be endorsed throughout the culture of the organisation.

h. Central Government and the devolved Governments need to implement an effective system of continuous improvement training focussing upon the need for candour and transparency, as well as innovation. Public servants should be measured in their performance against the upholding of those values.[2056]

i. The culture of the civil service needs to encompass discussion and debate of the values set out in the Code. Recruitment, promotion, and advancement should examine the personal values and ethics of the candidates and promote those who can demonstrate the values of the Code. The Inquiry should carefully examine the report of the Committee on Standards in Public Life due to be published in January 2023.

j. There must be some kind of objective system for examining if a public Inquiry should take place, particularly in respect of healthcare and patient safety. Such a system should be led by individuals who are independent of the actions concerned and ensure that the procedures which are then in place are structured, transparent and put those affected at the centre of the process. As to when a public Inquiry should be ordered, under the Public Inquiries Act 2005 this can only be ordered by a Minister (s1 of the Act). It is suggested that whilst this decision may still need to remain one for a Minister

[2053] Transcript 03/10/2022, p24-37; EXPG0000047_0008; The Northern Irish Code does have statutory underpinning and operates differently given the contentions set out in the Belfast, Agreement, the Northern Ireland Act 1998, and the St. Andrews Agreement and the NI Act 2006

[2054] RLIT0001838.

[2055] RLIT0001838; Transcript 14/11/2022.

[2056] Transcript 14/11/2022, p11, l14.

(in order to ensure accountability to Parliament), it could and should be informed by advice from the bodies described above.

k. At present, the recommendations of public inquiries do not need to be implemented by Governments. Successive academics and others have identified this as a major gap. This Inquiry should recommend that an independent body lead oversight and monitoring of Inquiry recommendations.[2057]

l. As part of reflective learning, the Government should continue to ensure that the minutes of relevant expert committees and the scientific advice provided to Government is given to Ministers directly, and any facts upon which a policy are made are published in order to ensure openness and transparency.[2058] As Professor Sir Jonathan Van Tam identified in his evidence, if there is disagreement, the fact of such disagreement and the broad nature of the disagreement should appear on the face of the minutes.[2059]

Recommendation 5: Patient safety

a. There should be a shared analytical resource that all four administrations could draw upon to inform policy development, operating via the UK Health Protection Committee.[2060]

b. There should be patient safety commissioners appointed in all four nations who are required on a statutory basis to co-operate with each other and whose role is, as far as possible, identical in all four nations. The Scottish Patient Safety Commissioner Bill was published in October 2022[2061] and provides that the Scottish commissioner will bring together patient feedback and safety data from all healthcare providers to identify concerns and recommend actions. They will also hold healthcare providers to account in their responsibility to listen to patients.

c. The duty of candour should be implemented in all four nations with consistent and identical understanding of when and how it should operate.

[2057] Sir Robert Owen, 'When Things Go Wrong, The response of the justice system, A report by JUSTICE', <https://files.justice.org.uk/wp-content/uploads/2020/08/06165913/When-Things-Go-Wrong.pdf> d

[2058] Lord William Waldegrave, Transcript 05/07/2022 and Transcript 06/07/2022.

[2059] Transcript 18/11/2022.

[2060] WITN7458001, p16, para 5.46

[2061] Scottish Government, *Patient Safety Commissioner Bill published* <https://www.gov.scot/news/patient-safety-commissioner-bill-published/>

d. Consideration should be given to each country's legislation implementing a four nations policy which requires co-operation between the devolved nations on health, and co-operation between the various national regulatory bodies to seek to promote similar guidelines and standards in respect of patient safety. Whilst the Public Health Protection and Health Security Common Framework[2062] does provide some arrangements for co-operation, it is yet to be seen if it is suitably comprehensive.

e. Consideration should be given to permitting and/or ensuring that the Health Care Safety Investigation Branch can investigate failings UK wide, not just in England.

f. For those with infected blood, there should be a four nations group made up of representatives from each administration which seeks to provide, as far as possible, identical support structures and systems of compensation. Consideration should be given to the establishment of specialist centres or at least a specialist centre for the IAP of this Inquiry in respect of HBV, HCV and HIV treatment, to provide support to deal with the particular issues that emerge for these individuals.

Recommendation 6: For Government implementation of UK wide healthcare improvements [2063]

a. Create a one stop shop for patients to raise concerns with the NHS, which has clearly defined outcomes and involves the system engaging with the patient.[2064]

b. Every clinical organisation should have someone who has responsibility and accountability to the Board of that organisation (or its management structure) to identify ways in which they have sought out, identified and addressed patient safety issues.

c. Focus groups and patient feedback should be sought on an in-depth basis.

d. Co-production frameworks should be used in policy, treatment, and improvement across the whole of the NHS (not just locally but also nationally).

e. The Patient Safety Commissioner should consider not just the safety of medicines and medical devices but also work with the various patient safety bodies in the UK and the

[2062] WITN7458008

[2063] Transcript 14/11/2022, p137-138.

[2064] Transcript 04/10/2022, p177.

devolved administrations to examine patient safety as a whole and provide benchmarks and standards for engaging with patients.

f. The Scottish Patient Safety Commissioner Bill was published in October 2022[2065] and provides that the Scottish commissioner will bring together patient feedback and safety data from all healthcare providers to identify concerns and recommend actions. They will also hold healthcare providers to account in their responsibility to listen to patients. In as much as the English patient safety commissioner does not do this, her remit should be extended to ensure that these actions are included.

g. Consideration should be given to a Health and Social Care Safety Commissioner who advises on addressing patient risk and has responsibility for the collation and aggregation of data; and monitoring safety information to identify emerging concerns. This must take place alongside a system to plan and track safety information at all levels of the NHS and in all bodies who provide health or social care. This should be a UK wide appointment.[2066]

h. The statutory duty of candour currently enacted for healthcare officials should be identical between the four nations and should provide clear requirements to (a) identify when the duty is triggered (b) ensure that understanding of the duty is embedded through training of all staff (c) audit the duty working in practice, with accountability to the board/management of every clinical organisation, and (d) ensure that breaches of the duty result in disciplinary action, acknowledging that the body that enforces this may differ between countries.

i. The DHSC, and the departments of health of the devolved administrations, should implement a wholesale programme of cultural reform, starting at leadership level, to implement just cultures within healthcare, and to assess the implementation of such a culture. The implementation of a health and psychologically safe culture should be communicated to all those working within or for the NHS, and in all private healthcare services in the UK.

j. All insurance companies, professional indemnifiers, Royal Colleges and professional organisations, patient groups, charities, health, and social care regulators should

[2065] Scottish Government, *Patient Safety Commissioner Bill published* <https://www.gov.scot/news/patient-safety-commissioner-bill-published/>

[2066] RLIT0001736; Transcript 04/10/2022, p92-94.

undertake a collaborative programme of work to identify and provide a 10-year programme to embed a culture of learning and candour within the system.

k. Those recruiting, promoting or performance managing practitioners in the healthcare system should assess their competence in and management of candour, and their implementation of learning cultures and their values and ethics as central features of any review, recruitment, or audit (just as with civil servants and Ministers above).

l. Research should be undertaken into how to encourage clinicians and all those working in health to report adverse effects using the Yellow Card system.

m. The MHRA should publish a dip sample of licensing decisions – not just new drugs - by way of public assessment reports on an annual basis, to encourage transparency and openness as routine in the licensing of medicines.

n. The MHRA, working with others, should endeavour to commission or produce a patient version of the British National Formulary available for patients to understand and be provided with accessible information about the drug and its risks.

o. The UK and devolved Governments should compel practitioners to note and send to the MHRA any prescriptions they give off licence and a body should be set up to research and examine this.

