Witness Name: Robert James
[W1004]
Statement No.2: WITN1004002
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Dated: 6 November 2020

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF ROBERT JAMES

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 13 January 2020. I, Robert Magnus Lee James, will say as follows: -

I. Introduction

1. My name is Robert James and I live at GRO-C. I was born GRO-C 1966.
2. I have a PhD in law and I am a lecturer of law in the context of community care and social work GRO-C. In my academic work, I have pursued research interests in HIV. I have used the story of my own infection with contaminated blood products as a way of educating the public through media interviews, conference presentations and in my own teaching. For the Inquiry's work, I am particularly interested in how stigma affected the assessment of risk at critical points in the unfolding scandal. I am also interested in how stigma affected progress in treatment and care and the impact on equality.

II. My approach to advocacy and campaigning

3. I have come to see the issues raised by this Inquiry as centrally engaging human rights. I have approached the making of this statement with that in mind. I believe there is a universal right to be treated with dignity, regardless of an

individual's situation. I think the state should only restrict or temporarily suspend a person's rights when that person has interfered with or violated the rights of another. I believe the state has failed me and other haemophiliacs in this infected blood scandal. They have failed by first removing the dignity of the groups that became most affected by HIV and viral hepatitis; promoting and reinforcing a stigmatised view of those groups; failing to prevent this stigma from affecting the decision making of those in positions of knowledge and authority; failing to acknowledge and implement risk reduction strategies; and ultimately failing to stop a significant number of vulnerable and disabled people in its care from becoming infected with debilitating and frequently fatal infections.

4. From the first appearance of AIDS, there were suggestions it was 'a judgment from God'[1] and that people with the syndrome deserved to die from it. This perception came on top of state-legitimised stigma against gay people, [2] drug users,[3] sex workers[4] and migrants. Immediately, it led to a separation between those with HIV that were infected through blood products and others with the condition. This implicitly divided all people with AIDS as either innocent and worthy of care [haemophiliacs] and others as guilty and worthy of blame [gay men, sex workers, IV drug users]. This division denied those deemed guilty of their human dignity and ultimately demeaned those deemed innocent. Those of us infected through blood or blood products were routinely exceptionalised and separated from the general service provision for people with HIV. I feel strongly that this haemophilia-exceptionalism affected the initial risk perception

[1] See Kowalewski, M. (1990). Religious Constructions of the AIDS Crisis. *Sociological Analysis, 51*(1), 91-96. doi:10.2307/3711343. Available online: https://academic.oup.com/socrel/article/51/1/91/1631648. This is primarily about homosexuality but was applied to a lesser extent to people who injected drugs.

[2] The differential laws on sex for gay men, lesbians and heterosexual people: under the Sexual Offences Act 1967 men had to be 21 to have sex with each other; and it had to be done in private and with no third person involved or watching while heterosexual people could legally have sex with a dozen others. Lesbians were ignored under the Sexual Offences Act 1967 but were sometimes convicted of gross indecency or sexual assault.

[3] The police watching needle exchanges to identify and prosecute injecting drug users in Edinburgh in the late 1980s as noted in "Choose Life: Edinburgh's Battle Against Aids", BBC Scotland, broadcast 16 June 2020.

[4] The highlighting of previous convictions with the use of the term 'common prostitute' court at the start of a trial of a woman for offences under the Street Offences Act 1959. This term was eventually removed from the statute book with the Policing and Crime Act 2009.

in the early stages of AIDS; the approach to the management of blood products; the provision of clinical care to those affected with AIDS, and the availability of community support services.

5. From the onset, the HIV and AIDS epidemic was fundamentally characterised by stigma. The groups that were initially publicised as being "high risk" were gay men, injecting drug users and sex workers.[5] The perception of guilt and innocence led to a long-standing separation of people with haemophilia and HIV from the wider HIV sector. Many with haemophilia and HIV themselves advocated for this separation, for fear that they would be tainted by association with homosexuality and drug users. But in effect, this separation left many haemophiliacs in a silo - with poorer and less cutting-edge HIV services.[6] I think this has also happened in a less pronounced way for those with hepatitis C.
6. Those infected with HIV through blood products and the small number through blood transfusions were - and still are - painted as innocent victims by the media.[7] The notion of innocence can be seen as a defence against the worst excesses of prejudice and an attempt to induce sympathy from those with homophobic views. But it is a privilege that is only available to a few and stands in opposition to the universality of human dignity. People infected with HIV through sex or sharing needles know that descriptions based on blame exclude them and instead, holds them personally responsible for HIV and AIDS.
7. It is important that the inquiry appreciates the climate that prevailed at the onset of AIDS. In 1981, a new syndrome with an extremely high fatality rate appeared and was frequently described as the 'gay plague'. It soon became clear that there was a risk of transmission in blood and blood products. At the same time factor VIII concentrate had revolutionised the treatment of haemophilia. It was easier to store dosages for surgery. Bleed management was easier to calculate. Dosages could be administered more easily. There were reduced

[5] British Social Attitudes 30. Available at https://www.bsa.natcen.ac.uk/media/38723/bsa30_full_report_final.pdf

[6] The UKHCDO meeting minutes 21 October 1985 [PRSE0001638, p10] highlights 2 volunteers from the society did not want to share a platform with any volunteers from the Haemophilia Society who "did not want to share a platform with any other 'At Risk' Group".

[7] In the opening speeches to this inquiry, the term was used by all but two of the barristers representing core participants in their opening addresses.

problems in treating children by managing volume. Concentrates appeared to produce less side effects and offered greater opportunity for home treatment. Unsurprisingly, factor VIII was hailed as promoting greater independence of people with haemophilia. All this placed haemophilia clinicians in the position of considering a product that had transformed the lives of their patients - and which could also pose risks to them: Risks that had been identified with the most stigmatised and reviled people in society.

