

Draft Recommendations made by the Leigh Day Core Participants

1. These recommendations are drafted in line with the Inquiry's "steer". They are provisional (and so can be subject to change or amendment at a later stage) and are primarily for the purpose of identifying whether further evidence or information is required prior to making its recommendations. In particular, as much of the material about central government, record keeping, vCJD and candour is still to be given, these submissions do not deal in any detail with potential recommendations relating to these topics.
2. They do not include any direct issues relating to compensation, albeit that some of the issues set out below are by necessity interlinked and interwoven with those considerations. The compensation framework recommendations of Sir Robert Francis were published on 6 June 2022. Given the timescales, we have not been able to include any recommendations which may emerge from that report but which do not relate directly to the issue of compensation.
3. The counsel team on behalf of the Leigh Day Core Participants has sought to liaise with other infected and affected counsel teams. It has also, through its representation of the Hepatitis C Trust as a core participant, been able to use their work and understanding. The Leigh Day Core participant team are aware that some of these recommendations, in particular those around education, commissioning, provision of psychological support and provision of health services and domiciliary services are supported by other groups.

HCV awareness and education

Recommendation 1: improved education for general practitioners

1. Hepatitis remains an underdiagnosed disease^{1 2} and our Core Participants have faced severe difficulties in diagnosis as recently as within the last five years,³ including GPs failing to

¹. As reported by the UK Health Security Agency here: [https://www.gov.uk/government/news/increase-in-hepatitis-liver-inflammation-cases-in-children-under-investigation#:~:text=Infectious%20diseases-,Increase%20in%20hepatitis%20\(liver%20inflammation\)%20cases%20in%20children%20under%20investigation,are%20being%20assessed%20in%20Scotland](https://www.gov.uk/government/news/increase-in-hepatitis-liver-inflammation-cases-in-children-under-investigation#:~:text=Infectious%20diseases-,Increase%20in%20hepatitis%20(liver%20inflammation)%20cases%20in%20children%20under%20investigation,are%20being%20assessed%20in%20Scotland). The NICE guidelines estimate 216,000 people had chronic HCV in 2012 but noted that "*a significant number of infections remain undiagnosed*": *Hepatitis B and C testing: people at risk of infection, Public health guidance PH43*. Published 12 December 2012. Available at: <https://www.nice.org.uk/guidance/ph43/chapter/1-Recommendations#recommendation-1-awareness-raising-about-hepatitis-b-and-c-among-the-general-population> (Accessed on 18 April 2022).

² The diagnosis of HCV has increased 8-fold between 1996 - 2017: we do not suggest that this is because there are higher rates of HCV in the UK, but the availability and access to testing has increased significantly: Hepatitis expert group report, p. 20. Although we recognise that the estimated prevalence of chronic HCV has declined significantly since 2015, to around 81,000 in 2020: see UKHSA 'HCV in England report 2022 headline data table' 2022 <https://www.gov.uk/government/publications/hepatitis-c-in-the-uk> (Accessed 18 April 2022) ('the 2022 UKHSA report').

³ See W0394, W1954, W2641, W2690

identify clear signs and symptoms of HCV,⁴ being required to self-diagnose,⁵ and being given little or no information upon diagnosis.⁶ This is despite the fact that the hepatitis expert group in their report identify that primary care clinicians need a reasonable knowledge base and that the clinician/patient relationship is particularly important in managing long term illness.⁷ Currently there is no routine screening for viral hepatitis in the UK. NICE guidelines recommend that testing for HBV and HCV should be made available for certain groups that are at a higher risk of presenting with the diseases. This particularly includes people who have used drugs intravenously and those who have unprotected sex.⁸ That rarely includes those who may have contracted HCV or HBV via a blood transfusion who are not “automatically” seen as potentially being at higher risk by many GPs.

2. GPs perform the largest proportion of screening for hepatitis B (33.1%) and hepatitis C (32.3%). Despite this, the Core Participants whom we represent experienced persistent late- and non-diagnosis with hepatitis, despite presenting over many decades with clear symptoms of HBV and / or HCV. Samantha May of the Hepatitis C Trust confirmed in evidence to the Inquiry⁹ that this problem of late or non-diagnosis of HCV persists in the present day.
3. Current medical education and information in the UK is focused heavily on current or former intravenous drug users and other ‘at risk’ groups, such as men who have sex with men, sex workers, and those who have had tattoos.¹⁰ 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 Hepatitis C as a result of infected blood and blood products. 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, when screening of blood donors for hepatitis C infection, or heat treatment for inactivation of viruses were introduced*”, there is a significant weight of evidence from our Core Participants and the Hepatitis C Trust that this is not adequately transposed into GPs’ knowledge or practice. To give an anecdotal example, out

⁴ W1967

⁵ W1907

⁶ W3697

⁷ Hepatitis expert report p61, and 67.

⁸ The NICE Guidelines and approach to testing are set out in detail in the Hepatitis Expert Group report at pp. 15-19.

⁹ Including WITN0912001, §§47-51.

¹⁰ See e.g. the 2022 UKHSA report, which focuses substantially on people who inject drugs.

of 7 recent contacts with GP's , only 1 knew about the issues in respect of Hepatitis C and infected blood.

4. In particular, we are concerned that the current knowledge and practice does not recognise, as the psychosocial expert report has identified, that there are significant impacts of inadequate and insensitive communication upon the individual.¹¹
5. 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. While the NHS and NICE guidance notes that "*people who received blood transfusions before September 1991 or blood products before 1986 in the UK*" are at an increased risk of hepatitis, we do not consider this accurately reflects the evidence which the Inquiry has heard about (i) the technological shortcomings of early generation HIV and/or HCV screening tests, and continuing technological shortcomings of HBV screening tests¹², 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,¹³ accepting that he could not exclude the possibility of untested blood being issued.¹⁴
 - b. Dr Wagstaff accepted that there was a very small chance of untested blood being in circulation after September 1991.¹⁵
 - 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

¹¹ Paragraph 13.4 of the Psychosocial expert report.

¹² [REF]

¹³ Oral evidence, 4 February 2022, transcript p. 157. Available at <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Friday%2004%20February%202022%20%28Dr%20Frank%20Boulton%29.pdf> (accessed 19 April 2022).

¹⁴ Ibid, transcript p. 177.

¹⁵ Oral evidence, 25 January 2022, transcript p. 126. Available at <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Tuesday%2025%20Jan%202022%20%28Dr%20Bill%20Wagstaff%29.pdf> (accessed 19 April 2022).

1985.¹⁶ She also accepted that untested fresh warm blood was being used in Harefield Hospital as late as March 1999¹⁷; 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 use¹⁸

e. NHS England has recognised that Factor VIII was not safe in Scotland before April 1987.¹⁹

6. In all these circumstances, we consider that the current “cut off” dates are arbitrary, and that any information should ensure that a longstop period is provided where individuals should be tested after the date of the introduction of testing and/or heat treatment. This is particularly the case given that no evidence has been given (to date) to support the dates introduced with the Skipton Fund in respect of HCV, and no cut-off date was ever provided for those infected with HIV.
7. Our Core Participants have repeatedly raised concerns about the failures in communication from their GP both during and after diagnosis. Samantha May described information being supplied in a “*heavy-handed, judgmental and frightening manner*”²⁰ and in oral evidence described infected people being given “*very little information or support*” with “*devastating*” effects.²¹ As recently as 2015 one Core Participant whom we represent was not given adequate information to understand or manage his condition.²² Another infected person was not followed up despite being told in 2014 that this would be done.²³ One Core Participant was not treated for 11 years after being diagnosed in 2004.²⁴ Another Core Participant was undiagnosed for 29 years and not identified until 2011.²⁵ Clear information on risk management, treatment and prognosis is essential but we also consider that this needs to be conducted in a trauma-informed fashion and buttressed by signposting to

¹⁶ Oral evidence, 3 December 2021, transcript pp. 37-45, available at <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Friday%203%20December%202021%20%28Professor%20Dame%20Marcela%20Contreras%29.pdf>.

¹⁷ Ibid, p. 131.

¹⁸ Ibid, p. 144.