Recommendation 7: Gender inequality

a. The Women's Health Strategy should consider the use of blood transfusions during pregnancy and postnatally as part of its approach to pregnancy and post-natal support and should seek to ensure that clinicians comply with guidelines in place about minimal use of blood transfusions during this period, and the use of tranexamic acid.[2067]

b. The experience of many women heard by this Inquiry of patronising, rude and belittling care immediately post-partum should be fed into the Women's Health strategy; there should be mandatory education and training for health and care professionals on this issue and on the impact it has upon women not just at the time, but for the rest of their lives. Many of our CPs continue to relive experiences which happened 40 or 50 years

[2067] Professor Ian Roberts, Transcript 10/11/2022.

ago, the vivid impression it has left upon them and the trauma and distress it has caused them is lifelong.

c. The Hepatitis C Trust and British Liver Trust are encouraged to work with the Women's Health Ambassador to examine disparities in treatment and outcomes for women with chronic liver disease resulting from HCV infection.

d. The Health Ambassador should look at the experiences of women infected with HBV and HIV and ensure that diagnosis and treatment of such conditions has similar outcomes to those of men.

e. Training of clinicians should recognise the bias in diagnosis and treatment of women's pain and ill health, as is understood by this this Inquiry and in the others mentioned above, there can no longer be a view that women should just put up with it.

Recommendation 8: Inequalities on the basis of race, ethnicity or nationality

a. The Inquiry should identify to the Office for Health Improvement the information that it has uncovered indicating that poor treatment and outcomes for conditions such as sickle cell and thalassemia are likely to have masked issues around infected blood.

b. The Government should recognise that those from some minoritised ethnic backgrounds have been discriminated against by their communities because of their infection status, as well as being treated in a manner which is discriminatory and derogatory by healthcare providers. As with other areas of healthcare practice, the Office for Health Disparities should examine the discrimination experienced by those from a minoritised ethnic background who are infected with HIV, HBV or HCV and identify ways in which their treatment, care or experience could be improved.

c. The Government should consider initiating a public inquiry into health inequalities.

Recommendation 9: Government records

a. Training should be given to all staff at all levels of seniority on a regular basis about the importance of keeping records and of maintaining adequate filing arrangements.

b. Decisions as to which documents are kept on registered files or the equivalent should be made by individuals who are familiar with the policy background and issues raised by the documents. There should be an assumption that material should be kept unless it looks obviously ephemeral.

c. All read outs from Ministerial discussions or civil service meetings should be preserved and archived as they provide the current day manner in which decisions are recorded.

d. Where records have gone missing, this should be acknowledged and communicated publicly.

e. Where internal investigations need to take place, these should follow the relevant GIAA policies.

Recommendation 10: General Recommendations in relation to central Government

a. An official apology should be issued by the UK Government. Such an apology must be given by appropriately senior members of the Government. We would recommend that the Prime Minister, Health Secretary, regional Health Ministers, and NHS leaders participate in the apology.

   i. It should be given in primary languages recorded as being spoken by the infected and affected, as well as in British Sign Language and braille where appropriate.

   ii. It should acknowledge the pain, suffering, and long-term trauma which the infected and affected have experienced. As the Inquiry has sought to do throughout, the experiences of the infected and affected must be foregrounded.

b. As the NHS is a revered and trusted public institution, there must be recognition of the suffering caused by the repeated refusals by the NHS and Government to acknowledge wrongdoing over a period of decades. The psychological impact upon the infected and affected of being expected to rely upon the institution which has failed them undermines their trust in authority and has serious consequences for the rest of their lives. That must be recognised and reflected in any apology.

c. The UK Government should candidly accept any findings the Inquiry may make about Government wrongdoing and specifically identify what steps it intends to take alongside health officials to (i) support the infected and affected immediately and on an ongoing basis and (ii) prevent the reoccurrence of such a failure.

d. A number of our CPs have expressed appreciation of the memorial at the Inquiry hearing centre. We recommend that an official memorial be arranged, with input from the infected and affected, after the Inquiry reports. While we would not wish to be prescriptive about the form of any memorial at this stage, we consider that an oral history project, featuring video and written accounts from infected and affected people,

made available online and curated as part of the National Archives would be one possible option.

e. Victims should be assisted by a public advocate, funded by the public purse, to act for victims of major tragedies (where they are not already entitled to representation as core participants, as has been done successfully in this Inquiry).

Recommendation 11: Recommendations in respect of Coroners' powers and procedure

a. Review of current Medical & Coronial Registration and Death Certificate Conclusions, with amendment to the notes to Schedule Form 2 of the Coroners (Inquests) Rules 2013, to add a new Short Form Conclusion of: 'Death from infectious illness HCV HIV, Variant Creutzfeldt-Jakob disease ("**vCJD**"), liver carcinoma or other arising from the provision of contaminated blood products/ blood.

ANNEX 2: LIST OF PHYSICAL AND MENTAL SYMPTOMS AND SIDE EFFECTS OF HCV INFECTION AND TREATMENT

Physical effects

Hepatic manifestations of viral hepatitis (i.e. liver related conditions)

- Decompensated cirrhosis[2068]
- Chronic liver disease[2069]
- Liver pain[2070]
- Liver cirrhosis[2071]
- Liver fibrosis[2072]
- Swollen liver[2073]
- Primary biliary cirrhosis[2074]
- Liver cancer[2075]

[2068] W2005 §24, W1832 §21
[2069] W2005 §24, W1814 §3, W1966 §9, W3710 §27, W1832 §21
[2070] GRO-D W1871 [ANON] §24, W1885 §26
[2071] W2055 [ANON] §27, 33, W1876 §30, W1878 §17, W1889 [ANON] §25, 44, W1905 §42, W1919 [ANON] §18, W1932 §36, W1935 §12, W1943 §28, GRO-D W1972 §21, W1974 [ANON] §21, W1982 §14, W2041 §33, W2042 §35, W2062 §25, W1998 §31, W1967 [ANON] §9, 17, W1999 §24, W1817 §16, W1819 [ANON] §17, W1823 §33, W1825 §7, W0709 §22, W1867 §44, W2819 §27, W1901 §18, W2991, W1926 §12, W1941 §16, GRO-D W1950 §23, W1961 §11, W1962 §49, W1975 §21, W2703 §22, W2026 [ANON] §13, GRO-D, GRO-D
[2072] W2009 §26, W1921 [ANON] §33, W1938 §45, W2059 [ANON] §22, W0508 [ANON] §13, W2702 §23, W1996 [ANON] §29, W1997 §36, W0394 §16, W1882 §21, W1975 §21, W2703 §10, GRO-D
[2073] W1899 [ANON] §6
[2074] GRO-D
[2075] W2019 §30, W1932 §56, W1947 [ANON] §31, W2062 §25, W1967 [ANON] §17, W1819 [ANON] §17, W1848 §21, W0709 §1, W1877 §17, W1941 §44, W2033 §1, W1977 §19, W2026 [ANON] §14, W3326 §18, GRO-D

Extra-hepatic manifestations of viral hepatitis (i.e. non liver related conditions)

- Debilitating fatigue/ extreme tiredness/ exhaustion/ lack of energy/ lethargic/ weakness[2076]
- Aches and pains and stiffness in joints/ muscles which are swollen[2077]
- Severe leg cramps and spasms[2078]
- Osteoarthritis[2079]
- Dizziness[2080]
- Vertigo[2081]

[2076] W2690 [ANON] §25, §30, W1826 [ANON] §21, 22, W1838 §29, §37, W1834 §25, W2005 §21, 23, W0072 §11, 23, W0622 §20– 23, W1855 §22, W2853 [ANON] §12, W2853 [ANON] §17, W1857 [ANON], W2055 [ANON] §28, W1953§25, W1820 [ANON] §15, W2009 §23, W1868 §6, 16, W0065 §11 §20, 27, W1860 §22, 27, 29 and 30, W1859, W2630 §19, W2631 [ANON] §21, W1871 [ANON] §8, W1876 §11, W1878 §22, W2012 §7, 27, W1880 [ANON] §6 21, 22, W1886 [ANON] §26, W1888 §8,W1889 [ANON] §13, W1890 §16, W1891 §9, W1892 [ANON] §21, W1895 §17, GRO-D , W1899 [ANON] §9, 23, W1896 §14, W0031 [ANON] §2.29, 2.30, W1900 [ANON] §5, W1902 [ANON] §25, GRO-D W2637 §17, W1905 §31, W1907 [ANON] §20, W1910 §11, W2019 §27, 31, W2638 §11, W1921 [ANON] §33, W1923 §15, W1925 [ANON] §8, W1932 §32, W1934 §11, 34, W1935 §8, 20, W1938 §14, W1945 §30, W1954 §18, GRO-D , W1960 §30, W1963 §23, W2644 §15, W1970 §22, W2645 §11, W1972 §22, W1974 [ANON] §22, W1982 §7, W2041 §32, W1987 [ANON] §14,W1987 [ANON] §29, W2042 §8, W1988 §18, W1990 §35, W2043 §21, W2702 §18, W1992, W1995 §19, W1999 [ANON] §18, W1997 §9, W2062 §25, W1998 §24, W2000 §10, 29, W2001 §11, W2002 [ANON] §16, W1967 [ANON] §8, GRO-D ,W1814 §17, W1819 [ANON] §9, W1823 §21, W1848 §26, W1850 §27, W0709 §21, W1867 §40, W1877 §17, W1882 §18, W1901 §31, GRO-D , W1928 §1, W1950 §22, W3918 §2, W1966 §25, W1968 [ANON] §8, W2039 §30, W1975 §6, W1977 §17, W2703 §18, W1994 §11, W2026 [ANON] §12, W1832 §7, W3712 §18

