Witness Name: Professor Graham R Foster

Statement No.: WITN3042004

Exhibits: WITN3042005

Dated: 28 September 2022___

GRO-C

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR GRAHAM FOSTER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 April 2021.

I, Professor Graham Foster, will say as follows:-

Section 1: Introduction

1. I am Professor Graham Russell Foster (dob GRO-C 1959). My address is known to the Inquiry. I trained in medicine in Oxford (BA - 1980) and London (MB BS-1983) and was awarded a PhD in London in 1989. I am a fellow of the Royal College of Physicians.

2. I make this statement to respond to the questions raised by the Infected Blood Inquiry (IBI) to me via a Rule 9 request dated 31 August 2022 (also sent to NHS England).

3. In producing this statement, I have sought some information from NHS England's Mark Gillyon-Powell, Head of Programme for HCV Elimination.

Question 2 - Please describe, in broad terms, your role and responsibilities as both NHS England's National Clinical Lead for Hepatitis C, and as National Clinical Chair for NHS England's Hepatitis C Elimination Programme

4. I was chairman of the Hepatobiliary clinical reference group from 2016 to 2022 and served as a member of the committee for the preceding 6 years. When the launch

of the all oral antiviral therapies for hepatitis C was imminent (2014), as the CRG member with expertise in viral hepatitis I approached NHS England (Mr J. Palmer and Mr M. Qualie) along with my colleague Dr Peter Moss (then chairman of the infectious disease clinical reference group) with a proposal to set up an early access program for people with advanced disease. These proposals were accepted and in collaboration with the pharmaceutical industry a program of therapy for people at high risk of dying from hepatitis C was launched using a network of treatment providers. When the all oral treatments for hepatitis C were licensed and NICE guidance relating to therapy was issued I worked with colleagues to establish a network of treatment providers and was later appointed clinical lead for the hepatitis C elimination program. As clinical lead for the program I am responsible for providing advice and guidance on all clinical issues relating to the program.

Question 3 - Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

5. I was president of the British Association for the study of the liver (2012-2014) and the founding chairman of the British Viral Hepatitis Group (2010 -2012) and I served as a trustee to The Hepatitis C Trust from 2015-2016.

Question 4 - Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.

6. I have not been involved in any previous investigations into transmission of blood borne pathogens in the United Kingdom but I responded to an allegation from a patient given to this enquiry. I have provided medical opinions and presented evidence to the Irish Hepatitis C Tribunal which examines issues around hepatitis C infection caused by transfusion of infected blood or blood products in Ireland.

Section 2: Work on identifying those infected with hepatitis C through blood and blood products

Question 5 – Please describe the contribution of the NHS England Hepatitis C Elimination Programme to identifying and treating people infected through blood and blood products

7. The hepatitis C elimination program has been funded by NHS England. As part of the funding arrangements and following a procurement process the three pharmaceutical companies who sell drugs for the treatment of hepatitis C have a contractual obligation to provide antiviral therapy at a fixed price and to invest in 'elimination initiatives' that synergise with the NHSE program. This program aims to harness the skills of the pharmaceutical industry in eliminating hepatitis C and has led to innovative work streams. As part of the elimination tender process the

pharmaceutical companies were obliged to provide programs of support that assisted case-finding in all populations at risk of infection, including those infected by contaminated blood. The proposals were modified by mutual discussion to generate an elimination program of unique breadth and scope. One of the proposals, from MSD, involved a 'primary care search tool' to identify patients with coded risk factors for hepatitis C infection (see later).