8. A significant number of people with haemophilia at the time were also young; and there was still a high fatality rate from bleeding before the availability of cryoprecipitate. I often heard many haemophilia doctors talk about their paediatric patients as "my children."[8] A paternal relationship often developed over many years. These doctors were now being asked to contemplate the possibility that "their" children could have acquired this monstrous disease from a treatment they had prescribed and which had seemed to be providing such a propitious future. It is difficult to imagine that this would not have provoked an emotional reaction that such a horrific disease of the unworthy could infect "their" children. I believe that the reticence in acknowledging the implications of a blood borne agent for HIV and the desire for a higher level of proof before acceptance[9] was a by-product of stigmatisation.
9. The exceptionalism of those infected through blood products meant that the vast majority of people with haemophilia were not treated at the genito-urinary medicine (GU) or infectious disease (ID) clinics where everyone else with HIV was treated but instead, in the haemophilia centres, and often by a clinician who was not an expert in the disease.[10] When a condition is new and little is known about it, there may be little difference between clinicians. But it did not take long for knowledge about treatments for, and the prevention of, opportunistic infections to develop around what was necessary to prolong people's lives. Some clinicians updated their knowledge of HIV to include this and some introduced joint clinics with HIV specialists. Others took much longer

[8] This phrase is also in Dr Brian Colvin's statement (WITN3343007)
[9] See my first statement for a review of the published medical literature and discussions about the likelihood of transmission through blood products at the very start of the epidemic.
[10] Any number of the witness statements bear this out. It is notable that those infected through blood transfusions were referred and treated by GU or ID clinics.

to make this link and so clinical care varied across the country.[11] This manifested itself in ludicrous situations such as when a GRO-C went to have an HIV test was required to go to a GU clinic. She would have been treated there by a GU doctor if she had tested positive for HIV. On the other hand, my care was managed by a haemophilia doctor.[12] In my first statement to the Inquiry, I provided another example of the prescribing of treatment for HIV through a haemophilia centre that was clinically wrong and unethical.

10. The different treatment pathways that existed for haemophiliacs infected with HIV meant that all of the support and many of the patient centred models of care developed in the HIV clinical setting in the wider HIV sector in the 1990s[13] were not experienced by the majority of those infected through blood products. Haemophiliacs remained under the more paternalistic system of haemophilia centres. HIV community organisations and services were rarely advertised or made available in haemophilia centres.

11. I was, and remain, heavily involved with general HIV organisations and welcomed and valued the support, knowledge and friendship they have always provided to me around my infection. I observed and was persuaded by the ways of working in the wider HIV sector - involving the promotion of the rights of stigmatised groups and patient involvement in all aspects of treatment, care and decision-making. When I led Birchgrove (discussed later), we worked with HIV organisations from early on, sharing premises with Cardiff Body Positive for some years and I was involved in national AIDS forums over many years.

12. For many haemophiliacs, the rub of the stigma from hepatitis C came through the association with IV drug use. Often, there is a deeply felt need to explain that one's infection did not come because of such drug use.[14] The development of an HCV antibody test around 1990 put clinicians in a situation of needing to tell almost all of their patients who had avoided HIV that they had a dangerous and sometimes fatal illness. Haemophilia clinicians would have been giving out these diagnoses at the same time as the number of deaths of their patients with

[11] Dr Mark Winter also highlights this at the end of his witness statement (WITN3437002).
[12] This was at Morriston Hospital Swansea in 1989.
[13] See https://www.healthcareworkersinhiv.org.uk/category/interview-themes/models-of-care
[14] Stigma also exists for people with HCV as has been demonstrated in witness statements to the Inquiry, and the reports from the Hep C Trust.

HIV was accelerating. Patients would therefore have been told that they had a virus (HCV) that was making them unwell and, though potentially deadly, seemed less so than HIV that was killing so many others of their peers. That would have been an extraordinarily difficult task to perform for clinicians. There was a catastrophic failure to appreciate the potential trauma in communicating this news to people who were already experiencing the unfolding disaster of HIV and AIDS. The communication of this information was left to be done by clinicians often with little or no involvement from mental health specialists. This remains to me one of the worst misjudgements of the scandal.

III. Campaigning activities

13. Over the last 30 years or so, I have been a part of various advocacy campaigns related to my infections from contaminated blood products. I have also become involved with the wider issues related to my infections, especially in the HIV sector. One major theme has been my involvement in the field of patient involvement and treatment activism regarding HIV and viral hepatitis.

UKCAB

14. I was one of a group of individuals that developed UKCAB – the UK-Community Advisory Board (CAB) - into a more independent and national forum for UK HIV activists. This was driven by the need to lobby pharmaceutical companies, share ideas and information and foster collaboration among key players. UKCAB was first set up in 2002 by HIV i-Base,[15] a HIV treatment information and advocacy organisation.
15. For background, pharmaceutical companies were in the habit of creating their own Community Advisory Boards for projects or studies in order to demonstrate consultation with patients and the "HIV community".[16] The individuals on these CABs were often simply people known to the company. By and large they lacked independence and diversity. Simon Collins, from the organisation i-Base, started UKCAB to create a more representative and independent CAB. He started by soliciting support from a small number of people from across the

[15] See http://i-base.info/.
[16] A general term to include carers, parents and those working in HIV organisations as well as people living with the virus.

HIV sector, including me, to arrange the first meeting. The meetings were successful at bringing together a range of people with HIV including those with haemophilia, and educating ourselves about HIV and lobbying pharmaceutical companies. At the end of 2005, I was contacted by Mark McPherson from i-Base as one of a group of 5 people asked to develop the UKCAB into a national and more independent group. It was felt that the UKCAB meetings had come to be seen as an i-Base activity rather than as a forum for presenting and sharing the views of the wider HIV sector. I, along with 4 other activists[17], formed a steering group to set up the quarterly meetings as a place to question pharmaceutical companies, share good practice across the sector and train individuals to work as patient advocates on matters of treatment, NHS structures and funding.