[2077] W2055 [ANON] §19, W0072 §11, 23, W2853 [ANON] §17, W1859, W2009 §23, W3325 §24, W1868 §16, W0065, §23, W1876 §11, W2012 §29, W1880 [ANON] §23, W1890 §27, W1895 §17, W1899 [ANON] §23, W1900 [ANON] §5, 24, W1902 [ANON] §28, W1905 §31, W1907 [ANON] §20, W1908 [ANON] §19, W1910§11, W2019 §28, W2638 §12, W1925 [ANON] §8, W1932 §34, W1934 §11, W1935 §8, 20, W1963 §23, W1972 §22, W1974 [ANON] §21, W2059 [ANON] §29, W2043 §26, W1992, W1996 [ANON] §9, 2000 §12, 29, W2001 §11, W2002 [ANON] §18, GRO-D , W1821 §26, GRO-D , W1928 §11, W1966 §20, W3326 §6, GRO-D , GRO-D

[2078] W2055 [ANON] §19, W0072 §11, 23, W1885 §5, W1896 §14, W1934 §34, W1945 §23

[2079] W1826 [ANON] §20 – 22, W1855 §22, W1860 §22, 27, W1899 [ANON] §24, W1900 [ANON] §24, W1908 [ANON] §20, W1923 §18, W1970 §23, W2645 §22, W2059 [ANON] §22, W2043 §26, A W1821 §26, W1877 §17, W1928 §22

[2080] W2055 [ANON] §19, W1910 §11, W1925 [ANON] §17, W5209 §8, W1867 §40, W3697 §11, GRO-D , W1966 §5

[2081] W2055 [ANON] §19

- Brain fog[2082]
- Memory lapses/ forgetfulness/ affect on cognitive thinking/ unable to finish sentences or concentrate[2083]
- Low blood sugar[2084]
- Confusion/ disorientation[2085]
- Nausea/ vomiting[2086]
- Insomnia/ strange sleeping pattern[2087]
- Constant itching all over body (described as coming from inside the blood, not from skin)[2088]
- Ascites[2089]
- Stomach ulcer[2090]
- Oesophageal or gastric varices[2091]

[2082] W1826 [ANON] §21, 22, W1838 §37, W1829 §25, W1834 §27, W0072 §50, W0622 §20, W2009 §23, W1876 §25, W1889 [ANON] §13, W1895 §17, W1905 §63, W1913 §18, W2638 §17, W1947 [ANON] §30, W1949 §19, W1963 §23, W2644 §22, W1972 §22, W1987 [ANON] §35, W2042 §23, W1988 §18, W2043 §27, W1996 [ANON] §33, 2000 §28, W2001 §11, W1999 §25, W2634 §24, W1850 §27, W1977 §17, W2703 §20, W3712 §18

[2083] W1826 [ANON] §21, 22, W1838 §37, W2005 §21, 23, W2005 §24, W0622 §20, W2853 [ANON] §17, W2055 [ANON] §28, W1876 §25, W1878 §23, W2012 §29, W1895 §17, W1902 [ANON] §27, W1907 [ANON] §20, W1913 §17, W2638 §17, W1923 §15, W1925 [ANON] §17, W1943 §27, W1945 §23, W1963 §23, W1972 §22, W1974 [ANON] §22, W1990 §35, W2043 §27, W1996 [ANON], W1950 §22, W3918 §2, W1968 [ANON] §8, W1832 §22

[2084] W1826 [ANON] §21, 22, W3326 §7

[2085] W1826 [ANON] §21, 22, W2012 §29, W1889 [ANON] §44, W1932 §37,W1825 §21, W0709 §32, W1967 §40, W2011 [ANON] §17, W1928 §11

[2086] W1838 §29, W1838 §37, W2853 [ANON] §17, W1860 §22, 27, W1868 §9, W2012 §27, 29, W1886 [ANON] §5, 26, W1891 §9, W1899 [ANON] §6, 23, W1910 §11, W1921 [ANON] §13, W1925 [ANON] §17, W1934 §11, W1935 §6, W1938 §14, W1987 [ANON] §29, W1990 §35, W1992, W1995 §22, 2000 §12, 29, W1967 [ANON] §8, GRO-D , W1848 §26, W0709 §32, W1901 §34, GRO-D , W3918 §29

[2087] W1838 §37, W2692 §33, W3103 §33, W2631 [ANON] §21, W1876 §26, W1896 §16, W2638 §14, W1935 §6, 20, W1963 §23, W2644 §15, W2645 §22, W1991 §20, W2000 §29, W2054 §7, W1968 [ANON] §8, W2703 §19

[2088] W1838 §37, W1111 §23, W1834 §7, W2005 §24, W2629 [ANON] §18, W2012 §29, W1879 §19, W1892 [ANON] §21, W1899 [ANON] §6, 19, W0031 [ANON] §2.29, W1907 [ANON] §20, W2019 §26, 31, W1925 [ANON] §17, W1963 §23, W1987 [ANON] §35, W1992, W1995 §24, W1996 [ANON] §33, W2000 §29, W2002 [ANON] §18, W1814 §17, W1819 [ANON] §16, W0709 §32, W1867 §43, W2011 [ANON] §17, W1877 §17, W1901 §32, W2991 §11, W2033 §27, W1968 [ANON] §19

[2089] W2005 §24

[2090] W1970 §23, GRO-D

[2091] W2005 §24, W1877 §17, W1928 §22, GRO-D

- Hepatomegaly[2092]
- Splenomegaly[2093]
- Portal hypertension gastropathy[2094]
- Portosystemic shunts [2095]
- Hiatus hernia[2096]
- Hepatic encephalopathy[2097]
- Fibromyalgia[2098]
- High stress[2099]
- Loss of appetite/ digestive problems/ weight loss (becoming skeletal)[2100]
- Kidney disease and kidney failure and kidney stones[2101]
- Jaundice/ yellow skin/ white of eyes turning yellow[2102]
- Dark urine/ urology problems/ pale stools[2103]

[2092] W2005 §24
[2093] W2005 §24
[2094] W2005 §24, W2703 §22
[2095] W2005 §24
[2096] W2005 §24, W2631 [ANON] §22, W1908 [ANON] §20, W1922[ANON] §32, W1934 §48, W2002 [ANON] §18, W2634 §30, W2703 §22
[2097] W2005 §24, W1932 §38
[2098] W0622 §23, W1921 [ANON] §33, W1934 §49, W1949 [ANON] §31, W2645 §11, W1966 §25, W2703 §18
[2099] W0622 §23, W1860 §29, 30, W1885 §25
[2100] W0622 §23, W2690 [ANON] §27, W2853 [ANON] §17, W1860 §22, 27, W2012 §7, W2012 §29, W1880 [ANON] §25, W1885 §9, W1889 [ANON] §44, W1902 [ANON] §28, W1907 [ANON] §22, W2638 §12, W1919 [ANON] §17, W1921 [ANON] §13, W1935 §6, 20, W1938 §14, W1945 §23, W1982 §7, W1990 §35, W1995 §23, W1967 [ANON] §16, W1967 [ANON] §17, GRO-D, W1819 [ANON] §16, W0709 §32, W1877 §17, W1901 §34, W3697 §12, GRO-D, W1966 §25, W2039 §29, W3326 §7, W2020 §21, GRO-D
[2101] W1855 §21, W2012 §7, W2645 §22, W1819 [ANON] §17
[2102] W2853 [ANON] §17, W1953§25, GRO-D, W3325 §11, 24, W1868 §9, W2012 §29, W1879 §19, W1885 §9, W1886 [ANON] §5, GRO-D, W2019 §30, W1938 §14, W2042 §8, W1997 §7, W2634 §24, W1814 §17, W2054 §7, W1819 [ANON] §16, W1823 §18, W1846 §7, W1850 §12, 27, W0709 §32, W2011 [ANON] §17,W1901 §34, W3697 §3, W1941 §16, GRO-D, W2039 §29, W1994 §13, W2026 [ANON] §12, W2020 §10
[2103] W2853 [ANON] §17, W1859, W2012 §29, W1879 §19, W1889 [ANON] §13, W3697 §8