¹⁹ See *Hepatitis C: guidance for GPs*, dated 25 November 2020. Available at: <https://www.gov.uk/government/publications/hepatitis-c-patient-re-engagement-exercise/hepatitis-c-information-for-gps#clinical-presentation>

²⁰ WITN0912001, §45.

²¹ Oral evidence, 4 March 2022, p. 141, 159.

²² W1913

²³ W1905

²⁴ W1963

²⁵ WITN1838006.

support services such as the Hepatitis C Trust and psychological support (see recommendation 12 below).

8. It is not enough that pre-existing guidance is merely re-iterated or that there is a mass circular emphasising best practice. The Hepatitis C trust produced *Guidance for the prevention, testing, treatment and management of hepatitis C in primary care*²⁶ in collaboration with the Royal College of General Practitioners (RCGP) in 2007, which aimed to increase testing. It is unclear what impact, if any, the new guidance had. The RCGP and Hepatitis C Trust built on this guidance by way of a pilot project to include better public information materials in GP surgeries about HCV and encourage patients to request HCV testing. However, Samantha May explained that this had poor uptake and little support from GPs.²⁷ The NHS long term plan does not address HCV.²⁸ Therefore, there needs to be mechanisms to check that best practice guidelines are being understood and followed.

9. Therefore, our sub-recommendations are:

- a. The information on the NHS website should be amended as follows: *“All people who have ever received blood transfusions. People who received blood transfusions before (a longstop date if needed) , and people who have received transfusions overseas, may be at particular risk”*.²⁹
 - i. The risk of transmission related to blood transfusions should be included on the first page – known as the “landing” page – on the Hepatitis C website, and not solely on the page specifically related to risk factors.³⁰
 - ii. It is essential the NHS be responsible for identifying this cohort and proactively offer testing. Our Core Participants’ experience demonstrates that many individuals may lack the information or ability to advocate for testing and, where they do so, they may be refused.

²⁶ Available at: <http://www.hepctrust.org.uk/sites/default/files/Prevention-Testing-Treatment-and-management-of-hep-C-in-primary-care%281%29.pdf> (accessed 18 April 2022).

²⁷ Oral evidence, 4 March 2022, transcript p. 153. She opined that “...it was a great shame. I think that would have worked very well”

²⁸ <https://www.longtermplan.nhs.uk/online-version/chapter-2-more-nhs-action-on-prevention-and-health-inequalities/smoking/>; <https://www.longtermplan.nhs.uk/areas-of-work/>;

²⁹ We consider that 1988 is an appropriate backstop given NICE’s acceptance that Factor VIII in Scotland was not safe until 1987. We represent Core Participants infected with HCV a significant time after September 1991, which is unsurprising in light of the imperfect nature of the screening tests, especially as first implemented.

³⁰ <https://www.nhs.uk/conditions/hepatitis-c>.

b. An education campaign 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 general practitioners 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),³¹

i. The ideal outcome would be for each GP to undertake a course such as the Royal College of General Practitioners' Hepatitis B & C course,³² however this should be alongside bespoke information about the risks attributable to infected blood. We can see no reason why this could not be implemented over a reasonable timescale. If the Inquiry disagrees, we consider that there should be at least one GP in every large practice and / or several GPs in every commissioning area with this expertise. 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 compensation framework.

We suggest that the Inquiry should make this a requirement within GP contracts.

- ii. GPs should also be made aware of the availability of the financial trusts and schemes / any compensation framework recommended by the Inquiry for supporting those infected with Hepatitis .
- iii. This training should 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.
- iv. To ensure GPs ask questions to identify those infected through blood transfusion doctor-facing guidance should include a 'tick box' or similar

³¹ 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 1995 and presents with symptoms of HCV that they must be offered a test.

³² Available here: <https://elearning.rcgp.org.uk/course/search.php?search=Hepatitis+B%26C>.

feature reminding GPs to explore histories of blood transfusion. This could be done, for example, at the NHS health check offered to all 44-year-olds currently or any other form of routine discussion (for example when registering with a new surgery).

- v. GPs must also be trained in how to communicate an HCV diagnosis to patients, signpost patients to support schemes, and to ensure their cases are appropriately followed-up.
- c. Posters and other information sources such as leaflets should be provided in GP surgeries encouraging patients with HCV symptoms to ask for a test.
- d. An HCV specialist 'lead' GP should be appointed in each region (and ideally within each GP practice), who would link with the current HCV "hub" (which we believe are called Operational Delivery Networks 'ODNs') to facilitate creation of a clinical pathway from GPs to appropriate HCV care for each patient within the hub. GPs must be made aware of the specialist lead HCV nurse in their area and able to refer patients on to the hub easily. The HCV "hub" system should continue and provide a multi-disciplinary team "around the patient".
- e. HCV elimination must be included in the NHS long-term plan.
- f. The NHS HCV pages³³ should contain a link to the Hepatitis C Trust in a similar way that organisations are linked which help and support for other conditions (such as HIV).
- g. 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, pp. 58-61).
- h. Given the strong relationship as seen in the evidence of the infected and affected between a diagnosis of various autoimmune conditions - for example fibromyalgia and ME with underlying hepatitis C, the inquiry should recommend that steps should

³³ In particular this page: <https://www.nhs.uk/conditions/hepatitis-c/#:~:text=The%20hepatitis%20C%20virus%20is,sharing%20razors%20or%20toothbrushes>

be taken to see if they have been tested for such and a test administered, if they may have been exposed to infected blood.

- i. GP records should include a 'flag' or some form of mechanism to alert the GP, noting that a patient has had (or is suspected of having had) a blood transfusion. GPs should also note, however, that many records omit details of such transfusions, and so absence of such in a set of records should not be seen as conclusive proof that one has not taken place, particularly prior to the 21st century. Asking a question about blood transfusion or blood and blood products when registering as a GP surgery may be a way of identifying patients who may require further scrutiny.
- j. 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"*. However, we consider such e-learning has its limitations and must be buttressed by specific information about the risks to those who have received infected blood.
- k. We further recommend that leaflets (including downloadable materials, and in adequately accessible formats) with clear information about the nature of HBV/HCV treatment, prognosis, risk management, and support organisations should be given upon diagnosis to all those infected.
 - i. The Hepatitis C Trust would be well placed to contribute to such materials and should be consulted or consideration given to whether their expertise, or that of other similar organisations, could be used to plan and co-produce the project.³⁴
- l. 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 GPs' contractual requirements and / or their appraisal and re-validation.
- m. NHS England need to 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 (2025).

³⁴ With funding .

Recommendation 2: public education campaign

10. NICE has recommended for a number of years that commissioners and providers of public health such as the UK Health Security Agency and Office for Health Improvement and Disparities should conduct awareness-raising campaigns about hepatitis B and C.³⁵ This campaign should highlight the experiences of those who received infected blood.
11. A high-profile semi-targeted public education campaign is necessary to enable infected but undiagnosed people to identify themselves and come forward. We recommend undertaking a one-off publicity exercise in a range of media, with a focus on addressing those age 50 and over.
12. Public health specialists should make radio and TV appearances on a range of programmes such as the Today Programme, the One Show, and both news and general interest programmes. Adverts should be taken in a wide range of publications, including national and regional newspapers, specialist magazines (including publications targeted at the over-50s, such as Saga), outdoor and transport billboards, and as an increasing number of older people use social media a targeted advertising campaign should be conducted via Facebook and / or other appropriate platforms. Public health campaign experts should naturally be asked to advise on which media platforms are likely to reach the most people in a cost-effective way. Such a campaign would require a close collaboration between the Chief Medical Officer and Senior Medical Director, and we recommend they consult the Hepatitis C Trust, the British Liver Trust and other specialist organisations who run media campaigns concerning health and testing awareness. We suggest that it is linked to the proposed web portal launch to try and get those who have not yet approached their GP to order an HCV test both discreetly and privately. We understand that this campaign is due to launch at some point in late 2022/early 2023.
13. The media campaign should highlight the variety of symptoms associated with HCV and emphasise the possibility of contracting HCV as a result of transfusion.
14. This would also be a useful opportunity to address the concern raised by the Palliative Care expert group, namely that *“increased public awareness of the burden of liver disease in the*

³⁵ See *Hepatitis B and C testing: people at risk of infection, Public health guidance PH43*. Published 12 December 2012. Available at: <https://www.nice.org.uk/guidance/ph43/chapter/1-Recommendations#recommendation-1-awareness-raising-about-hepatitis-b-and-c-among-the-general-population> (Accessed on 18 April 2022).