16. UKCAB acts as a community sector hub for organisations such as the MRC, BHIVA and NHIVNA[18] to identify suitable community or patient representatives for trial steering groups, clinical guideline writing groups and other formal committees. Although I left the steering group in 2010, I remain involved with UKCAB and have done research for them on the impact of the community reps and guidelines for reps on clinical guideline writing groups. I have provided training at their residential weekends for developing activists.[19] In addition, I have frequently given presentations to UKCAB meetings on topics ranging from NHS funding streams to the history of HIV and hepatitis C co-infection.

17. In many ways the rationale for UKCAB captures the way that I have always felt about what is important to drive treatment progress - a networked, collaborative approach that brings together different affected groups, working towards achieving the best outcome.

Birchgrove

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[17] GRO-A GRO-A GRO-A and GRO-A all played a major part in the development of UKCAB.

[18] Medical Research Council, British HIV Association, National HIV Nurses Association, respectively.

[19] The research was presented at BHIVA and NHIVNA conferences with the abstract here; Kwardem, L, James, R and Shepherd, J (2018) 'What is the impact of having UK-CAB representatives on guideline writing committees and academic/clinical research study boards' HIV Medicine, 19 (Suppl. 2), s21–s15. Available online: https://onlinelibrary.wiley.com/toc/14681293/2017/18/S1
I have provided training on patient involvement in the NHS systems and research methods.

18. A significant part of my campaigning history in the field of haemophilia, is my involvement with the national Birchgrove group - and a local group called Birchgrove South East,[20] with Cady Khudabux.[21] I first got involved with Birchgrove in the late 1980s - possibly 1987 – when it was only based in South Wales. A haemophilia nurse at Morriston Hospital, Swansea passed on their details to me and I attended some meetings and a residential weekend with them in Torquay. I became friends with Paul Jenkins and Gareth Lewis who were then running the organisation. I remained friends with Paul until he died and also got to know the other committee members, including Paul K GRO-A, Mike O'Driscoll, GRO-A GRO-A and Martin Price.[22] I became chair of Birchgrove and as chair of the national group, spoke when we unveiled the stone on the opening day at the Birchgrove wood in Swindon.

19. The main activities of Birchgrove were to provide peer support and disseminate information to people with HIV, HCV and haemophilia, on those co-infections. The organisation initially raised its own funds to provide for residential support. We later received funding to employ some support workers in Wales and to produce a free quarterly newsletter. Later when the Macfarlane Trust (MFT) changed their policy and decided that residential support weekends were within its funding remit, Birchgrove discontinued running the residential support events and instead supported the organisation of them.

20. Birchgrove also commissioned reports on the provision of support to people and the families of people with haemophilia and HIV.[23] Birchgrove lobbied the Haemophilia Society to change its campaign strategy to agitate for

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[20] After Birchgrove in South Wales had a weekend in London, we met people who were trying to set up a support group for those with haemophilia and HIV. I, along with others who had moved to Hertfordshire, formed Birchgrove South East. After a conference that invited people from across the UK, many decided to continue meeting locally often. The group thereafter took the name Birchgrove.

[21] Cady Khudabux had haemophilia, HIV and HCV and was an active campaigner within the Haemophilia Society, and from his own hospital, for the provision of support for the people infected with HIV and HCV. He was a bio-chemist by background. Cady was also a member of the national Birchgrove committee.

[22] All these men and I were members of the national Birchgrove management committee at various points during my involvement. Cady Khudabux, Paul Jenkins, Paul K GRO-A and Gareth Lewis have all since died.

[23] See for example [GRO-D] (1995) *Keeping it in the Family – Access to information and service provision. Findings from a study on behalf of the Birchgrove Group and the Haemophilia Society* (HSOC0005046) '*HIV and the Family'* by Debbie Khudabux. Debbie Khudabux was the wife of Cady Khudabux. She died GRO-A in 1999.

compensation for everyone with hepatitis C and not to exclude those living with HIV. As an illustration of the blind spot in awareness at the Haemophilia Society at the time, I recall a conversation with the then chairman of the Haemophilia Society, Chris Hodgson, who informed me that the Society was campaigning for compensation for the widows of those men with HIV who had died of liver failure and liver cancer but excluding from compensation those still alive and who were co-infected with HIV and HCV. Because HIV accelerates the progression of hepatitis C, the vast majority of the men who had died from cirrhosis and liver cancer at this point had had HIV. Eventually, when the Skipton Fund was set up in 2003, it included everyone with hepatitis C infected through blood or blood products regardless of whether or not they had HIV. However, initially the Skipton Fund excluded the widows of anyone who had died before the 29th August 2003. The fund's initial exclusion will have predominately excluded the bereaved families of those with HIV and HCV because of the faster progression to cirrhosis and death that HIV generates.

IV. Committees and/or Working groups

H-CAB and EATG

21. I have been involved with two international groups that work to promote drug development in hepatitis: H-CAB and EATG. H-CAB was a joint North American and European group of treatment activists. EATG is a European and Central Asian group of HIV treatment activists that does some work in the fields of viral hepatitis and TB.[24] Both these groups have a specific interest in reducing the time before availability of newer drugs for HCV. They especially want to ensure inclusion in the groups of people most likely to need the treatment[25] at the start of new drug trials in order to reduce the numbers of deaths.

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[24] EATG covers the WHO Europe region that includes all of Europe, Turkey and the central Asian states that became independent from the Soviet Union. As people with HIV in this region have a high rate of viral hepatitis and TB coinfection the group also works in those areas.

[25] These groups vary between conditions but with hepatitis C, they would be those that are likely to progress and die more quickly, including those with HIV or hepatitis B coinfection, as well as people with cirrhosis. With HCV, existing drug users were often excluded on moral grounds, in situations where there was no scientific basis to exclude them.

22. H-CAB was initially a group of about 10 US and European treatment activists, who met with pharmaceutical companies to lobby, challenge and promote drug development in hepatitis C (mainly the Direct Acting Antivirals or DAAs). The group was coordinated by Tracy Swan from the Treatment Action Group (TAG) in New York. I was a part of this group from 2007-2013.