- Stomach pain/ indigestion[2104]
- Severe migraine/ headaches[2105]
- Mouth ulcers/ gum disease[2106]
- IBS/ diarrhoea/ incontinence[2107]
- Lymphoedema[2108]
- Persistent coughing[2109]
- Pneumonia[2110]
- Loss/ blurred vision/ threat of blindness[2111]
- Acute obstructive sleep apnoea[2112]
- Angina[2113]
- Erectile dysfunction[2114]
- Epilepsy[2115]
- Heart palpitations[2116]

[2104] W2853 [ANON] §17, W3325 §24, W1868 §9, W2012 §29, W1886 [ANON] §5, W1902 [ANON] §28, W1908 [ANON] §20, W2019 §26, W5209 §7, 2000 §12, W1967 [ANON] §8, W1819 [ANON] §9,W1901 §31, W3697 §11, W1928 §11

[2105] W2853 [ANON] §17, W1859, W2631 [ANON] §21, W1892 [ANON] §7, W1899 [ANON] §6, W1896 §16, W2638 §12, W1925 [ANON] §17, W2059 [ANON] §29, W1995 §22, W1998 §24,W2000 §12, W2001 §11, W1967 [ANON] §16, W1848 §26, W1850 §12, W1901 §31, W3697 §11, W1977 §17, GRO-D

[2106] W2853 [ANON] §17, W2631 [ANON] §22, W1995 §24

[2107] W1860 §22, 27, W1868 §9, W2012 §29, W1880 [ANON] §25, W1895 §17, W1899 [ANON] §23, W1908 [ANON] §20, W1921 [ANON] §33, W1925 [ANON] §17, W1934 §34, W1945 §23, W2634 §26, W1821 §26, W0709 §32, W1877 §17

[2108] W1860 §23

[2109] W1859, GRO-D

[2110] W1859, GRO-D, W1963 §23, W1832 §21

[2111] W1859, W2012 §27, W1899 [ANON] §24, W5209§23

[2112] W1859

[2113] W1859, W2059 [ANON] §22

[2114] W1859

[2115] GRO-D

[2116] W2009 §25, W3325 §24

- Abdominal pains/liver pain/ swelling[2117]
- Psoriasis[2118]
- Trigger finger and frozen shoulder[2119]
- Cold sores[2120]
- Raised dark patches on skin/ rashes[2121]
- Inflamed lymph glands in neck and armpits[2122]
- erratic pulse[2123]
- Acute cholecystitis[2124]
- Left Ventricle hypertrophic cardiomyopathy[2125]
- Stroke[2126]
- Polyps on colon[2127]
- Gall stones[2128]
- Cataracts[2129]
- Cyst on ovaries[2130]
- Neuropathy[2131]

[2117] W3325 §11, 24, W1880 [ANON] §25, W1892 [ANON] §21, W1895 §17, W1908 [ANON] §20, GRO-D, W1987 [ANON], W1997 §12, W1877 §17, W1882 §18, W1928 §22, W1966 §29
[2118] W1868 §6
[2119] W1868 §18
[2120] W0065 §19
[2121] W0065 §19, W1899 [ANON] §23, W2000 §29 W0709 §21
[2122] W0065 §23
[2123] W0065 §17 (second statement)
[2124] W2631 [ANON §22
[2125] W2631 [ANON] §22
[2126] W2631 [ANON] §22, W1900 [ANON] §24
[2127] W2631 [ANON] §22
[2128] W2631 [ANON] §22
[2129] W2631 [ANON] §22, W2012 §29
[2130] W2631 [ANON] §22
[2131] W1876 §28

- Nose bleeds[2132]
- Bleeding/ bruising easily[2133]
- Slurred speech[2134]
- Spider blood vessel on legs[2135]
- Ulcers on legs/ hands[2136]
- Dry/ easily broken/ blistered skin[2137]
- Hair loss[2138]
- Vascular calcification[2139]
- High blood pressure[2140]
- Itchy eyes[2141]
- Arterial disease[2142]
- Night sweats[2143]
- Frequently cold[2144]
- Hidrandenitis Suppurativa[2145]
- Deterioration in hearing[2146]

[2132] W2012 §6, W1889 [ANON] §44, W1926 §25
[2133] W2012 §29
[2134] W2012 §29
[2135] W2012 §29
[2136] W2012 §29
[2137] W2012 §29, W1889 [ANON] §44, W1894 §10, W1814 §17, W1825 §7, W1848 §26
[2138] W2012 §29, W1885 §25, W1908 [ANON] §20, 35, 2000 §12, W2707 [ANON] §24
[2139] W2012 §29
[2140] W2012 §29, W1934 §11, W1967 [ANON] §16
[2141] W1880 [ANON] §25
[2142] W1885 §26
[2143] W1889 [ANON] §13, W1891 §16, W1899 [ANON] §23, W1896 §14, W2000 §29
[2144] W1892 [ANON] §21, W1908 [ANON] §20, W1925 [ANON] §17, W1967 [ANON] §16, GRO-D GRO-D
[2145] W1895 §18
[2146] W1899 [ANON] §24

- Myalgic Encephalomyelitis[2147]
- Left-sided intracerebral haemorrhage[2148]
- Muscles shakes/ spasms[2149].
- osteoporosis[2150]
- Tinnitus[2151]
- Myalgia[2152]
- Skin rashes/boils/ eczema which blisters/ dry skin/ skin cracks[2153]
- Thyroid[2154]
- Geographical tongue[2155]
- Fibroids[2156]
- Hypertension[2157]
- UTIs[2158]
- Enlarged spleen[2159]
- Bruising all over body[2160]
- Swollen testicle[2161]

[2147] W1899 [ANON] §28, W1925 [ANON] §18
[2148] W1896 §19
[2149] W1902 [ANON] §28, W1967 [ANON] §16
[2150] W1907 [ANON] §23, W1821 §26
[2151] W1907 [ANON] §23
[2152] W1907 [ANON] §23
[2153] W1908 [ANON] §20, W1990 §42, W1867 §46, W1901 §31
[2154] W1908 [ANON] §20
[2155] W1908 [ANON] §20
[2156] W1908 [ANON] §20
[2157] DEBORAH JONES W1913 §17, W2059 [ANON] §22, W1819 [ANON] §17
[2158] W1919 [ANON] §18
[2159] W1919 [ANON] §20, W1921 [ANON] §33, GRO-D, W1972 §22, W0394 §17, W1819 [ANON] §17, W1928 §22, W2703 §22
[2160] W1919 [ANON] §20, W1932 §35, W1945 §23
[2161] W1919 [ANON] §20

- Anaemia[2162]
- Thyroid cancer[2163]
- Undifferentiated Connective Tissue Disease[2164]
- Miscarriages[2165]
- Barrett's oesophagus[2166]
- Urticaria[2167]
- Severe nosebleeds[2168]
- Chronic Obstructive pulmonary Disease[2169]
- Hemochromatosis[2170]
- Prolapsed discs[2171]
- Deterioration in eyesight[2172]
- Raynaud's disease[2173]
- Heart disease[2174]
- Supraventricular tachycardia[2175]
- Agoraphobia[2176]

[2162] W1919 [ANON] §20, W2059 [ANON] §30, W2062 §25, W1928 §22, W1941 §43
[2163] W1921 [ANON] §33
[2164] W1921 [ANON] §33
[2165] W1921 [ANON] §33
[2166] W1922 [ANON] §32, W1954 §19
[2167] W1954 §19
[2168] W1963 §8
[2169] W1963 §23
[2170] W1963 §24
[2171] W1972 §22
[2172] W1988 §18
[2173] W1988 §18
[2174] W2059 [ANON] §22
[2175] W2059 [ANON] §25
[2176] W1991 §20