UK is vital".³⁶ The media campaign should consult bodies such as the British Liver Trust to ensure effective and consistent messaging.

15. Leaflets and information posters regarding HBV and HCV should also 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).
16. Issues concerning lost records and inadequate reporting back from hospitals to GPs also mean that GPs often are unaware that their patients have had a blood transfusion. Given this, any awareness campaign should seek to alert individuals that their general practitioner 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.
17. We consider that the Inquiry may be assisted by hearing evidence from individuals who have run public health campaigns for the NHS (such as breast cancer screening and HIV prevention) or from the HCV elimination team at NHS England to inform such a recommendation.

HCV testing

Recommendation 3: mass HCV testing for those who received blood or blood products before the longstop period identified by the Inquiry

18. The NICE Guidelines on HBV and HCV testing provide that GPs and practice nurses should offer testing for HBV and HCV to adults and children at increased risk of infection. However, NICE places particular emphasis on *"migrants from medium- or high-prevalence countries and people who inject or have injected drugs"*.³⁷ The NICE guidance emphasises these two groups as those in which HBV and HCV are most prevalent. Blood transfusion is not stated to be a risk factor for HBV and in relation to HCV the groups stated to be at increased risk include *"People who received a blood transfusion before 1991 or blood products before 1986, when screening of blood donors for hepatitis C infection, or heat treatment for inactivation of viruses were introduced."*
19. Regular screening is also recommended in prisons, immigration removal centres, drugs services facilities, and GUM and sexual health clinics. These settings are not particularly well

³⁶ P. 18.

³⁷ Ibid.

placed to identify those infected through the receipt of infected blood or blood products. While the NICE guidance acknowledges that GPs should screen new patients and antenatal services should screen pregnant people who are at higher risk of hepatitis, we do not consider that this is adequate to identify those who have received infected blood.

20. We consider that:

- a. GPs are not regularly or effectively identifying those who received blood and blood products in the period identified above.
- b. Patients are often unaware that they (or a close family member) received a blood transfusion or blood products.
 - i. Further, if they (or a close family member) have received a blood transfusion, many are unaware of the risks associated with that transfusion.
- c. Medical records do not consistently record whether blood was given, nor was record-keeping adequate to ensure that look backs would identify those who received infected blood or blood products.
- d. The understandable emphasis on other groups that are at higher risk is liable to detract attention from the infected and affected with whom this Inquiry is concerned.

21. Therefore, we recommend that all those who received a blood transfusion prior to a reasonable long stop date identified by the Inquiry (taking account of the evidence about the “cut off “ date as it currently operates being arbitrary and potentially not capturing individuals who may have been infected by products after the introduction of testing) should be offered a HCV test.³⁸ 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. Whilst we do not necessarily identify that this is required in the UK, the Inquiry should carefully consider if this type of screening programme would be helpful to ensure that all those who may possibly have HCV are identified and can be treated.³⁹

³⁸ This 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 Core Participants.

³⁹ Hepatitis Expert report, p21.

- a. As patients may not be aware whether they received blood or blood products prior to the longstop date all those with potential HCV symptoms (including chronic extrahepatic symptoms) should be offered testing for HCV.
 - i. 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 this population, menopause and more recently the rise of long Covid.⁴⁰ 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.
- b. We endorse Dr Hewitt's recommendation⁴¹ 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. We appreciate that she suggested this would be an "*enormous exercise*", but we consider that at least a scoping project should be undertaken to assess the viability of such a database.
 - i. As recommended above, patients who have received blood before the longstop date (or are suspected of having received blood) should have this flagged on their records. The CQC should be asked to ensure compliance with such a requirement.
- c. 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.⁴² The web portal should make this significantly easier.

22. Testing should not only be made available through GPs, it should also be available on a walk-in basis at pharmacies. Pharmacies already provide a wide range of services, including chlamydia screening and blood pressure, cholesterol, and blood sugar testing.⁴³ Some pharmacies are already offering an HCV testing service through the Community Pharmacy

⁴⁰ Many Core Participants' symptoms were disregarded by their doctors as symptoms of exhaustion due to parenting or other life stresses.

⁴¹ Oral evidence, 10 December 2021, transcript p. 140. Available at: <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Friday%2010%20December%202021%20Dr%20Patricia%20Hewitt.pdf> (accessed 19 April 2022).

⁴² Around 50 of our Core Participants were infected through obstetric or gynaecological interventions.

⁴³ See <https://www.nhs.uk/nhs-services/prescriptions-and-pharmacies/pharmacies/how-your-pharmacy-can-help/> (Accessed 18 April 2022).

Hepatitis C Antibody Testing Service, which started on 1 September 2020. This only operates in certain areas and focuses on people who inject drugs, so is unlikely to benefit the infected and affected people being considered by this Inquiry.

23. We also understand that NHS England has just 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 2023.⁴⁴ 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.
24. 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”*.⁴⁵ However, the experience of our Core Participants suggests that this is often overlooked in practice and should be re-emphasised as part of GP education.
25. This testing programme should be publicised through the media campaign discussed in recommendation 2.

Recommendation 4: amendment of the NICE guidance

26. As discussed above, screening of blood and viral inactivation were not panaceas and therefore the limitation on the NICE Guidance testing recommendation to those who received blood products before 1986 and blood before September 1991 should be amended. The JPAC’s transfusion handbook accepts that, even with modern screening methods, blood transfusions are not completely safe.⁴⁶
27. We consider that there should be no temporal limitation within the NICE Guidance. We suggest the Guidance instead refer to:

⁴⁴ <https://www.contractfinder.service.gov.uk/Notice/348b567-ebef-4122-b8f6-005bdc8b2031>

⁴⁵ *Hepatitis C: information for GPs*, updated 25 November 2020. Available at: <https://www.gov.uk/government/publications/hepatitis-c-patient-re-engagement-exercise/hepatitis-c-information-for-gps#clinical-presentation> (accessed 18 April 2022).

⁴⁶ Transfusion Handbook, §5.3: <https://www.transfusinguidelines.org/transfusion-handbook/5-adverse-effects-of-transfusion/5-3-infectious-hazards-of-transfusion> (accessed 19 April 2022).

“All people who have received blood transfusions. People who received blood transfusions before (the longstop date to be determined by the Inquiry) in the UK may be at particular risk”

HCV treatment and care

Recommendation 5: psychological support

28. Diagnosis of, and living with, a chronic disease can have severe psychological effects.⁴⁷

Depression is a recognised symptom of HCV. However, the Core Participants whom we represent have only exceptionally been offered any specialist mental health support, even when part of the trusts and schemes. 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 session⁴⁸ and so it is unrealistic to expect this to be covered privately. The process of accessing the limited psychological support offered by the schemes is, on the basis of the evidence received, especially that of the HCV Trust, humiliating, time consuming and has to be organised by the patient themselves, which they can often find difficult.

29. 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, facilitated through the psychosocial support discussed in relation to recommendation 12. Family members of those infected should be offered psychological support, as has been done successfully in Ireland.

30. As Samantha May and many of our Core Participants have explained in their evidence to the Inquiry,⁴⁹ 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

⁴⁷ The expert report on psychosocial issues sets out the serious psychological impact on living with medical conditions and long term treatment.

⁴⁸ Oral evidence, 4 March 2022. Transcript, p. 180.

⁴⁹ See WITN0912001, §209. The psychosocial report also identified these need in their report.

infected by this route.⁵⁰ 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 delivered via the regional HCV/ODN hubs in England discussed below under recommendation 6.

31. Treatment should not be viewed as the end-point of psycho-social difficulties for those suffering with HCV. The Hepatitis C Trust's post-treatment survey⁵¹ found that 90% of respondents reported ongoing symptoms more than 12 months after treatment with Interferon, which was the main treatment for many of this group. These principally included fatigue, joint pain, brain fog, depression and mood swings. A large number of respondents explained that they felt worse after treatment. Access to HCV support should not be time-limited and should be provided on the basis of need. The new treatments seem to have fewer side effects, but the Inquiry may well wish to obtain some evidence as to what side effects, if any, there are to this treatment psychologically and ensure that the psychological needs are appropriately provided for in that situation.
32. Alongside psychological support, there is a need for day-to-day support via support groups, helplines and information lines to assist in helping people manage the impact of living with the 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 well not be sustainable in the long term. The Inquiry may wish to consider if such helpline or information should be funded through an NHS grant.