23. The EATG brings together activists in the WHO Europe region with an aim "*to achieve the fastest possible access to state-of-the-art medical products, devices and diagnostic tests that prevent or treat HIV and improve the quality of life of people living with or who are at risk of HIV/AIDS*" and with its main focus being on "*treatment literacy and treatment advocacy*"[26]. It works closely with the European Medicines Agency within the EU and sponsors a treatment literacy and advocacy programme across Europe and Central Asia, called STEP-UP. EATG also lobbies pharmaceutical companies about access to medicines in countries, trial design and pipeline research. EATG held an annual hepatitis meeting in Sitges, Spain, to try and pressure pharmaceutical companies into changing trial protocols and widening access. I was regularly invited because of my hepatitis expertise and was formally invited to become a member of EATG in 2014.

24. The standard approach to running clinical trials in new drugs is to test them in healthy people for toxicity, establish the appropriate dosage in a small number of people with the condition and then finally, execute larger scale trials in order to demonstrate drug efficacy. Even in the final efficacy phase, there are exclusion criteria which very often excludes the people who most need the treatment.[27] In other instances, there are practices that serve to exclude people indirectly. For example, some trials for hepatitis drugs initially insisted on biopsies for people who were to take part. This effectively ruled out people with haemophilia.[28] The consequence of this exclusion was that trials for treatment in people who desperately needed what the new drugs had to offer, often would

[26] http://www.eatg.org/about-us/

[27] The justification for this has usually been around safety - ensuring a drug is safe in people with the condition, who are otherwise as healthy as possible, before trying it in those for whom there are greater risk of problems with the treatment. What it inevitably does is provide the best chance of boosting the success rate of a medicine for a company.

[28] There is increased bleeding for anyone having a biopsy and they were not recommended for people with haemophilia after a recorded death. Later trans-jugular biopsies were possible that lowered the risk of bleeding and then non-invasive methods such as fibroscans.

only come years after the initial trials in people less sick or with fewer complications. In addition, the knowledge about the efficacy of treatment in the people who are the most difficult to treat is not known because they were not part of the trial. It becomes complex to calculate the interaction with other medications –instead, there is reversion to guesswork and assumption.

25. When the DAAs first appeared, it was the patients with cirrhosis that were most in need of these new treatments. The relevance of this to the inquiry is that by this time, those infected through blood products would already have had HCV for at least 25 years and so many had progressed to cirrhosis, or were likely to soon; some were co-infected with chronic HBV; and many were co-infected with HIV that accelerates HCV disease. The notion of working with treatment activists in HIV and hepatitis to accelerate the availability of drugs to these people promised a major impact on the treatment prospects of people infected through blood and blood products.

26. People with HIV had been excluded from the original trials with pegylated interferon and ribavirin.[29] It took another 2-3 years before there were trials of people with HIV and HCV with pegylated interferon and ribavirin.[30] This meant that the knowledge was always a few years behind in terms of efficacy, side effects and drug-drug interactions. It precluded the development of a good evidence base for treatment guidelines.

27. By 2013 there was also a collection of new DAAs[31] that were being trialled by a number of pharmaceutical companies. It was important to know which, if any, DAAs were contra-indicated for specific HIV medications. Since both of these treatments needed combinations of drugs rather than single drugs, this added to the complexity. It was also very clear that these drugs would be over-priced

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[29] Manns M.P., McHutchinson J.G., Gordon S.C., Rustgi V.K., Shiffman M., Reindollar R., et al. (2001) Peginterferon alfa-2b plus ribavirin compared to interferon alfa-2b plus ribavirin for the treatment of chronic hepatitis C: A randomised trial. Lancet 358: 958–965 [WITN1004003]

[30] E.g. the Ribavic study; Carrat F, Bani-Sadr F, Pol S. *et al* Pegylated interferon alfa-2b versus standard interferon alfa-2b, plus ribavirin, for chronic hepatitis C in HIV-infected patients: a randomized controlled trial. JAMA. 2004;292(23):2839–2848 [WITN1004004]

[31] Although Boceprevir and Telaprevir can be classed as DAAs, they could only be used with pegylated interferon and the desire was for interferon-free treatments.

when they finally came on the market and so trials presented an opportunity for people to get access to new drugs at no cost to the NHS.[32]

28. H-CAB and EATG wanted to avoid these issues with the DAAs when they were being developed by companies. If people with HIV, or those with compensated cirrhosis, are included as sub-populations within the original efficacy trial of a new drug, not only do we start with much better knowledge on how to treat those who most need the medicine, but it also encourages pharmaceutical companies to do drug-drug interaction studies prior to the trial.[33] This means that clinicians are able to know what works for those likely to die soon from cirrhosis and what HIV medications should be avoided or dose adjusted where in combination with a new drug, as soon as that drug comes to market and not 2-3 years later.

29. Working alongside the clinical organisations, these two groups were broadly successful in accelerating the time before trial data was available about DAAs in people with cirrhosis and those co-infected with HIV. The issues remain though with any new treatment coming through, as companies and regulators can easily slide back into old habits. I am still a member in EATG and regularly chair their viral hepatitis meetings and review trial protocols. I have provided training to members on research methodologies.

Health Technology Assessments

30. I have been involved in a number of Health Technology Assessments (HTAs) for hepatitis C treatments.[34] The first was as a Haemophilia Society representative for the assessment of pegylated interferon and ribavirin. This had a general and a personal focus for me. The general aspect was to push for approval of the treatment so it would be available on the NHS for everyone with HCV. The personal aspect was to try and increase availability of the treatment for those with HIV co-infection and also, to promote a change in the

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[32] This inevitably comes with some risk as it is not clear the drug will be an improvement on the current standard of care. It was clear that DAAs were going to be more effective than pegylated interferon.

[33] This involves blood level monitoring of a person without the condition, taking two or more medications. This is even more complex for people with cirrhosis if the drug is absorbed through the liver.