- Cellulitis[2177]
- Hemochromatosis[2178]
- Condyloma/ HPV[2179]
- Twisted bowel[2180]
- Subarachnoid brain haemorrhage[2181]
- Kidney disease/ cysts[2182]
- Weight gain[2183]
- Type 2 diabetes[2184]
- Gallstones[2185]
- Prostate pain[2186]
- Cataracts[2187]
- Glaucoma[2188]
- Constipation/ painful defecation[2189]
- Bloating[2190]
- Lymphedema[2191]

[2177] W2062 §225
[2178] W2062 §25
[2179] W2062 §30
[2180] W2062 §30
[2181] W2062 §30
[2182] W2062 §30, W1967 [ANON] §17
[2183] W2000 §12, W1926 §25
[2184] W2000 §29, W1967 [ANON] §16, W1848 §21,W1928 §11, W1941 §44, W3710§24, W1832 §21, GRO-D
[2185] W2002 [ANON] §18
[2186] W2002 [ANON] §18
[2187] W1967 [ANON] §16
[2188] W1967 [ANON] §16
[2189] W1967 [ANON] §16
[2190] W1967 [ANON] §16
[2191] W1999 §27

- Oedema[2192]
- Dyspepsia[2193]
- Collapsed vertebrae[2194]
- Hypothyroidism[2195]
- Polyuria[2196]
- Deterioration in teeth[2197]
- Tongue stomach[2198]
- Duodenal ulcers[2199]
- GRO-D
- Diverticular disease[2201]
- Oesophagitis[2202]
- Cryoglobulinaemia[2203]

Side effects and/or secondary conditions caused by treatment

- Hair loss/ thinning[2204]

[2192] W2054 §16, W1817 §16
[2193] W1821 §26
[2194] W1821 §26
[2195] W1821 §26
[2196] W1848 §21
[2197] W1867 §45, W1926 §25, GRO-D, W2694 §26, GRO-D
[2198] W1877 §17
[2199] W1877 §17
[2200] GRO-D
[2201] W1928 §11
[2202] W1928 §22
[2203] W1928 §28
[2204] GRO-D 4, W1834 §30, W1826 [ANON] §25, W1838 §30, W3693 §26, W1829 §34, W1834 §34, W1820 [ANON] §16, W0065 §32, W2631 [ANON] §26, W1892 [ANON] §26, W1899 [ANON] §33, W1011 §21, W1900 [ANON] §26, W1902 [ANON] §36, W2637 §29, W2019 §15, W1919 [ANON] §27, W1921 [ANON] §39, W1922 [ANON] §34, W1923 §24, W1925 [ANON] §22, W1935 §23, W1938 §41, W1947 [ANON] §49, W1974 [ANON] §47, W0580 [ANON] §36, W1991 §24, W1992, W2001 §11, GRO-D, W0709 §33, W3712 §22, GRO-D

- Deterioration of skin[2205]
- Deterioration of nails[2206]
- Deterioration of teeth/gums[2207]
- Lost weight[2208]
- Exhaustion/ severe fatigue/ lethargic[2209]
- Nausea/ vomiting[2210]
- Bowel problems[2211]
- Mouth ulcers[2212]
- Thrush[2213]
- Pain in chest[2214]

[2205] GRO-D , W1922 [ANON] §34
[2206] GRO-D , W1921 [ANON] §39
[2207] W1111 §34, W1834 §30, W3693 §26, W2005 §29 and 31, W2012 §58, W1891 §16, W1922 [ANON] §37, W1923 §18, W1935 §29, GRO-D , W5209§22, W2644 §17, W1990 §45, W1997 §26, W1998 §36, W2001 §11, W0394 §18
[2208] W1834 §30, W3693 §26, W1834 §30, W1820 [ANON] §16, W2012 §47, W1888 §25, W1891 §16, W1892 [ANON] §26, W1894 §24, W1895 §22, GRO-D W1900 [ANON] §26, W1910 §25, W2019 §15, W1923 §24, W1925 [ANON] §22, W1935 §23, W1938 §41, GRO-D W1943 §20, W1945 §33, W1954 §22, W1972 §24, W1974 [ANON] §47, W2041 §36, W2702 §23,W1992, W1996 [ANON] §24, GRO-D , W2028 §31, W3712 §22
[2209] W1834 §30, W2692 §15, W2053 [ANON] §24 – 25 GRO-D , W3693 §26,W1829 §32, 34, W1834 §34, W2005 §29 and 31, W1855 §30, W3916 §31, W1857 [ANON] §22, W1857 [ANON] §29, W2629 [ANON] §31, W1820 [ANON] §16, W1868 §16, W1871 [ANON] §29, W1879 §50, W1888 §25, W1889 [ANON] §52, W1891 §16, W1892 [ANON] §26, W1894 §24, W1895 §22, GRO-D W1908 [ANON] §29, W1910 §26, W1923 §24, W1932 §52, W1935 §23, W1938 §41, GRO-D , W1943 §17, W1954 §22, GRO-D , W1974 [ANON] §25, W1990 §21, W1991 §26, W1992, W1997 §26, W1998 §28, W0394 §18, W1817 §13, W2028 §31, W1962 §43, GRO-D GRO-D , GRO-D
[2210] W1834 §30, W2055 [ANON] §25 – 26, W2053 [ANON] §24 – 25, W3693 §26, W1834 §30, W2005 §29 and 31, W1855 §30, W2629 [ANON] §31, W1820 [ANON] §16, W1879 §25, W1879 §50, W1885 §27, W1888 §25, W1892 [ANON] §26, W1895 §22, W1899 [ANON] §33, W1900 [ANON] §26, W2637 §27, W1910 §25, W2019 §15, W1925 [ANON] §22, W1932 §52, W1935 §23, W1938 §41, GRO-D , W1945 §33, GRO-D , W2645 §33, W1990 §35, W2702 §23, W1996 [ANON] §24, W1997 §30,W2062 §29, W0394 §18, W1821 §31, W0709 §33, W1961 §24, W1977 §20, GRO-D GRO-D
[2211] W1834 §30, W1834 §30, W2019 §15
[2212] W1834 §30, W1834 §34, W1859, W1899 [ANON] §33, GRO-D , W0072 §46, W1987 [ANON] §29
[2213] W1834 §30
[2214] W3916 §32, W3916 §31

- Aching/ cramps in joints and pain[2215]
- Lichenoid keratosis[2216]
- Tumour on my tongue[2217]
- Flu-like sweats/ fever/ shakes[2218]
- Boils[2219]
- Memory loss[2220]
- Forgetfulness/ loss of concentration[2221]
- Loss of appetite[2222]
- Panic attacks[2223]
- Jaundice/ yellow skin/ white of eyes turning yellow [2224]
- Headaches/ migraines[2225]
- Insomnia/ difficulties sleeping[2226]
- Heart palpitations[2227]

[2215] W3916 §32, W2005 §29 and 31, W1855 §30, W2629 [ANON] §31, W1859, W3693 §45, W1891 §16, GRO-D GRO-D W1908 [ANON] §29, W1932 §52, W1935 §23, W1943 §17, W5209 §22, W2014 §26, W2702 §23, W1997 §26, GRO-D

[2216] W0072 §46

[2217] W0072 §46

[2218] W2692 §17, W2055 [ANON] §25 – 26, W1838 §30, W3693 §26, W1829 §32, W2005 §29 and 31, W0622 §48, W1876 §32, W1891 §16 GRO-D GRO-D, W2036 §28, W1972§29, W1988 §26, W2702 §23, W1991 §26, W1996 [ANON] §24, W0394 §18, GRO-D, W1819 [ANON] §16