Recommendation 6: improved HCV treatment and support

33. Those who have been infected with HCV experience serious, life-long symptoms both as a result of their underlying diagnosis and the invasive and damaging treatments they have received, such as Interferon.⁵² Many Core Participants report that HCV is treated as a disease of the liver, without extrahepatic problems and psychological sequelae being adequately addressed.

⁵⁰ 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, pp. 128-129.

⁵¹ WTN0912002.

⁵² See evidence of Dr Prescott, WITN6979001.

34. We consider that a model of care specifically for people with HCV is necessary, which ensures joined-up care and continuity of support.⁵³ This should be managed on a multidisciplinary basis⁵⁴ which embraces the patient's entire physical and psychosocial needs. This should include:

- 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 'ODNs'), and these systems should continue after the elimination programme has ended (in 2025).
- b. Integrated care with effective communication between practitioners.
- c. Oversight and management of each individual's care by a specialist HCV nurse.
- d. Psychosocial support as described in recommendation 12.
- e. Regular and consistent follow-up for those not currently under active clinical care. Currently there is no consistent clinical practice, and some patients receive no clinical surveillance: see Claire Foreman's evidence at WITN3953053, §§29-37, John Dillon's evidence at WITN4062001_03 and Chris Jones' evidence at WITN4065001_0003. We consider this is liable to lead to patients being overlooked and even neglected.
 - i. While we cannot be prescriptive, there should be a minimum of an annual check-up for all those living with HCV, and those who have "cleared" the virus (if the individual wishes such) with 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. The cost of such follow-up is significantly lower than the cost of treating those with liver cancer.

- 1. In Ireland dedicated times / days have been set aside for treatment, follow up and appointments of those who fell ill as a result of

⁵³ This has been successfully used for thalassaemia patients, see oral evidence of Dr Prescott, 3 March 2022, p. 132.

⁵⁴ Dr Bogod referred in his oral evidence to "*any meeting between multidisciplinary specialities*" as "*extraordinarily helpful*"; oral evidence, 23 February 2022, transcript p. 144: <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Wednesday%2023%20February%202022%20%28Professor%20Philip%20Steer%20and%20Dr%20David%20Bogod%29.pdf>. Multidisciplinary working must be facilitated and encouraged in HCV care and palliative care for those with advanced liver disease, as recommended by the Palliative Care expert group: EXPG0000043, pp. 15-16.

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.

- f. Involvement of specialist HCV nurses, as recommended by the Palliative Care expert group, to bridge the gap between hepatology and palliative care, and between primary and secondary care.⁵⁵ The role of the specialist HCV nurse is vital in the current elimination programme, but no evidence has been heard to date from such an individual. The Inquiry may well benefit hearing from such an individual about this model of provision and the role they play in outreach, education, treatment, and awareness.

Recommendation 7: ensuring patient consent

35. The Inquiry has heard that a startling number of infected Core Participants were given blood transfusions without their knowledge or consent. The very significant majority of our Core Participants who received blood transfusions were not asked to consent to transfusion and where consent was nominally sought there was no discussion of the risks involved. Where they were unconscious when a blood transfusion was given, many were not informed when they regained consciousness that the transfusion had taken place.

36. In a distressing example, a Core Participant refused consent to a blood transfusion for her daughter, which was ignored by hospital staff who nevertheless transfused her daughter who later died as a result of receiving infected blood.⁵⁶ The damage that cases such as these have done to patient trust in the medical profession and in professionals on whom they are dependent for care is incalculable. The fact that the Supreme Court was required to restate the necessary elements of consent in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 as recently as 2015 shows that this is a continuing problem.⁵⁷

37. Issues of informed consent have to be at the heart of HCV treatment. At a minimum, this should involve:

- a. Explaining all risks associated with treatment, even where these are minimal. Following the *Montgomery* approach, this should be patient-centred, and doctors

⁵⁵ EXPG0000043, pp. 15-16, 18-19.

⁵⁶ W1823

⁵⁷ The Cumberledge report, discussed further below, also identified significant, recent shortcomings in seeking informed consent from patients.

should be expected to discuss subjective concerns and priorities as part of treatment discussions;

- i. We would recommend that these discussions are normally led by a hepatologist, gastroenterologist or specialist nurse.
 - b. Ensuring medical professionals are allocated sufficient time to discuss diagnosis and treatment options with patients, including answering questions.
 - c. Signposting patients to recognised specialist support organisations such as the Hepatitis C Trust for further information and support when discussing treatment as an option.
 - d. Providing written materials to patients confirming matters that have been explained to them.
 - i. This should incorporate information stating the risks as explained to them and the support available, such as from the Hepatitis C Trust.
 - e. Allowing patients to take adequate time before making treatment decisions, even if it requires more than one appointment.
 - f. Providing patients with prompt questions that they may like to raise with their doctors.
 - g. Not using technical or jargon-filled language.
38. Moreover, we invite the Chair to consider recommending that the *Montgomery* duty in relation to patient consent is placed on a statutory footing, which may 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 was brought into law in 2014 for NHS Trusts and 2015 for all other providers and 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.
39. We also consider that conversations around consent must be part of a broader process of communicating clearly and compassionately with patients, and all those involved in the care of infected persons should be required to undertake CPD on communication and listening skills.

Medical education

Recommendation 8: improved education regarding the viral and non-viral risks of transfusion

40. While the current aim is to eliminate HCV by 2025, this will not be achievable as patients continue to be identified over time. These patients are a residual group whose best interests need to be safeguarded by a proper understanding and treatment.
41. In considering these recommendations it may be helpful for the Inquiry to recall the evidence of Professor Dame Sally Davies about the difficulties of effecting a culture change within the NHS. We consider that any culture change must be rooted in changes to medical education.⁵⁸
42. Stronger emphasis of both the viral and non-viral risks of blood transfusion, including HCV, within the medical curriculum will assist with the diagnosis and care of infected patients. It is not enough to provide medical students or junior doctors with a set of best practice guidelines and expect that they will understand and apply it. Professor Steer's evidence was that there was no formal mechanism requiring trainees to read guidelines or for testing their understanding.⁵⁹ We suggest that the Inquiry considers obtaining further evidence regarding current medical education, both at medical school and at CPD level once doctors enter practice.
43. We make a number of sub-recommendations:
- a. Even against the backdrop of aiming for elimination by 2025, HCV should be re-emphasised within the current medical curriculum alongside other transfusion-transmitted infections.

⁵⁸ See in particular Sir Brian Langstaff's summary of her recommendations in oral evidence on 3 March 2022 at p. 79: <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Thursday%203%20March%202022%20%28Professor%20Dame%20Sally%20Davies%20and%20Emma%20Prescott%29.pdf>

⁵⁹ Oral evidence 23 February 2022, transcript p. 81. <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Wednesday%203%20February%202022%20%28Professor%20Philip%20Steer%20and%20Dr%20David%20Bogod%29.pdf>. It is also worth noting that both Dr Prescott and Dame Sally Davies told the Inquiry that they could not recall being taught about the risks of viral transmission through blood during their medical training.

- b. All specialists working on (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.
 - c. There should be a formal mechanism for ensuring national guidelines are understood and implemented after CPD is undertaken.⁶⁰
44. Sufficient resourcing must be provided to enable attendance at CPD and / or other training sessions, obtaining, and sharing best practice.
45. GP training is already addressed above, and so no separate recommendation is made regarding such practitioners here.
46. There are still too many preconceptions amongst clinical practitioners about the “type” of people who receive a diagnosis of these conditions which fails to recognise or reflect those infected by way of blood or blood products, and still leads to unconscious biases which play into (a) lack of diagnosis and (b) treatment which fails to take account of the needs of individual patients. There is still a degree of moralizing and/or preconceived judgment or opinion amongst clinicians regarding the source of the HCV infection, which is unnecessary, counterproductive and harmful.
47. We are aware that the NHS has an obligation under the 2012 Act to tackle health inequalities (under s13G of the NHS Act 2006).⁶¹ Part of this should be examining and seeking to ensure that during clinical training unconscious biases should be recognised and all clinicians should understand how the NHS can exacerbate health inequalities through the attitudes of its staff.