[34] 'Hepatitis C - alpha interferon and ribavirin' NICE Technology Appraisal Guidance No. 14, issued in October 2000 [WITN1004005].

guidelines about treatment duration for rarer genotypes. As it turned out, I had one of these rare types, with HCV genotype 5.[35]

31. An indication of the rarity of genotype 5 is that in communication with spokespeople in the UK from the two companies that made pegylated interferon and ribavirin,[36] neither could find any data on anyone with genotype 5 who had been treated in Europe.[37] None of the consultants I contacted in the UK had ever treated a person with genotype 5 - and in a US cohort study with over 3,500 people with HCV, only one person had genotype 5.

32. Historically, the treatment interferon, both standard and pegylated, had been tried in 24 and 48-week durations. The 48 weeks of treatment cost twice as much as the 24 weeks. Naturally, a funder would opt for the shorter treatment, if possible. 24 weeks was the recommended treatment duration for people with genotypes 2 or 3; and 48 weeks treatment for people with genotype 1. The rarer genotypes in the Western Europe and the US – genotypes 4, 5 and 6 - had no specific treatment duration assigned to them. Genotypes 5 and 6 had no trial data about duration at all. There was growing evidence that genotype 4 needed 48 weeks of treatment rather than 24 at this point, but this evidence was derived from small cohorts. The recommendations in British guidelines at this point said, "Patients infected with non-HCV 1 (mostly genotype 2 or 3) should be treated for 6 months irrespective of the level of viraemia".[38] On the basis of little or no data, genotypes 4, 5 and 6 were therefore put together with genotypes 2 and 3, which had data supporting 24 weeks. Those clinicians following the research would opt for 48 weeks for genotype 4, particularly if there was high viraemia, because of this cohort data. Many of the clinicians

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[35] A higher than expected proportion of genotypes rare in Europe have always been found in people with haemophilia in this country, e.g. Preston et al (1995) Heterogeneity of hepatitis C virus genotypes in haemophilia: relationship with chronic liver disease, *Blood* Mar 1; 85(5):1259-62. Available online [here].

[36] This was usually the medical director for hepatology from Roche and Scherring-Plough (now part of Merck and Co).

[37] Roche were in the process of completing a study of a thousand people comparing 24 and 48 weeks and their medical manager, Colin Hayward, sent me details of the 7 people with genotype 5 treated in the trial. It came a month after my PCT decided on my treatment duration.

[38] Clinical guidelines on the management of hepatitis C, RCP and BSG (2001), p3. Available online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1766890/pdf/v049p000I1.pdf

recommended to NICE that their guidelines should have a recommendation of 48 weeks treatment for genotype 4.

33. I lobbied for a reversal of the way the British guidelines was written, to read that genotypes 2 and 3 can be treated for 24 weeks while all other genotypes should be treated for 48 weeks. This would have been consistent with the way the Canadian treatment guidelines were written[39] - and would have brought in as a precautionary principle that genotypes 5 and 6 would have a default of a 48-week treatment until further data was available.

34. Pegylated interferon was approved for HCV monotherapy.[40] The price was below the cost-effectiveness threshold NICE used. My own lobbying was successful: only partially at first, but over time in full. Initially 48-week treatment was accepted for genotype 4 and treatment for people with HIV and HCV co-infection was recommended for research. No recommendation was made for genotype 5 and 6 because of the lack of evidence, although it was no longer implied as only needing 24 weeks. However, in the 2004 update,[41] treatment for HIV co-infection was recommended without any need for research and in the 2006 update, treatment duration for genotypes 5 and 6 was specified as 48 weeks.[42]

35. I started pegylated interferon at the end of 2001 and lobbied my Primary Care Trust (PCT)[43] for them to pay for 48 weeks of treatment rather than 24. To support my lobbying for 48 weeks of treatment, I wrote a document bringing together the current treatment knowledge for genotype 5. I produced this from the recommendations of hepatologists, infectious disease specialists and

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[39] See CASL, (1999), "Report from The Canadian Consensus Conference On The Management Of Viral Hepatitis", Canada, CASL. Available online: https://www.hindawi.com/journals/cjgh/2000/309605/

[40] The results of Manns' study, noted above, had already been presented at conferences before publication of the paper allowing for NICE to approve on the basis of a number of trials. No large-scale trials had been done for people with co-infection and so it was approved for research, I believe.

[41] Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C: Technology appraisal guidance [TA75] Published date: 28 January 2004. See paragraph 2.22 available here https://www.nice.org.uk/guidance/ta75/chapter/2-Clinical-need-and-practice

[42] Peginterferon alfa and ribavirin for the treatment of mild chronic hepatitis C: Technology appraisal guidance [TA106] Published date: 23 August 2006. See paragraph 3.5 available at https://www.nice.org.uk/guidance/ta106/chapter/3-The-technology

[43] The NHS commissioning body at the time.

virologists in the UK and South Africa. At the time, the only place where genotype 5 was known to be prevalent in significant numbers was in South Africa. Nothing had been published on this genotype. I received helpful information from Professor Song at a medical school in Witwatersrand, Johannesburg, who had treated 12 patients. The material helped me in successfully lobbying my PCT to pay for the extended treatment.[44]

36. I was successful with my PCT agreeing to fund the 48 weeks of treatment. However, the drugs were only partially successful as they got rid of genotype 5 but left me with genotype 2. This outcome from multiple genotypes was so unusual that I co-authored a paper on it[45] with my treating consultants and a microbiologist for the Journal of Virology.

37. Through my membership of the BHIVA Hepatitis Society committee, I was involved in 7 or 8[46] of the HTAs concerning DAAs, attending a number of meetings in Manchester and responding to documents as each combination went through the HTA process. These processes were very different to that for pegylated interferon and ribavirin because of the pressure put on NICE by NHS England. Initially, even when Sofosbuvir was being proposed in conjunction with pegylated interferon and ribavirin, the exorbitant price of Sofosbuvir[47] meant that they had understandable concerns about the affordability of this treatment. However, the tactics and continued undermining of the NICE appraisal system were a constant battle.