[2219] W2692 §17

[2220] W2692 §15, W3916 §31, W1857 [ANON] §29, W2696 §23, W1943 §20, W1962 §43, GRO-D

[2221] W2692 §15, W1859, W2631 [ANON] §26, W1891 §16, W1990 §31, W1992, W0394 §17, W1962 §43

[2222] W2055 [ANON] §25 – 26, W GRO-D W3693 §26, W1857 [ANON] §22, W1820 [ANON] §16, W2631 [ANON] §26, W2012 §47, W1892 [ANON] §26, W1894 §24, W1895 §22, W1899 [ANON] §33, W2637 §27, W1961 §24, W1932 §52, W1938 §41, W1945 §33, W1947 [ANON] §49, W1954 §22, W2041 §36, W1821 §31, GRO-D

[2223] W2055 [ANON] §25 - 26

[2224] W2055 [ANON] §25 – 26, W2631 [ANON] §26, W1890 §26, W1908 [ANON] §29, W2028 §31, GRO-D

[2225] W2053 [ANON] §24 – 25, W1855 §30, W2629 [ANON] §31, W1878 §27, W1879 §50, W1899 [ANON] §33, W1938 §41, W1945 §33, W2645 §33, W2702 §23, W2062 §29, W0394 §18, W1977 §20, GRO-D GRO-D

[2226] W2053 [ANON] §24 – 25, W0622 §48, W1857 [ANON] §22, W1868 §22, W2696 §23, W1892 [ANON] §26, W1905 §31, W1919 [ANON] §27, W1935 §23, W1938 §41,W1943 §22, W1945 §33, W1947 [ANON] §49, W2645 §33, W1974 [ANON] §26, W2041 §36, W1990 §21, 34, W2702 §23, W1997 §30, GRO-D

[2227] W2053 [ANON] §24 - 25

- Persistent dry cough[2228]
- Itchiness all over[2229]
- Hip and back pain[2230]
- Skin rashes/ eczema which blisters/ skin cracks/ dry skin[2231]
- Cognitive disability[2232]
- Anaemia[2233]
- Breathlessness/ breathing problems/ asthma[2234]
- Abdominal pain[2235]
- Bleeding in the anus[2236]
- IBS/Diarrhoea[2237]
- Deterioration in eyesight[2238]
- Shakes and muscle spasms[2239]
- Urinary tract infection[2240]
- Sinusitis[2241]

[2228] W2053 [ANON] §24 – 25, W1820 [ANON] §16, W1895 §22, W0394 §18
[2229] W1826 [ANON] §25, W1838 §33, W1829 §34, W2853 [ANON] §22, W2629 [ANON] §31, W2012 §47, W1891 §16, W1892 [ANON] §26 GRO-D , W2637 §27, W1938 §42, W1972 §29, W1997 §30, W0394 §18
[2230] W1826 [ANON] §25
[2231] GRO-D W1829 §34, W2853 [ANON] §22, W2629 [ANON] §31, GRO-D W1910 §28, W1991 §24, W1997 §30, W2028 §30, GRO-D
[2232] GRO-D
[2233] W1838 §30, W1829 §34, W0622 §48, W3916 §31, W1871 [ANON] §29, W1878 §25, W1902 [ANON] §36, W1974 [ANON] §25, W2041 §36, W2702 §23, W1991 §26, W1901 §30
[2234] W1838 §30, W1829 §34, W1857 [ANON] §22, W1871 [ANON] §29, W1899 [ANON] §33, W1935 §29, GRO-D GRO-D W1947 [ANON] §49, W1990 §35, W1997 §30, W1967 [ANON] §8, W1901 §34, GRO-D W1926 §25
[2235] W1838 §33, W1945 §33, W5209§22
[2236] W1838 §33, W1889 [ANON] §44
[2237] W3693 §26, W1855 §30, W1910 §28, W1935 §29, W1938 §41, W1945 §33, W5209§22, W2702 §23
[2238] W3693 §26, W2005 §29 and 31, W3916 §31, W3693 §45, W0065 §15 (second statement), GRO-D W1910 §28, W1974 [ANON] §25
[2239] W1829 §32
[2240] W1829 §34, W1967 [ANON] §16
[2241] W1829 §34

- Dizziness[2242]
- Acne[2243]
- Severe whole-body infected psoriasis[2244]
- Throat and jaw pain[2245]
- Voice slurs[2246]
- Arthritis[2247]
- Bulging/ protruding discs[2248]
- Crumbling spine[2249]
- Osteoarthritis[2250]
- Severe pancreatitis[2251]
- Tinnitus[2252]
- Brain fog[2253]
- osteoporosis[2254]
- Put on weight[2255]
- Vitiligo on legs/ arms/ hands[2256]

[2242] W2005 §29 and 31, W1857 [ANON] §22, W2629 [ANON] §31, W2012 §47, W1921 [ANON] §39, W1945 §33, W1990 §35, W1967 [ANON] §8, W1961 §24
[2243] W1855 §30
[2244] W2853 [ANON] §22, W2630 §22
[2245] W3916 §31
[2246] W1857 [ANON] §22
[2247] W1859, W1820 [ANON] §16, W2009 §37, W1876 §28, W1935 §29, GRO-D, W2031 §10
[2248] W1859
[2249] W1859
[2250] W1859, W3693 §45, GRO-D
[2251] W1859
[2252] W1859, W3693 §45, W1905 §31
[2253] W1859, W2696 §23, W1891 §16, W1947 [ANON] §49, W1990 §21, W1997 §26
[2254] W3693 §45
[2255] W1820 [ANON] §18, W1832 §21
[2256] W1820 [ANON] §19

- Numb toes and fingers[2257]
- Periods stopped[2258]
- Hypertension[2259]
- Intestine pain[2260]
- Loss of taste[2261]
- Bleeding gums[2262]
- Mitral valve prolapse[2263]
- Sjogrens syndrome[2264]
- Early menopause[2265]
- Oesophagitis[2266]
- Gastroenteritis[2267]
- Polymyalgia[2268]
- Hypoglycaemia[2269]
- Swollen lymph glands[2270]
- Pancreatic enzyme deficiency[2271]

[2257] W0065 §32
[2258] W2631 [ANON] §26
[2259] W1878 §27
[2260] W1885 §27
[2261] W1891 §16
[2262] W1891 §16
[2263] W1910 §28
[2264] W1910 §28, W1947 [ANON] §49
[2265] W1923 §24
[2266] W1934 §48, W2002 [ANON] §18
[2267] W1934 §48
[2268] W1934 §49
[2269] W1935 §29
[2270] W1943 §23
[2271] W1943 §25

- Early menopause[2272]
- Developed type 2 diabetes[2273]
- Thyroiditis[2274]
- Thrombocytopenia[2275]
- Piles[2276]

Mental/ psychological effects

Of infection

- Depression[2277]
- Stress/ anxiety[2278]
- Suicidal/ suicidal thoughts[2279]

[2272] W1974 [ANON] §25
[2273] W2041 §36
[2274] W1996 [ANON] §32
[2275] W1901 §30
[2276] W2028 §30
[2277] W2690 [ANON] §26, GRO-D, W1818 §27, W1822 [ANON] §17, W1111 §30, W1834 §27, W2005 §21, 23, W0072 §50, W0622 §23, W2853 [ANON] §12, W1859, W2055 [ANON] §28, W0065 §25, W2631 [ANON] §21, W1871 [ANON] §8, W1878 §23, W2012 §22, 36, W1880 [ANON] §26, W1889 [ANON] §44, W1935 §6, W1908 [ANON] §20, W1890 §15, W1893 §17, W1895 §16, W1899 [ANON] §23, 25, W1896 §16, W1900 [ANON] §5, W1902 [ANON] §25, W1907 [ANON] §22, W1913 §17, W2019 §25, W2638 §12, W1921 [ANON] §10, 33, W1923 §15, W1929 §10, W1932 §31, W1935 §20, W1943 §23, W1947 [ANON] §30, W1954 §15, W5209§21, W1963 §22, W2644 §15, W1970 §21, W1987 [ANON] §15, W1988 [ANON] §22, W2043 §21, W1997 §37, W2062 §24, W1998 §25, W2001 §11, W1999 §30, W2013 §19, W1814 §17, W2054 §7, W1819 [ANON] §9, W1821 §26, W1825 §23, W1848 §20, W0709 §32, W1877 §17, W1882 §20, W1901 §35, W1917 §10, GRO-D, W1950 §22, W1961 §21, W1977 §17, W2703 §19, W2026[ANON] §21, W2031 §9, W3710 §23, W1832 §22, GRO-D
[2278] W0072 §24, W1822 [ANON] §17, W2853 [ANON] §12, W1860 §29, 30, W3325 §20, W2631 [ANON] §21, W1878 §23, W1880 [ANON] §26, W1886 [ANON] §32, W1888 §21, W1889 [ANON] §44, W1892 [ANON] §21, W1893 §17, W1895 §16, W1902 [ANON] §37, W1907 [ANON] §22, W1908 [ANON] §20, W1925 [ANON] §17, W1932 §31, W1943 §23, W1954 §16, W5209§7, W1963 §22, W1970 §21, W1987 [ANON] §35, W1990 §18, W2043 §24, W1997 §37, W2062 §24, W0709 §32, W3326 §16, W2694 §28
[2279] W1818 §27, W1826 [ANON] §20, W0072 §34, W1859, W1857 [ANON] §27, W1855 §25, W2631 [ANON] §21, W2012 §37, W1889 [ANON] §47, W1902 [ANON] §25, W1921 [ANON] §19, W1935 §6, W1963 §22, W2043 §24, W1997 §37, GRO-D