8. The NHSE Hepatitis C Elimination program has proceeded in three phases. The first phase began with the licensing of all oral therapies and was introduced, prior to NICE assessment of the medications, to ensure immediate access to therapy for all patients at imminent risk of death or life-threatening complications. At this stage operational delivery networks (ODNs) were established to provide clinician led treatment services throughout England and networks were obliged to provide regular multi-disciplinary meetings where patients with hepatitis C could be discussed by an experienced clinical team and appropriate management decisions taken. Access to treatment was soon extended beyond patients at imminent risk of death to include all patients with advanced disease (cirrhosis) and those at imminent risk of harm. NHSE encouraged clinicians to assess and prioritise patients according to their perceived risk of physical and mental harm. We recognised that psychological harm was a not uncommon complication of infection and therefore encouraged treatment prioritisation for those suffering in this way as well as those with the non-hepatic manifestations of infection, such as fatigue. Many patients infected by blood or blood products received therapy during this phase in line with NHSE's aim of prioritising treatment for those most in need.

9. The second phase of the NHSE elimination program focussed on those at risk of transmitting the infection to others and involved establishing out-reach treatment services for people whose life-styles made hospital-based services unattractive. Treatment services were established in addiction centres, community homeless programs and other centres frequented by the vulnerable and the socially disadvantaged. A wide variety of organisations joined the program to ensure that the most vulnerable in our society were able to access therapy and avoid transmission to others. Included in the second phase of our elimination program were patients known to services (e.g. patients attending clinics for people with haemophilia, those on haemodialysis and those with HIV infection) that included a large proportion infected by blood or blood products.

10. During the second phase of the elimination program, NHSE introduced an initiative to identify and offer testing/treatment to people with hepatitis C who had been previously tested but had no reported treatment outcome. This involved a review of all hepatitis C positive tests reported to UKHSA (formerly PHE) followed by attempts to contact these individuals. Details of all known hepatitis C positive individuals on the PHE database were distributed to the hepatitis C operational delivery networks and the networks were asked to contact each patient and arrange appropriate further management including testing and treatment. This 'lookback exercise' has now been completed.

11. The third phase of the NHSE elimination program involves identification of people at risk of infection who have not been tested. This is likely to include some people

in receipt of blood and blood products who are no longer in contact with services and have not previously been tested although the size of this cohort is unknown. This phase is currently on-going. We have introduced initiatives to promote testing in primary care for those at risk (talks and articles in primary care journals), developed a case-finding search tool, initiated research to identify the prevalence of infection in those who would not have been identified using our 'case-finding search tool' and developed an on-line testing portal that can be widely advertised to allow people to access testing without any contact with other health services. To provide further insights into the remaining populations at risk of hepatitis C we have introduced testing in emergency departments where all those attending who have blood tests are tested for blood borne viruses and we are conducting a program in Liverpool that will test 'surplus blood samples' taken for other clinical reasons. These initiatives will provide detailed information on groups at risk of hepatitis C who have not been identified by other means. All treated patients must be entered onto the treatment registry; this is mandatory and there are financial penalties for failure to complete it. The registry includes a field describing the source of infection so this data is recorded for all treated patients.

12. The case-finding support tool is now at an advanced stage of development and has undergone a number of evaluations, with results and a deployment plan anticipated later this year. The aim of these evaluations is to define the proportion of people with hepatitis C who have a risk factor coded on the general practice records so that we can stratify the risk of infection by risk factor. This will allow us to develop a targeted testing approach with the most intensive testing approaches being reserved for those at greatest risk and less intense approaches being used for those at lower risk. To refine and identify the most effective deployment strategy for the search tool we have begun to assess the sensitivity and specificity of the tool and develop an approach to test all of those at risk. We envisage that we will adopt three different approaches to testing patients. Those at very high risk (we anticipate that this will include those with a history of a positive hepatitis C test and a history of receipt of blood or blood products), those at medium risk (probably those with two or more modest risk factors) and those at low risk (probably those with a single risk factor). We envisage that those in the high-risk group will be contacted directly by either the general practitioner or a member of the ODN, those in the medium risk group will be texted and advised to access the testing website and have a tag place on their medical records informing the GP of their 'need to test' status, and those at lower risk will be advised to visit the testing website. Once the sensitivity and specificity of the tool has been established we will work with colleagues in primary care to decide what threshold of detection should be used for each of the different testing methods. We have conducted a number of pilot studies using the patient search tool and this has shown a large number of people have risk factors for infection (~5% of a GPs practice) and, given this very large number of patients requiring testing we believe that some degree of stratification is required.