38. A number of approaches were used by NHS England to delay the availability of and reduce access to DAAs for patients, including requiring areas to set up a new and unnecessary system for prescribing DAAs, called Operational Delivery Networks (ODNs); lobbying that they only be approved for research purposes; extending the time between NICE approval and the date from which Sofosbuvir had to be available on the NHS; and then the explicit rationing of the number of

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[44] Personal email correspondence, the final document sent to my PCT is available on request.
[45] Buckton AJ, Kulasegaram R, Ngui SL, Fisher M, James R, Rangarajan S, Teo CG (2007) 'Selection and persistence of occult minority genotype 2b hepatitis C infection in a patient treated with 48 weeks of pegylated interferon alpha-2b and ribavirin for genotype 5a' *Journal of Clinical Virology*, 40 (1), 60-63 [WITN1004006]
[46] I cannot remember if there was an HTA for Telaprevir and Boceprevir. I was involved in the HTAs for Sofosbuvir, Simeprevir, Daclatasvir, Sofosbuvir and Ledipasvir, Sofosbuvir with Velpatasvir and Voxilaprevir, elbasvir and grazoprevir, paritaprevir and ombitasvir, etc
[47] The list price Sovaldi, the brand name for Sofosbuvir, was $1,000 per tablet in the US.

people who could be prescribed DAAs through the use of *run rates*. There was also a preference for the use of the slightly less expensive combinations with greater side effects and the complete unavailability of some combinations that were approved for use in Scotland. England and Scotland had different availability of DAAs for people with HCV, leading to the prescribing of different combinations for some genotypes between the two countries.

39. There are 90 days after NICE approval for a treatment to be made available to patients by the NHS in England. Extensions to the 90-day period are permitted[48] if "*certain health service infrastructure requirements including goods, materials or other facilities*" are not currently in place. NHS England claimed that prescribing Sofosbuvir required a new infrastructure. No extra facilities were needed for prescribing Sofosbuvir that were not available in liver clinics. The prescribing of a DAA combination actually required less infrastructure than the prescribing of interferon. DAAs do not need patients to learn to give their own subcutaneous injections. Less nursing support is needed around medication problems because of no injection site reactions and fewer side-effects. The BASL (British Association for the Study of the Liver), BHIVA and particularly the BSG (British Society of Gastroenterologists) all responded to NICE about this claim. They disputed the assertion by NHS England that there was a need for a new prescribing network.[49] Despite no clinical body seeing the need for a new network, the need to set up ODNs was accepted as a justification for a delay in the availability of DAAs in England through the NHS. On top of the delay this also required clinicians from a number of hospitals in a particular geographical area to come together to set up their ODN, building in more delay. These ODNs became the only route to access this treatment on the NHS as the cost would not be covered for any other prescriber.[50]
40. During the HTA for Sofosbuvir, when it was to be used with pegylated interferon and ribavirin, NHS England asked for an extension, of an extra 90 days, before

[48] See s.7(5ii) The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013
[49] These letters by BASL, BHIVA and BSG are all in the NICE approval documents folder. Available online: https://www.nice.org.uk/guidance/ta330/documents/committee-papers
[50] It was possible to buy Sofosbuvir, Ledipasvir and Daclatasvir online from India or China and a number of people did so. An Australian organisation was particularly helpful in facilitating this for people in the UK.

it had to make it available. The BHIVA Hepatitis Society, along with the Hepatitis C Trust, BASL and the UKCAB lobbied NICE to refuse the extension request from NHS England. The Royal College of Physicians wrote to NICE criticising the constant delays to the process caused by NHS England holding up availability of Sofosbuvir to patients; and for NHS England's request for an extension of the time before implementation of the HTA from 90 to 180 days.[51] NICE added a 30-day extension. I believe this was the first time an extension had ever been granted by NICE.[52]

41. Up until this much delayed NICE approval, the only place Sofosbuvir was available in the NHS was through a compassionate access programme for people considered within 6 months of death. This was not a lot of people in comparison to the number with HCV treated elsewhere. In an email exchange of the EATG Hepatitis steering Group in July 2015, I highlighted that NHS England had provided DAAs to the same number of people with hepatitis C as had the Greek health service, a country with a fifth the UK population and in the middle of massive financial cuts to its public sector.[53]

42. NHS England gave each ODN what was called a "*run rate*": or, the number of patients that could be treated each month. There would be no funding for the treatment of any more patients above this number; and if an ODN did not treat the specific number, the run rate would be reduced. This was explicit rationing

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[51] NICE accepted a delay but it was for 120 days.

[52] https://www.channel4.com/news/by/victoria-macdonald/blogs/nhs-england-accused-interfering-approval-hep-drug

[53] Personal communication 16 July 2015. Extract from my email below, the friend mentioned is a core participant of the inquiry.

"*Currently none of the DAAs are available to people with HCV in England unless they have been diagnosed with cirrhosis - and we have only just expanded that from 'likely to die in the next six months' to people with cirrhosis - Sof, Lep, Dac and Sim available on the scheme. So far 600 people have got them - the same number Christina said had had treatment in Greece.*

Only Sof is approved by NICE as cost-effective, and only with IFN and Rib, but under an exceptional circumstances clause, that I think has never been used before, they have allowed NHS England to extend the time before it is available.

All the other DAAs (Dac, Sim, Lepi, Ombi+++,) are in the process of being assessed for cost-effectiveness and so not available in England. The decision about them has also been delayed as NHS England says it cannot afford them.