- Mood swings/ more emotional[2280]
- Angry[2281]
- Low mood[2282]
- Symptoms of trauma[2283]
- Panic attacks[2284]
- PTSD[2285]
- OCD[2286]

Of treatment

- Depression[2287]
- Anxiety[2288]
- Mood swings[2289]
- Aggressiveness[2290]
- Lack of emotion/ empathy[2291]

[2280] W1829 §25, W1888 §6, W1890 §29, W1902 [ANON] §28, W1932 §37, W1943 §23, W1970 §21, W2645 §22, W1832 §22

[2281] W2005 §21, 23, W1902 [ANON] §28, W2644 §22, W1825 §22

[2282] W2009 §25, W1892 [ANON] §21, GRO-D, W1935 §6, W1990 §18

[2283] W2009 §25

[2284] W2009 §51, W1913 §17, W1921 [ANON] §46, W2043 §24, W1991 §20

[2285] W1921 [ANON] §34, W1991 §20

[2286] W2013 §19

[2287] W1829 §33, W1834 §27, 30, W1857 [ANON] §19, 27, W2692 §15, W1818 §29, 41, W1826 [ANON] §25, GRO-D, W1834 §30, 34, W0622 §48, W1855 §31, W1857 [ANON] §29, W1859, W2630 §22, W3693 §45, W1820 [ANON] §16, W1868 §22, W2696 §23, W2631 [ANON] §26, W1876 §32, W1879 §50, W1894 §24, W1895 §22, GRO-D, W1900 [ANON] §26, W1935 §33, W1938 §42, W1943 §16, W1954 §22, W1987 [ANON] §29, W1990 §30, W1992, W1997 §26, W1998 §28, W0394 §18, GRO-D, W1962 §43, W1966 §17, W1968 [ANON] §8, GRO-D

[2288] W1834 §30, W1826 [ANON] §25, W1834 §30, 34, W1834 §34, W1868 §22, W2696 §23, W1895 §22, W1935 §23, GRO-D, W1990 §30, 2000 §28

[2289] GRO-D, W2692 §15, W1855 §30, W1859, W2631 [ANON] §26, W1889 [ANON] §52, W1891 §16, W1895 §22, W1011 §21, W1902 [ANON] §36, W2637 §20, W1921 [ANON] §39, W1954 §22, 2000 §28, W1832 §23

[2290] W2692 §15, W1818 §41, GRO-D, W3916 §31, W1889 [ANON] §52, W1895 §22, W2637 §20, W1919 [ANON] §27, W1950 §22

[2291] W2692 §15

- Recurring nightmares[2292]
- Suicidal[2293]
- Paranoia[2294]
- Hallucinations[2295]
- Argumentative[2296]
- PTSD[2297]
- Low mood[2298]
- Panic attacks[2299]

[2292] GRO-D

[2293] GRO-D W1859, W2630 §22, W1935 §33, W1938 §42, W1947 [ANON] §49, W1988 §27, W1996 [ANON] §24, GRO-D, W1966 §16, GRO-D GRO-D

[2294] W1829 §34, W1876 §32, W1996 [ANON] §24

[2295] W0622 §48

[2296] W1859

[2297] W0065 §33, W1935 §33

[2298] W1871 [ANON] §29, W1879 §50, W1990 §30, W1991 §26, 2000 §28, W1966 §16, W1968 [ANON] §8

[2299] W1987 [ANON] §29, W1990 §35

ANNEX 3: LIST OF PHYSICAL AND MENTAL SYMPTOMS AND SIDE EFFECTS OF HBV INFECTION AND TREATMENT

Physical effects

Hepatic manifestations of viral hepatitis (i.e. liver related conditions)

- Liver cysts[2300]
- Liver disease[2301]

Extra-hepatic manifestations of viral hepatitis (i.e. non liver related conditions)

- Extreme tiredness[2302]
- Yellow skin/ Jaundice[2303]
- Epilepsy[2304]
- Pain in abdomen[2305]
- Nausea[2306]
- Breathless[2307]
- Achy bones/ joints[2308]
- Diarrhoea[2309]
- Bruising[2310]

[2300] W3713 §27
[2301] W3710 §27
[2302] W2590 [ANON] §17, W3103 §32, W2638 §8, W2641 §16, 23, W3713 §26, W1832 §7
[2303] W2590 [ANON] §17, W1906 §6, W2638 §17, W3713 §28, W2870 §13
[2304] GRO-D
[2305] W1906 §6, 19
[2306] W1906 §19
[2307] W2638 §8
[2308] W2638 §8, W2641 §16
[2309] W2638 §8
[2310] W2641 §24

- Weight loss[2311]
- Kidney failure[2312]

Side effects and/or secondary conditions caused by treatment

- Sickness[2313]
- Dizziness[2314]
- Headaches[2315]
- Nausea[2316]
- Struggling with eating[2317]
- Gums grown other teeth making eating difficult[2318]
- High blood pressure[2319]
- diarrhoea[2320]
- Short term memory loss[2321]
- Degeneration of joints[2322]
- Breathlessness[2323]
- Lowered immune system[2324]

[2311] W2641 §23, W2870 §13
[2312] W1951 §30
[2313] W3103 §36
[2314] W3103 §36
[2315] W0671 [ANON] §26
[2316] W0671 [ANON] §26
[2317] W0671 [ANON] §26
[2318] W1951 §27
[2319] W1951 §27
[2320] W1951 §27
[2321] W1951 §27
[2322] W1951 §27
[2323] W1951 §27
[2324] W1951 §27

- Diabetes[2325]

Mental/ psychological effects

Of infection

- Self-harm and suicidal[2326]
- Depression[2327]
- Anxiety[2328]
- Stress[2329]
- Insomnia[2330]

Of treatment

- Nausea/ vomiting[2331]
- Headaches[2332]
- Dizziness[2333]

[2325] W3710 §24
[2326] W0671 [ANON] §17 – 19, W2638 §16
[2327] W0671 [ANON] §17 – 19, W1906 §20, W2638 §16, W3710 §23
[2328] W0671 [ANON] §22, 32
[2329] W0671 [ANON] §32
[2330] W3103 §33
[2331] W1906 §24
[2332] W1906 §24
[2333] W1906 §24

ANNEX 4: LIST OF PHYSICAL AND MENTAL SYMPTOMS AND SIDE EFFECTS OF HIV INFECTION AND TREATMENT

Physical effects

Manifestations of HIV

- Chronic intracerebral haematomas[2334]
- Epilepsy[2335]
- Pneumocystis pneumonia[2336]
- Shingles[2337]
- Extreme weight loss[2338]
- Fatigue/ extreme tiredness/ lethargy[2339]
- Chest infections[2340]
- Jaundice[2341]

Side effects and/or secondary conditions caused by treatment

- Fatigue/ extreme tiredness[2342]
- Night sweats[2343]
- Vomiting[2344]

[2334] GRO-D
[2335] GRO-D
[2336] W2701 §6, W3920 §6, W2004 [ANON] §12
[2337] W2701 §17, W3920 §6
[2338] W3920 §6
[2339] W3920 §6
[2340] W3920 §6
[2341] W2004 [ANON] §12
[2342] W1862 §22, W3323 [ANON]
[2343] W1862 §22, GRO-D
[2344] W1862 §22