Recommendation 9: providing patients with question prompt lists

48. As discussed above, many of the Core Participants whom we represent did not give effective consent to their treatment. We are concerned that, throughout the medical profession, there remain persistent problems in seeking and obtaining effective consent as required by law. Without patronising patients, we believe that conversations around consent need to recognise that patients struggle to understand medical advice, due to cultural, educational, social, psychological and other factors. As Arvind and McMahon put it, few patients correspond to *“the ideal type of the self-aware, informed, perfectly confident patient-*

⁶¹ Guidance on NHS Commissioners on equality and health inequalities legal duties published by NHS England in December 2015.

consumer”.⁶² Professor Jackson rightly explains that “*medical decisions are not always made in [a] rational, linear way*” as envisaged by Montgomery, adding “*Patients may not understand what they have been told, and the information they receive may have little impact upon their choices. This should not be surprising. If psychologists and behavioural economists are right about the limitations on human beings’ reasoning capacities and their decision-making biases, it would be peculiar if these had no impact at all in other decision-making contexts*”.⁶³

49. Patients must be supported to participate in decision-making effectively and on their own terms. This of course involves providing clear, relevant information in a range of media as well as improving medical education as is discussed in these recommendations. We also recommend that patients be provided with ‘prompt sheets’ prior to making important medical decisions to highlight potential questions they may want to raise with their doctor, along the lines of the ‘question prompt list’ used effectively in the context of palliative care.⁶⁴ There is no principled reason why this would not facilitate effective communication in all other areas of decision-making.

Recommendation 10: include mandatory education on communication at all levels of medical practice

50. We recommend that all medical students and trainee doctors be required to undertake training in effective patient communication – including active listening. This should include a practical element and should be tested.
51. Effective patient communication should also be a mandatory part of revalidation accreditation for medical professionals at all levels.
52. Finally, we consider that it is unacceptable that executive directors, chief executives, hospital trustees and other senior non-clinical members of leadership teams are not required to undertake any training in patient safety, consent, effective communication or best practice in building a learning culture. These are essential components of effective oversight and should not simply be delegated to clinical staff. Therefore, we consider that

⁶² TT Arvind and AM McMahon, ‘*Responsiveness and the Role of Rights in Medical Law: Lessons from Montgomery*’ (2020) 28 Medical Law Review 445–77.

⁶³ E Jackson, ‘*Challenging the comparison in Montgomery between patients and ‘consumers exercising choices*’ (2021) 29 Medical Law Review 595–612.

⁶⁴ See Palliative Care expert group report, p. 6/

both prior to appointment and on an annual basis after recruitment members of senior leadership teams must undertake training in these areas.

Official acknowledgment and ongoing support

Recommendation 11: official apology

53. An official apology should be issued by the UK government. Such an apology must:

- a. 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.
- b. 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.
- c. 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.
- d. Given the NHS being 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.
- e. Candidly accept any findings the Inquiry may make about government wrongdoing.
- f. Specifically identify what steps the government and health officials intend to take to (i) support the infected and affected immediately and on an ongoing basis and (ii) prevent the reoccurrence of such a failure.

Recommendation 12: psychosocial support forum

54. We consider that the Inquiry, and the opportunity of meeting in person at the hearing centre, has given infected and affected people a valuable and belated forum in which to

meet, form links, and provide invaluable peer support. Infected and affected people should be offered a forum after the close of the Inquiry in which they can continue to meet virtually and in-person and share their experiences. An immediate withdrawal of the peer support that the Inquiry has offered over a number of years now might be traumatising or cause harm to those who have come to rely on it.

55. It may be appropriate for this to be provided by a specialist organisation such as the Haemophilia Society or Hepatitis C Trust or them working together. It is important that the good work of the Inquiry in bringing together and uniting under a common cause different infected and affected groups is not undone.
56. We would suggest that psychological support should be available to anyone affected by the Inquiry as part of the Inquiry's "closure" work in the form of individual or group support for at least three years after the end of the Inquiry.

Recommendation 13: official memorial

57. A number of the Core Participants we represent 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.

Recommendation 14: adequate resource for transfusion committees and audits

58. Lack of understanding of the risks associated with blood and poor auditing of blood use have historically led to patients being transfused unnecessarily and given more blood than needed. Most blood service witnesses acknowledged that practice had improved, but none claimed it was operating perfectly. The Inquiry may wish to obtain further evidence about the current operation of transfusion committees and blood audits, on which it has not heard substantial evidence to date.
59. Poor attendance at Hospital Transfusion Committees was a common theme in much of the blood services evidence. Professor Contreras and other Regional Transfusion Directors

rightly identified the value of representatives from the Blood Service sitting on Hospital Transfusion Committees and assisting in audits of appropriate and safe blood use.⁶⁵ Haematologists should provide training to hospital staff on safe blood use and be included on Hospital Transfusion Committees. Sufficient resources in terms of both funding and time must be allocated to ensure adequate attendance both from hospital transfusion staff and from blood service staff at Transfusion Committee meetings.

60. Similarly, adequate resourcing for blood use audits is essential in order to work with the other recommendations set out above to lead to greater awareness and education about the use of blood and its risks.

61. As an additional step, the NHSBT could and should raise awareness of transfusion risks through the materials it provides and its website. Whilst the NHSBT website does provide some information in respect of vCJD and transfusion risk, it should provide information about hepatitis C, hepatitis B, HIV and CMV.

Health inequalities and racial discrimination

Recommendation 15: tackling health inequalities and racial discrimination

62. Patients from ethnic minority groups, who have sickle cell disease and thalassaemia, have faced stigma, inequality in care, and discrimination on grounds of their race and ethnicity.⁶⁶ They therefore should be provided with specialist psychosocial support that acknowledges and is informed by the unique obstacles they have faced.

63. We recommend that the Inquiry obtain an expert report addressing racial and ethnic discrimination and inequality in respect of those infected and affected in respect of infected blood and examining the inequalities in access to treatment, in diagnosis and provision of help and support in these communities. There has not been substantial evidence on this important issue to date and we believe that the Inquiry will require specialist input in order to make effective recommendations, especially as it has not heard substantial evidence from

⁶⁵ See e.g. WITN5711001, §597

<https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/WITN5711001%20Written%20Statement%20of%20Professor%20Dame%20Marcela%20Contreras%2014%20Oct%202021.pdf>; oral evidence of Dr Martlew 20 January 2022, transcript p. 43

<https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Thursday%2020%20Jan%202022%20%28Dr%20Vanessa%20Martlew%29.pdf>

⁶⁶ See evidence of Dame Sally Davies, in particular her oral evidence at e.g. pp. 40-42.

sickle cell and thalassaemia patients to date. This evidence must also cover any disparities in funding between diseases which are more prevalent in ethnic minority groups.

Obstetrics and gynaecological care

Recommendation 16: proactively discuss transfusion with pregnant women

64. Dr Philip Steer identified significant historic failings in obstetric and gynaecological care. The Inquiry may be assisted by further evidence as to current practices but the issues indicated by Dr Steer's evidence were:

- a. A lack of training regarding the risks of blood transfusion for obstetrics / gynaecology specialists;
- b. An overuse of blood transfusion to 'top up' new mothers where this was not necessary;
- c. A failure to keep proper records of blood used from the 'just in case' fridge in the labour ward;
- d. Failures to inform patients that they had received a transfusion; and
- e. Paternalistic attitudes whereby doctors did not wish to 'worry' mothers so did not give them adequate information either prior to or post-transfusion.

65. In addition to the improvements to medical education discussed above, we recommend that proactive discussions regarding transfusion 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 obstetric team understand their attitude to transfusion. They 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.

Palliative care

Recommendation 17: achieving consistent, high quality palliative care

66. As the leading cause of death amongst working-age people, we consider that improving care around advanced liver disease has the potential to achieve substantial wider public benefits in addition to improving outcomes for those who have been infected with hepatitis.