As of today, I am not able to access any DAAs in England for my HCV. A friend has an appt on August 1st as that is the current date NHS England have said Sof will be available but they said July 1st before."

and undermined the purpose of NICE, which had been set up to approve or disapprove medicines for the whole NHS. In addition, it was in contradiction to the NHS constitution. The NHS Constitution includes a right to "*drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you*". A judicial review[54] by the Hepatitis C Trust on the rationing system in 2016 was refused.[55]

43. In further "Joint Technology Appraisals" of DAAs,[56] NHS England strongly opposed approval, proposing treatment only be "*recommended with research*" when further research was not necessary on these medicines to demonstrate efficacy. NHS England claimed the approval of DAAs would significantly reduce funding for all other specialised services; asked that NICE change and alter its processes because of this cost,[57] and then just ration the availability of all DAAs through the "run rate" system described above. This continued until April 2019 when DAAs were made available under a tendering process that had been suggested by me, the chief executive of the Hepatitis C Trust and clinicians at the original HTA meetings with NHS England - and had been done for the purchasing of Factor 8 concentrates for over a decade.[58]

44. All this delayed the availability of NICE approved treatment to a number of people with severely damaged livers. Although this rationing covered everyone with HCV, it will have had a specific impact on those infected through blood and blood products because of the high numbers who had been infected for many years and so were likely to have greater liver damage. People with haemophilia and some of the other long-term conditions treated with blood or blood products in England would generally have been in touch with hospitals because of their other condition, and so been left in the position of waiting for a treatment until the rationing process criteria reached the level of liver damage they had.

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[54] See https://www.theguardian.com/society/2016/jul/28/nhs-abandoning-thousands-by-rationing-hepatitis-c-drugs

[55] http://www.hepctrust.org.uk/blog/oct-2016/hepatitis-c-trust-ends-its-legal-challenge

[56] NICE joined the Technology Appraisals for sofosbuvir/ledipasvir, daclatasvir, parateprávir/r, ombitasvir and dasabuvir.

[57] See WITN1004007 to WITN1004013. Note that WITN1004013 is an email from an internal BHIVA Hepatitis Group discussion.

[58] See https://www.england.nhs.uk/2019/04/nhs-england-strikes-world-leading-deal-to-help-eliminate-hepatitis-c/ for details of the HCV agreement.

V. 'Living Stories'

45. Sian Edwards and I created the HIV and haemophilia life history projects. I had known Sian since 1989 and had spoken as a patient in the nurse training courses on HIV that she ran at the Nightingale School of Nursing in London. She then worked for a period of time at St Thomas' Haemophilia Centre. Through talking, we both felt the story of those with haemophilia and HIV had been an extraordinary piece of history that should be recorded. The death of my friend, Cady Khudabux, before the project, also inspired me to record these stories before everyone who could bear witness had died. She and I put together a steering group and obtained funding for the project. We set up a support system for people after interviews; arranged for the British Library to store the recordings in the National Sound Archive; undertook oral history training, and then collected the life stories of the participants. We advertised the project through Birchgrove, the Macfarlane Trust and the Haemophilia Society in order to find people prepared to provide their stories.
46. Having completed this project - and recognising the need to record the stories of the families, particularly the bereaved families - we acquired a second round of funding, and undertook the HIV in the family project. In the first project, I interviewed people, edited transcripts, and prepped recordings for storage in the British Library and for the second, I managed the documentation, budget and preparation of recordings for storage.
47. This project ensured the story of people's infections and the families' stories will be available for future generations to hear in the words of the people who lived it. The project was successful because of the powerful impact that it had on those who took part. It ensured that stories were stored for posterity and available for those interested. Importantly, it allows the voices of the dead to be heard in this Inquiry.
48. I use the 'Living History' material when teaching on the haemophilia nurse training,[59] to provide an understanding of our patient history to newly appointed haemophilia nurses. I have presented findings at the 27th World Federation of

[59] This is the Essentials of Haemophilia Care; a post-qualifying Continuing Professional Development course that provides specialist training for nurses working in haemophilia centres.

Haemophilia Congress in Vancouver,[60] as well as at some Macfarlane Trusts weekends and Haemophilia Society events.

VI. Individual campaigning

Bad treatment and care practices

49. After a residential weekend organised by Birchgrove and the Haemophilia Society - which was pitched at young people with haemophilia and HIV and their partners and held in 1999 in Brighton - I became aware of a small number of people receiving inadequate treatment for their HIV. These haemophiliacs were being treated for their HIV at the Haemophilia Centre at St Thomas', by a haemophilia consultant, who was in charge of their care and treatment.
50. I understood the treatment they were receiving at that time - AZT monotherapy - was not merely inadequate. Because of the inevitable resistance HIV would develop against the drug, rendering it useless and removing an option in combinations, it was also an unethical treatment for people with HIV. BHIVA treatment guidelines in 1998 accepted only combinations of 3 drugs should be used for HIV treatment. [61] This consensus statement from the previous year does not even mention AZT monotherapy as an option; and even the use of 2 drugs was not seen as an effective regime. There had been major controversies about the 1997 guidelines, one part of which was on this very issue. The reasons included the failure to involve people with HIV in the guideline writing process, appearing equivocal about dual or triple therapy and not obviously ruling out the use of AZT monotherapy. These issues had already caused significant disagreement within the writing committee prior to publication. Treatment activists had disrupted the British HIV Annual Conference following this and recommended patients not use clinicians following these guidelines.[62]

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[60] May 21-25, 2006, see https://www.wfh.org/congress/en/about/wfh-world-congress for a history of this international conference.

[61] The statement says, "*An initial combination of two nucleoside analogues is no longer considered a reasonable standard of care and therefore should only be considered in very exceptional circumstances.*". See p315, Gazzard, B., & Graeme, G. (1998). 1998 revision to the British HIV Association guidelines for antiretroviral treatment of HIV seropositive individuals. *Lancet, 352(9124), 314–316.* doi:10.1016/s0140-6736(98)04084-7 (HSOC0019290).

51. The 1998 BHIVA guideline statement which altered the position so as to clearly support triple therapy - and which did not even mention monotherapy as an option - was notable for including two treatment activists on its writing group. It would have been unusual for someone working in the HIV clinical field not to be aware of the issues around these 1997 guidelines and the 1998 update. This treatment provision, being made by a clinician at the Haemophilia Centre, was happening one year after the guideline controversies and more than 2 years after the Vancouver World AIDS Conference[63] that demonstrated the markedly reduced death and hospital admissions with triple combination therapy.