- Diarrhoea[2345]
- Hell's palsy[2346]
- Pneumocystis pneumonia[2347]
- C. difficile[2348]
- High blood pressure[2349]
- Skin cancer[2350]
- Osteoporosis[2351]
- Kidney failure[2352]
- Deterioration in teeth/ gums[2353]
- Headache[2354]
- Aching arms and legs[2355]
- Kaposi sarcoma (blue ulcers in the mouth)[2356]
- Extreme weight loss[2357]
- Loss of feeling in hands/ feet[2358]
- Loss of eyesight[2359]

[2345] W1862 §22
[2346] D W1862 §22
[2347] W1862 §22, W2643 [ANON] §27
[2348] W1862 §22
[2349] W1862 §22
[2350] W1862 §22
[2351] W1862 §22
[2352] W2701 §20
[2353] W2701 §20, W2643 [ANON] §27
[2354] W3323 [ANON], GRO-D
[2355] W3323 [ANON]
[2356] W2057 §11
[2357] W2643 [ANON] §19
[2358] W2643 [ANON] §27
[2359] W2643 [ANON] §27

- GRO-D

Mental/ psychological effects

Of infection

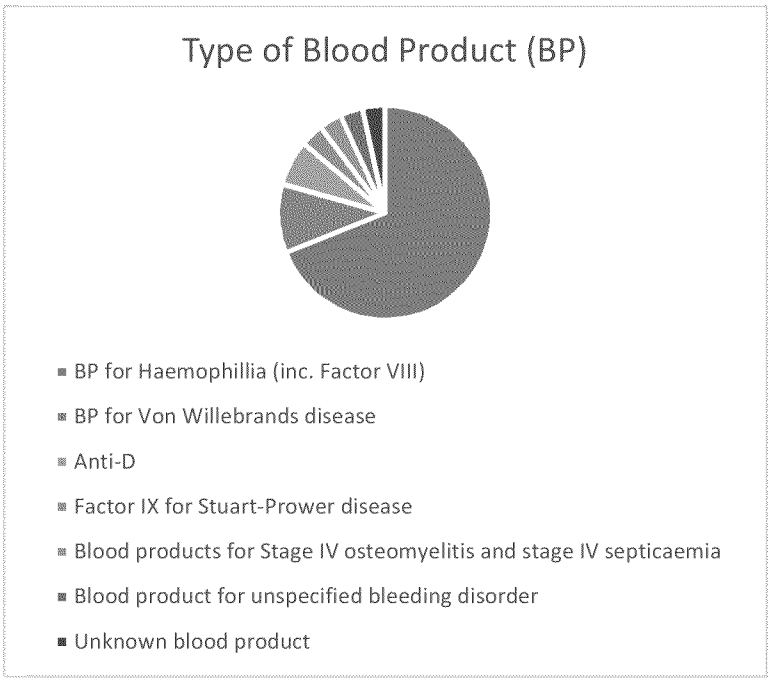
- Anxiety[2361]
- GRO-D

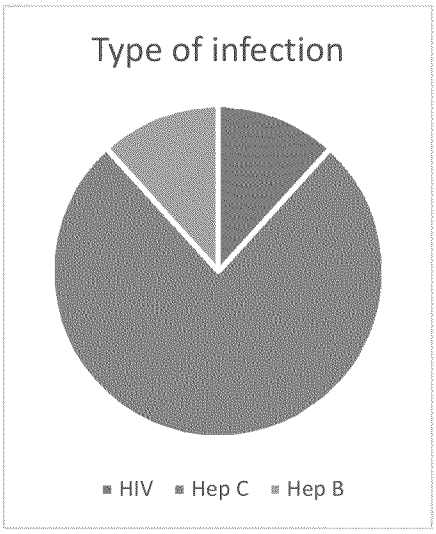
Of treatment

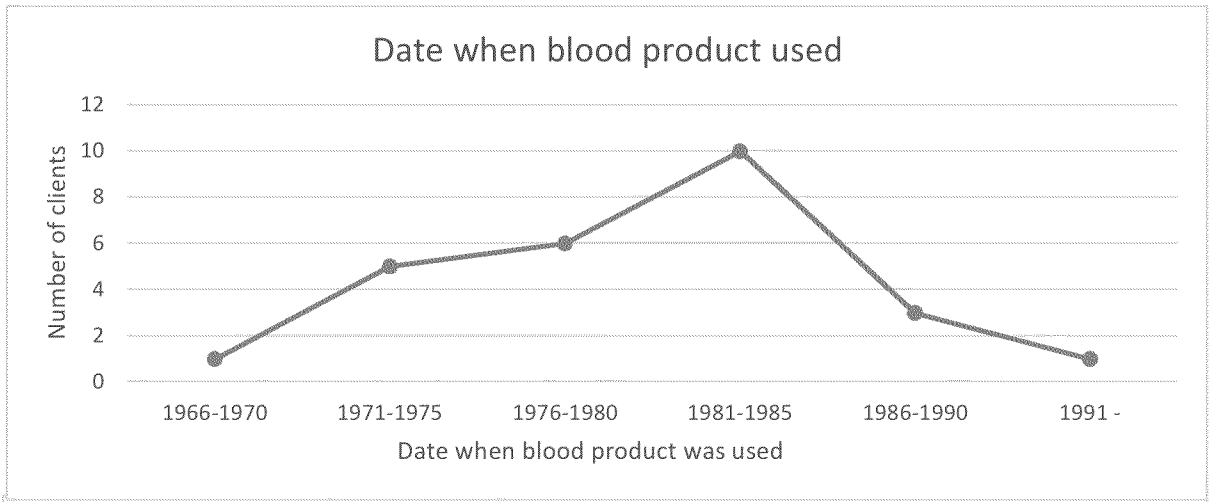
- Depression[2363]

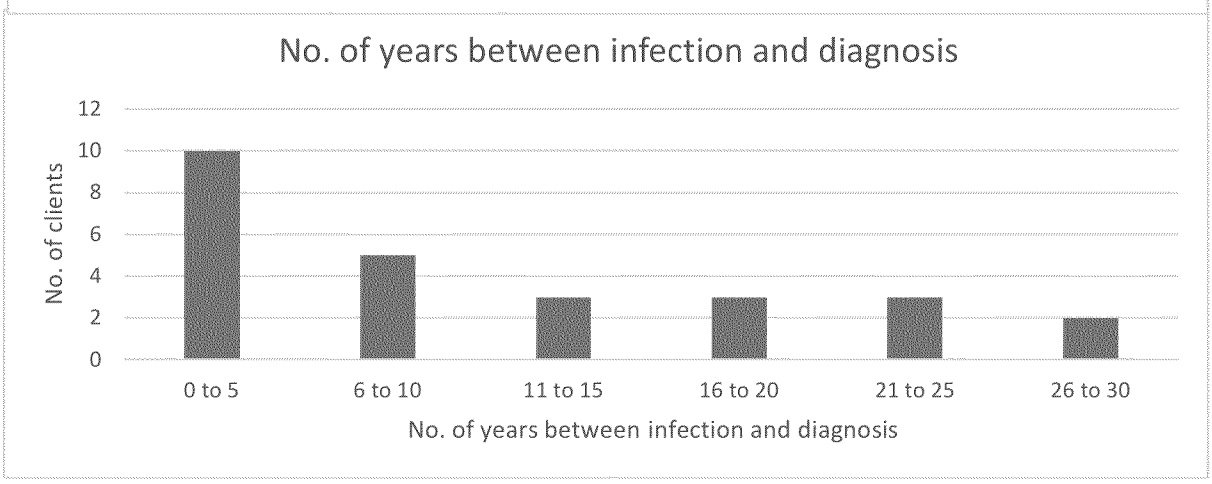
[2360] GRO-D
[2361] GRO-D, W1862 §22
[2362] GRO-D
[2363] W1862 §22

ANNEX 5: GRAPHICAL REPRESENTATION OF STATISTICS ON INFECTIONS VIA BLOOD PRODUCTS









ANNEX 6: GRAPHICAL REPRESENTATION OF STATISTICS ON INFECTIONS VIA BLOOD TRANSFUSION