67. We endorse the analysis and conclusions of the Palliative Care Expert Group and do not intend to repeat them here.⁶⁷ We consider the key recommendations to be:

- a. Including palliative care within speciality-specific treatment guidelines; this should promote care planning and improve the standard and consistency of care.
- b. As discussed above, 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.⁶⁸ There are currently only four accredited services in the UK.
- c. Using the CQUIN (Commissioning for Quality and Innovation) payment framework to incentivise multidisciplinary working and integration of palliative care.
- d. Funding high quality, large scale research studies into best practice in palliative care.
- e. Employing specialist hepatitis nurses to support palliative care and ensure best practice.
- f. Facilitating 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.

Government

⁶⁷ EXPG0000043_0019. The experts' recommendations pp. 14-20.

⁶⁸ <https://www.iqils.org/>

Recommendation 18: duty of candour

68. We recommend the consideration of the introduction of a duty of candour for public officials on a statutory footing . This would emulate the proposed Charter for Families Bereaved Through Public Tragedy proposed following the Hillsborough disaster and the recommendations made by Robert Francis QC in his report following the Mid Staffordshire NHS Foundation Trust Inquiry.⁶⁹ Such a duty should oblige public servants (including those in retirement) to provide candid evidence to public inquiries, criminal investigations, and inquests. We already have a model in the duty of candour regulations,⁷⁰ which requires a health services body to be open and transparent where a notifiable safety incident has taken place, and in the context of judicial review, in which the duty of candour has been described as follows:

“... a common aim, namely the maintenance of the highest standards of public administration... What is discreditable is a reluctance to explain fully what has occurred and why ... It is a process which falls to be conducted with all the cares face upwards on the table and the vast majority of the cares will start in the [public] authority’s hands.”⁷¹

69. The Inquiry may wish to consider ways in which the Civil Service and Ministerial Code of Conduct could be amended, or greater emphasis placed upon aspects of the code to facilitate greater candour and transparency in government. The current code for civil servants indicates that the “facts and relevant issues” should be set out truthfully and that errors should be corrected as soon as possible, and that they should act in a way which retains the confidence of those with whom they have dealings.⁷² The Ministerial Code suggests both that accurate and truthful information should be given to Parliament, correcting any inadvertent error at the earliest opportunity, and that Ministers should be as

⁶⁹ See

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf.

⁷⁰ See Reg 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. These were recently reinforced with a joint statement on the professional duty of candour from the Chief Executives of the statutory regulators of healthcare professionals in 2019:

https://www.pharmacyregulation.org/sites/default/files/joint_statement_on_the_professional_duty_of_candour.pdf.

⁷¹ *R (Huddleston) v Lancashire County Council* [1986] 2 All ER 941.

⁷² <https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code>.

open as possible with Parliament, alongside requiring civil servants who act under their directions to provide accurate, truthful and full information.⁷³

70. We particularly consider that accessible and comprehensive record-keeping must be a mandatory and essential part of any such duty of candour. The need to keep such records is emphasised by both the Civil Service and Ministerial Codes, but as the Inquiry has heard, in the past that has been honoured in the breach. We are concerned by the recent Divisional Court judgment in *R (All the Citizens and Good Law Project) v Secretary of State and ors* [2022] EWHC 960 (Admin), in which the use of non-Government communication systems such as WhatsApp and Signal, including those which automatically delete communications, was lawful. While the Court has granted permission to appeal to the Court of Appeal, we nevertheless consider that a statutory duty of candour must ensure that all government business must be recorded in accessible, written form.

71. 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). The Inquiry may welcome evidence from those who are fulfilling the role of Victim's Commissioner or other commissioners who operate discrete roles to raise awareness of particular issues (such as for example in respect of domestic violence and children in other contexts) in order to explore how their role is used by individuals to promote change, influence governmental policy and ensure that individuals are listened to and heard whilst acting wholly independently or at arm's length from central government/NHS decision making. The Inquiry may also wish to receive evidence about the role and purpose of the Patient Safety Commissioner and how a sub commissioner could be appointed or identified to issue guidance or advocate in respect of blood, tissue and organs.

Cultural change

Recommendation 19: address paternalistic and dismissive attitudes

72. Much of the avoidable harm suffered by infected and affected people stemmed from paternalistic attitudes which have not yet been eradicated from the health system. Women were given unnecessary 'top ups' of blood without discussion of risks. Reports of decades-

⁷³

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1079310/Ministerial_Code.pdf.

long symptoms of hepatitis were dismissed or baselessly treated as signs of alcoholism.⁷⁴ Women were dismissed as “*histrionic*”, “*taking on too much*” or even told to “*stop hovering*”. We are concerned that failures to seek consent and decisions to ignore patients’ wishes and concerns are rooted in racist and / or sexist attitudes.

73. We are not the first to suggest that there are pervasive cultural problems within the NHS. The Francis Report, referred to above, 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*”.⁷⁵ Those criticisms and that recommendation remains valid.

74. Moreover, the NHS has already been recognised as having attitudes and approaches towards women which 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,⁷⁶ Baroness Cumberledge noted numerous recent 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*”.⁷⁷ She also noted the damage which these dismissive attitudes caused to patient faith in those treating them. The report also records repeated failures to obtain informed consent. Baroness Cumberledge concluded that “*put simply, the system has not been listening as it should*”. She recommended that a Patient Safety Commissioner be recruited, which is currently underway.⁷⁸

75. That report was issued in 2020 and its recommendations were substantially accepted by the Government in its response in 2021.⁷⁹ There is no reason to be confident that this

⁷⁴ See e.g. W1867.

⁷⁵ Francis Report, p. 4:

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.

⁷⁶ Available at:

https://www.webarchive.org.uk/wayback/archive/20200721101148mp_/https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf (accessed 19 April 2022)

⁷⁷ *First do no harm*, p. 17.

⁷⁸ <https://publicappointments.cabinetoffice.gov.uk/appointment/patient-safety-commissioner/>

⁷⁹ Government response to the Report of the Independent Medicines and Medical Devices Safety Review, 26 July 2021. Available at:

dysfunctional culture has changed or improved since that time. The accounts of infected and affected individuals regarding their recent experiences of late and misdiagnosis, combined with poor communication and follow-up, demonstrates that this is a widespread problem throughout the NHS. We consider that the Inquiry would be assisted by hearing evidence from a clinical health psychologist, particularly one with expertise in unconscious bias and gender- and race-based discrimination in healthcare.

76. We consider that, as a minimum, the following steps need to be taken to address the longstanding cultural issues identified:

- a. A Patient Safeguarding Commissioner - or sub commissioner for recipients of infected blood should be appointed. Their role would be both to advocate for the rights of infected persons, to monitor standards of their care, and review blood safety practice. We do not consider that the Patient Safety Commissioner, with their very broad remit and prohibition on advocating for individual patients, would have capacity to cover this role alongside the rest of their remit.
- b. Publish and implement the proposed Framework for Involving Patients in Patient Safety, which has not been updated since July 2019⁸⁰ and which was due to be published in 2021/22.
- c. Medical professionals' performance reviews should reflect their adherence to this Framework.
- d. All medical professionals should be required to undertake unconscious bias training.⁸¹

Trusts and funds and financial support

77. We note that surveys of those who currently benefit from the schemes⁸² made it clear that they did not want to lose any support through the ex-gratia schemes, as the support

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf (accessed 19 April 2022).

⁸⁰ Available at <https://www.england.nhs.uk/wp-content/uploads/2021/06/B0435-framework-for-involving-patients-in-patient-safety.pdf> (accessed 19 April 2022)

⁸¹ In this context, we reiterate our recommendation above for expert evidence on racial and ethnic discrimination within the healthcare system.

⁸² We understand the UK Haemophilia Society and the Scottish Infected Blood Forum/Haemophilia Scotland have carried out surveys which identified the majority of those who currently receive monies with them to continue.

received on a regular basis is necessary and should continue irrespective of what position is reached in respect of compensation. Losing support which has been vital to individuals for a large number of years would be both unnecessary and disproportionate. This is the position reached by Sir Robert Francis in his framework scheme (Recommendation 15 (b)). We also note the recommendation that these payments should be guaranteed for life - with which we agree and ask that the Inquiry makes this recommendation. Any payments which continue to be made should be uplifted appropriately to ensure equity between the various schemes. More detailed submissions will be made about the Trusts and Schemes in the final submissions and following the evidence of Sir Robert Francis.