52. I lobbied my own Haemophilia Centre regarding its out-of-date and unethical prescribing of HIV medications to people with haemophilia and HIV in 1999. I wrote to highlight this to the centre Director, GRO-D [64] The incident highlighted to me the inadequacy of clinicians (in this instance, haemophilia doctors) treating a condition (namely, HIV) that was not within their primary field of expertise.[65] This issue of failing to set up strong links and joint clinics between haemophilia and HIV in a number of centres was also highlighted in the 1995 report commissioned by Birchgrove and Haemophilia Society.[66] The problem was personally so depressing since there had been strong links and combined clinics with orthopaedic surgeons in most Haemophilia Centres for a number of years. This meant that the dual management of patients was not a new thing for haemophilia centre directors.

53. In other examples of individual campaigning, I wrote to my then MP, David Lepper, on a number of occasions between the start of 2001 to 2003 about the lack of availability of recombinant factor 8 in England. I received a number of replies from him and one enclosing a reply to his letter to Philip Hunt, then

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[63] See Kallings and McClure (2008) '20 Years of the International AIDS Society' page 28 available at https://www.iasociety.org/Web/WebContent/File/IAS_20yearsIAS_book.pdf

[64] See [WITN1004014] and [WITN1004015].

[65] There were a small number of haemophilia clinicians who did maintain current knowledge about HIV care or who passed on care to HIV specialists having appropriately acknowledged they no longer were able to manage HIV treatment. Has Dasani at Cardiff and Mark Winter in Canterbury are such examples.

[66] [GRO-D] (1995) *Keeping it in the Family – Access to information and service provision. Findings from a study on behalf of the Birchgrove Group and the Haemophilia Society* (HSOC0005046).

Minster of Health with responsibility for issues involving blood. When recombinant was finally made available to all it was only through a 3-year funding package. I also wrote letters concerning the end of the initial 3 years funding for recombinant in England contending that people should not be moved back to plasma derived factor VIII. I also took part in the consultations about the setting up of the Skipton Fund.

Haemophilia Society

54. I was in the HS project, "*Get Involved – Get the Best*", promoting the involvement of people with haemophilia in NHS systems, particularly Strategic Health Authorities.[67] I took part in a number of UKHCDO triennial audits of haemophilia centres as the patient member of the audit team for some centres from 2003.[68] These audits had been started by the UKHCDO to provide some peer review of the services at centres. Along with the Haemophilia Nurses Association, the Haemophilia Society lobbied to ensure that nurses and patients were involved in the developments of the audit tool and taking part in the audits.

55. I developed the first standard questions in the audit for the patient representatives to use. Although it was not universally adopted in the 2003 audit, the questions were included in the patient audit sheet drawn up by Sue Rocks and Keith Colthorpe for 2006. As a result of this, I was also asked to join the UKHCDO Audit Development Committee as a patient representative.[69] This committee further developed the audit tool.

User trustees

56. I lobbied both individually and as part of Birchgrove, for the re-introduction of *user trustees* within the Macfarlane Trust. This was ultimately successful, although it took until the year 2000 - many years after it was permitted by the Charity Commission. The stipulation was that user trustees were permitted, as long as individuals did not decide on their own applications. Other hardship

[67] These were created in the National Health Service Reform and Health Care Professions Act 2002 and abolished in the Health and Social Care Act 2012.
[68] I know I took part in the 2003 and 2006 audit round but I cannot remember if I also took part in previous audits.
[69] I believe this was 2009 or 2010 but it may have been later. I left the committee in 2012.

funds such as that managed by THT, the Cruisaid's hardship fund, had already instituted user trustees.[70] The Macfarlane Trust only agreed to this when the trustees received specific confirmation in writing from the Charity Commission, even though it was permitted under general Charity Commission guidelines. This appeared to me to be another sign of the reluctance of these organisations to expose themselves to criticism.

Media Advocacy

57. I took part in the original media campaign for compensation for HIV infection through blood products and I have appeared in a number of parts of the media. I have also done more general media work in highlighting awareness of HIV and highlighting the fact that there are still people with haemophilia and HIV living. This has included interviews for a wide variety of audiences including Bella Magazine in 1990, the BBC on not forgetting about people with haemophilia for World AIDS Day in 2003 and Buzzfeed in 2016 about life after having not died with AIDS.[71]

VII. Conclusion

58. I had no expectation my life would be so taken up by the issues of risk, death and viruses when I was a child. The experience of my own infections, the prejudice meted out to those of us infected, and the irrational restriction on the rights of people with these viruses, regardless of how they were infected, was not something I could ignore. My campaigning both in the haemophilia world and the wider HIV and hepatitis sectors came from a refusal to accept these inequalities and a belief that society could be made more just.
59. Although I have not been involved in any formal campaigning about infections in blood products for many years, I still passionately want to know the details of how these infections occurred and how decisions were reached. I also see the Inquiry as a perfect opportunity to produce recommendations on how to

[70] Cruisaid merged into the Terrence Higgins Trust in 2012 which then took over the management of this hardship fund for people with HIV. See https://www.tht.org.uk/our-work/about-our-charity/our-history/2010s
[71] See http://news.bbc.co.uk/1/hi/health/3251822.stm and https://www.buzzfeed.com/patrickstrudwick/this-is-what-its-like-to-be-dying-of-aids-and-then-survive

manage situations where an expensive and easy to manage treatment puts patients at risk. I also see my efforts as a way to get past unsound responses from political decision-makers, withstand pressure from pharmaceutical companies and overcome organisational inertia in government departments on decisions concerning health risks. For these reasons I am happy to assist the inquiry in any way I can.

Statement of Truth

I believe that the facts stated in this written statement are true.

Signed GRO-C

Dated 06 November 2020