78. If the trusts and funds continue to operate in some capacity after the Inquiry finishes, a number of alterations should be made to their practice and the way in which they support infected and affected individuals which we set out below.
79. Core Participants have differing views as to whether or not the payments currently received should be the same irrespective of clinical diagnosis or should differ depending on the diagnosis or co-morbid diagnoses. It is not possible to present a “one size fits all” view of this subject: some Core Participants wish to have identical payments under a scheme for everyone, and others consider that the differential is significant and should be maintained.

Recommendation 20: Include HBV and remove the cut-off date for HCV in compensation schemes

80. There is no principled reason to exclude HBV from the schemes as they exist or from any compensation framework. Infected individuals who have had their lives and health adversely affected by the HBV infection via infected blood be entitled to financial support and/or compensation on an equal basis to other infected individuals. We note that Sir Robert Francis does not consider that most of those affected with HBV should be included in any scheme (paragraphs 4.77 - 4.86) but does consider that those with HBV who develop a chronic infection with serious symptoms who require treatment to prevent cirrhosis, or who have actually contracted cirrhosis should be eligible for compensation (paragraph 4.85 of his framework study). We consider that the Inquiry is in a better position than Sir Robert to reach conclusions on this eligibility but would ask that it considers if it currently has sufficient evidence about (a) those infected with HBV alone (b) the impact of HBV infection on day to day life and (c) the impact of developing a chronic infection and (d) the

psychosocial impacts of having HBV and obtaining further evidence if required to ensure an adequate evidential basis to reach any conclusions it may consider appropriate.

81. We have referred above to the evidence that blood which may have been infected with HCV remained in the system after September 1991. Maintaining this cut-off date is no longer justifiable and the evidence of Mr. Gutowski and others provides no rational basis for the imposition of any cut-off date or in fact suggests a mistaken view that no blood could have been in circulation after September 1991 which could have been infected with HCV. That is wrong as evidence to the Inquiry shows that such blood, and plasma was in circulation and was not recalled.⁸³ We consider that there should be no temporal limitation on financial support for those who receive infected blood. Transfusion-transmitted infections remain a minimal but real risk.⁸⁴ Just because the risk is much lower today does not mean that an infection with a disease such as HCV is unworthy of financial support.

Recommendation 21: Amendments to the current running of the schemes .

82. The evidence received by this Inquiry establishes that blood transfusions were often simply not recorded in patients' notes.⁸⁵ There was often no system in place to ensure accurate recording.⁸⁶ Patient records were often lost or destroyed,⁸⁷ either negligently or accidentally. Paper-based records were particularly prone to being incorrect and were liable to loss⁸⁸ but computerised records were not introduced until the late 1980s / early 1990s. Even then, the balance of evidence shows that blood transfusions would not necessarily have been placed in patient records which were kept, or which were accessible by a patient.

83. These failures of reliable and consistent record-keeping have resulted in many infected individuals being wrongly denied access to the schemes to date. It is particularly surprising

⁸³ Evidence of Mr. Gutowski, 10 June 2022.

⁸⁴ See the JPAC's Transfusion handbook, §5.3: <https://www.transfusionguidelines.org/transfusion-handbook/5-adverse-effects-of-transfusion/5-3-infectious-hazards-of-transfusion> (accessed 19 April 2022).

⁸⁵ Dame Contreras accepted that there were problems with hospitals maintaining accurate records: see e.g. oral evidence 2 December 2021, transcript p. 114. Available at: <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Thursday%2024%20December%202021%20%28Professor%20Dame%20Marcela%20Contreras%29.pdf> (accessed 19 April 2022).

⁸⁶ See Dr Bogod's evidence, 23 February 2022, transcript p. 135.

⁸⁷ See e.g. W1963, W2644, W1970. Dr Wallis accepted that record-keeping was variable in quality and it became increasingly difficult to find records over time: oral evidence, 24 February 2022, transcript pp 22-24. <https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/Transcript%20-%20London%20-%20Thursday%2024%20February%202022%20%28Dr%20Jonathan%20Wallis%20and%20Professor%20Michael%20Murphy%29.pdf> (accessed 19 April 2022).

⁸⁸ See e.g. evidence of Dr Boulton at HCDO0001093, p. 3.

that the approach of the schemes has been to require proof of transfusion when it was known before the inception of any scheme that poor record keeping would mean that many would not have such records available. The risk of abuse of the system is very limited given the need to demonstrate that the applicant is suffering with a qualifying disease. We therefore propose that:

- a. Any body responsible for awarding compensation/financial support applies the lower standard of proof,⁸⁹ namely a reasonable degree of likelihood that the applicant received infected blood and / or that the burden of proof, if maintained as the balance of probabilities, should be approached in a “sympathetic” 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 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, treatment may be inferred where there are surrounding circumstances which can reasonably infer that blood may have been administered, and there is no persuasive alternative evidence supporting an alternative cause of the infection (we note that this is the approach of Sir Robert Francis at paragraph 6.14 of his framework report).
- 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 do.
- d. Where applicants are refused on the papers they should be entitled to appeal and be heard at an oral hearing.⁹⁰ They should be entitled to bring advocates with them to that meeting if they wish.

⁸⁹ 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.

⁹⁰ Dr Hewitt spoke about the importance of hearing oral evidence from infected individuals in order to assess their account properly, especially where there is limited documentation.

- e. Any applications for the scheme should have an advocacy and support service attached to provide advice, assistance and guidance on navigating what can be a daunting process for those who are unwell and often unfamiliar with the bureaucratic processes of government.

Recommendation 22: all applicants for financial compensation should be offered comprehensive welfare rights advice and advocacy and access to insurance and other benefits using a “level playing field”.

- 84. It is well-recognised that the UK benefits system can be hostile and byzantine to navigate.⁹¹ Any public body responsible for delivering compensation should support applicants to access comprehensive welfare services, including housing, income support, and social care.
- 85. The advice service should also offer 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.
- 86. As a sub-recommendation, we suggest that the issue of applicants’ inability to get mortgages without life insurance be examined, as should the impact which this has had on affected individuals whose partners have died. We recommend an investigation of the nature and extent of this problem and possible solutions, including examining the solutions reached in Ireland whereby the government has in effect underwritten a scheme so that mortgages, life insurance and travel insurance can be provided for those infected by reason of infected blood on a level playing field with non-affected members of the public. There should be no person affected who is non insurable.
- 87. 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 infected and affected individuals receive. A number of the 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 they received from the Trusts and Schemes should not be off set against benefits. Again, this is a question of ensuring that adequate information is disseminated for decision makers.

⁹¹ See the evidence of Neil Bateman, WITN3487002, as to the difficulties faced by applicants in obtaining support and public benefits. Professor Sally Davies also noted that she often needed to advocate on behalf of her patients when they were not receiving appropriate support: oral evidence, 3 March 2022, pp. 46-47.

Recognising historic injustice in the provision of care

Recommendation 23: infected status should be recognised in the allocation of services

88. The recipients of infected blood have been victims of unique failures in their care at the hands of the NHS. Their faith in the institution has been damaged and they have been forced to rely on the very institution which failed them. Training for those working with the infected and affected should cover the need to provide proactive and comprehensive support to bolster their confidence in the public health service.
89. We are aware that in Ireland recipients of infected blood have received free dentistry and optometry services as of right and recommend that the same practice be adopted in the UK. Whilst some individuals may well receive such free services at present, not all will do. Given, in particular, the delay in the provision of NHS dental treatment, and the evidence presented that those with HCV are frequently denied treatment because of concerns of dentists or given “special” consideration when usual barrier medicine practices would be sufficient, it is suggested that there are a cadre of dentists recruited to whom those patients could be referred for treatment (with private provision if required). HCV, HBV and HIV are not currently conditions which enable medical exemption certificates to be provided for free prescriptions, and the regulations should be amended to include these.⁹²
90. ⁹³ Consideration should also be given to the provision of free domiciliary support and social care services to those infected and affected. We know that this is the position in Ireland. The welfare state operates differently in that country but that is no reason to discount this as a requirement. Various ways of provision of such services could be made – whether by way of being “passport” in the continuing healthcare framework,⁹⁴ or by excluding someone’s income from assessment under the Care Act 2014 and the Statutory Care and Support Guidance⁹⁵ or by the provision of services via the schemes/any compensation framework.

⁹² <https://www.nhs.uk/infected-blood/exemption-certificates/medical-exemption-certificates>.

⁹³ The NHS Framework for Continuing Healthcare provides that where certain criteria are met then someone has a “primary health need”. If that is the case, then the provision of both health and social care related provision is free at the point of access.

⁹⁴ https://assets.publishing.service.gov.uk/government/uploads/system/attachment_data/file/1079650/national-framework-for-nhs-continuing-healthcare-and-nhs-funded-nursing-care_july_2022_revised.pdf.

⁹⁵ Chapter 8 of the Care and Support Guidance . <https://www.gov.uk/government/publications/care-act-statutory-guidance/care-and-support-statutory-guidance/charging-and-financial-assessment>

91. Alongside this, consideration should be given to whether or not the calculation for being eligible for a liver transplant (or other forms of transplant or treatment, if required and linked to someone's clinical diagnosis because of infected blood) should take account of their source of their infection and be recognised as a relevant factor in the way that transplant allocation takes place. Evidence may be required from the NHS Transplant service on the current mechanism for allocation of liver transplantation and the feasibility of having infected blood as a factor to be considered.

Best interests decision-making

Recommendation 24: where treatment is given without consent on an emergency basis there must be a duty to inform patients afterwards

92. Many infected individuals received blood without consent being sought or given as blood was required on an emergency basis while the individual was unconscious. Such decisions can properly be made in a patient's best interests under the Mental Capacity Act 2005. However, we are concerned that there is no express duty on doctors to inform patients about the medical treatment they received whilst unconscious.
93. The requirement of informed consent is not simply about ensuring that a doctor has legal protection, it is about involving patients in their care and ensuring that they can make decisions about their health and treatment on their own terms and as the best judge of their own interests. As the stories of those infected plainly show, even decisions made on an emergency basis in a patient's best interests may have life-changing effects and be of ongoing significance. The Mental Capacity Act Code of Practice 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.
94. 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 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 should be requested to amend their guidance in the same terms.

Record-keeping

Recommendation 25: further evidence regarding record-keeping

95. The Inquiry has heard evidence of longstanding failures in record keeping within the NHS, which has negatively impacted care and support for infected people. We are particularly concerned about the failure to ensure that different NHS records held by different bodies are comprehensive and complete.⁹⁶ At this stage, we consider that it may be appropriate to recommend that, insofar as possible, blood transfusion should always be included in a patient's records, included in their discharge letter, and notified to their GP.
96. There should be a clear system of identifying who destroyed documents together with the date and reason for this. This will provide some explanation for those who may be unable to access their records in the future. We also invite the Inquiry to consider seeking more evidence on the viability of giving notice to patients whose records are shortly to be destroyed.
97. We suggest that the Inquiry obtain sufficient evidence from NHS Digital to identify if these problems have been solved and, if so, how. We also recommend that the Inquiry obtain evidence from GPs about their current record-keeping practices.

Commissioning

Recommendation 26: specialised commissioning

98. Currently, NHS England commissions specialised treatment and care services for people with HIV and HCV and some elements of care for HBV.⁹⁷ This does not extend to specialist commissioning for psychological services, which remain largely in the hands of CCGs and those who need psychological help are referred accordingly.
99. We recommend that there be specialist commissioning for multi-disciplinary care for HCV patients. The commissioning body must have training in the infected blood scandal and the particular needs of infected individuals, including the need for joined-up care including psychological support.

⁹⁶ The Palliative Care Expert Group complained of problems caused today by “*the existence of multiple information technology systems, that are frequently not connected [which] hampers straightforward data collection and analysis.*” EXPG0000043, p. 5.

⁹⁷ See WITN3953061 and WITN3953053_0006.

Other recommendations

Recommendation 27 -Health Economics and Mortality data

100. It is recognised that the health statistics expert group have not as yet produced their report. The Inquiry should consider if as part of its expert report the health statistics expert group should consider (a) health inequalities evident from the data on infected blood (b) issues of different levels of mortality between different groups of those infected. For example, the mortality data suggests that those with mild haemophilia may be at greater risk of mortality because they are not provided with prophylactic factor 8 and so requires further consideration by the Inquiry.

101. The health economics expert group has also not yet reported. The Inquiry should consider if as part of its report it should address

(a) the question of allocation of funds during and as a result of public health emergencies (for example in matters relevant to the Inquiry the comparison between early investment in self sufficiency and costs of treating patients with advanced liver disease) and

(b) how and when expert advice from a health economist is sought by the Department of Health when making decisions about allocation of budgetary funds

Recommendation 28 - making recommendations and responses transparent

102. There is no obligation under the Inquiries Act 2005 for the government to “report back” to the Inquiry as a matter of routine as to which recommendations that the Inquiry makes have been implemented, and which have not (with reasons). Other inquiries have sought to ask the relevant government department, body or organisation to provide information as to what they have done six months after an interim report (but that has been in situations where the Inquiry is ongoing). We would ask that NHS England / the DHSC / Cabinet Office are recommended to provide some kind of “dashboard” which is publicly available on the Inquiry website after the Inquiry has been completed which identifies what has been agreed, what steps have been taken towards implementation and in what format and provides an explanation as to why certain matters have not been implemented despite recommendations.

Recommendation 29 - decisions about public inquiries in cases concerning systematic health service failures

103. Many of those involved in public inquiries under the Inquiries Act 2005 and many of the Core Participants we represent have identified unhappiness that the decision as to hold such an inquiry lies with a Minister,⁹⁸ and in fact, under the Ministerial Code, after the Minister has consulted the Prime Minister.⁹⁹ It is recognised that whether or not to hold a public inquiry could be considered to be a wholly “political” decision. However, when it relates to health provision – and this case has been described by many of those who have come to give evidence as a “national tragedy” – thought should be given as to whether or not a body independent of the executive should be tasked with deciding whether or not the criteria for a public inquiry have been met. As the evidence to this Inquiry shows already, the instinctive reaction of many working in central government is that such an Inquiry is unnecessary and/or would not be helpful even if it is something acknowledged as a matter of widespread public and parliamentary concern. There is a natural and foreseeable reluctance for bodies to “mark their own homework”.

104. The Inquiry may wish to consider or explore if a recommendation should be made to have an independent body tasked with deciding if an inquiry should be undertaken in respect of the provision of NHS services if it demonstrates systemic or widespread failings in patient care or safety, and to appoint and set the parameters of such an inquiry and provide a roster of individuals qualified to carry out such inquiries (in a similar way, for example, to the Child Safeguarding Practice Review Panel¹⁰⁰ which commissions national and local reviews in respect of safeguarding concerns). That would, it is submitted, avoid the current plethora of different forms of internal reviews, independent reviews, inquiries which are not public inquiries or public inquiries and create a standard of consistency of approach between the very many different NHS bodies where problems may occur.

105. Any form of body needs to have the power to compel the production of documents and witnesses, but may be able to exercise discretion as to how and in what way the inquiry is conducted to enable it to happen quickly, and if necessary, to deal with discrete topics so that it can occur with less of the formality or rigidity that can sometimes attend a public inquiry. Individuals could seek to have the body determine whether an inquiry is needed, and if so, the nature of the inquiry and this body could be subject to oversight by way of

⁹⁸ S1 of the Inquiries Act

⁹⁹ Paragraph 4.12 of the Ministerial Code

¹⁰⁰ <https://www.gov.uk/government/organisations/child-safeguarding-practice-review-panel>.

judicial review, if so required (but being given a broad remit to exercise its discretion). Criteria could be set out which were flexible, but which sought to identify issues of widespread/national concern or which related to systemic flaws in the system as the basis for the commissioning of an inquiry. Further submissions will be made about this issue, but it is raised now so that thought can be given as to what evidence may be needed to seek to identify how, on a practical basis, such a body could work. Its primary focus would be to listen, but also to learn lessons and provide recommendations to improve patient care in the future.

Fiona Scolding QC

Miranda Butler

Hannah Gibbs

Landmark Chambers

On behalf of those Core Participants represented by Leigh Day

17 June 2022