13. The patient search tool uses coded risk factors in GP records. The tool will include proxies for hepatitis C infection (for example ALT) but not transfusion. It is possible that a population at risk who do not have coded risk factors will exist and to assess this possibility we have commissioned the University of Bristol to assess the risk of hepatitis C in 100,000 people with no obvious risk factors. This program of work is

under way and will provide NHSE with information to inform the development of a further testing program. Once all of the data has been analysed and the results of the Bristol study are available, we will be able to determine whether further risk factors need to be included in the tool. All those who test positive will be offered antiviral therapy and, as noted above, mode of infection will be recorded on the treatment registry. We hope to have preliminary results by Q1 of next year and a publication should be available 6 months later.

14. NHSE does not currently have accurate information relating to the number of undiagnosed people who may have acquired hepatitis C from infected blood or blood products, nor do we have accurate information on the population at highest risk of undiagnosed blood product acquired infection. Basic information on age and gender distribution is unknown. The work that we are currently undertaking in primary care will begin to address these issues – specifically the assessment of people with a risk factor of 'blood or blood receipt' will identify the numbers currently coded in primary care, the assessment of people with other risk factors (such as abnormal liver function tests) will determine whether an at risk cohort can be identified by surrogate tests and the research at Bristol will determine whether people infected by blood products who have no evident risk factors are common in the population. Once this information is available NHSE will be in a position to determine what, if any, further steps are needed to address infection in people in receipt of blood or blood products.

Question 6 - In the published UKHSA report titled 'Hepatitis C in England 2022: Working to eliminate hepatitis C as a public health problem', a series of recommendations are presented with regard to public health stakeholders. How has this report influenced the Hepatitis C Elimination Programme? Have the recommendations been implemented and how so? If not, when are these planned to be implemented?

15. NHSE works closely with UKHSA to develop approaches to hepatitis C elimination based on the data from UKHSA taken in conjunction with NHSE data on the elimination program. The UKHSA report has influenced the elimination program and, where appropriate, the recommendations have been implemented.

Question 7 - Please outline the contribution of the pilot programme using Patient Search Identification (PSI) software, including whether the programme takes account of missing transfusion records and identifies other indications of transfusions and any collaboration with the other three nations.

16. The PSI tool has been discussed in detail in my response to question 5 at paragraphs 7 to 14.

Question 8 - A submission made by one of the Inquiry's core participant to the Inquiry is that there should be a high-profile, semi-targeted public education campaign to enable infected but undiagnosed people to identify themselves and come forward. Has the HCV elimination team considered this as part of their strategy? Would this be conducive to eliminating HCV in England?

17. The team have discussed at length a public health education campaign to identify those at risk of hepatitis C and discussions are continuing between NHS England, DHSC and UKHSA about the feasibility and scope of a national communication/public health education campaign. These meetings are held by colleagues at DHSC, and developed at NHSE's request. At this stage it is unclear to whom this campaign should be targeted and how patients should be directed to seek testing. The UKHSA data suggests that the vast majority of undiagnosed patients are those with a history of previous injecting drug use. These data are derived from modelling studies which use estimates of disease progression and past prevalence of injection drug use and the models have wide confidence intervals. It is therefore unclear whether a campaign to alert people at risk of infection should be targeted at 'past injection drug users' or another population (such as those in receipt of blood products). Given that the putative largest target population (those with a history of injection drug use) may be reluctant to seek testing from conventional health care services we have developed a web-based confidential testing portfolio (due to launch in Q4 2022) that will allow any public health campaign to direct people to a testing resource. As noted above NHSE is committed to a series of testing programs looking to identify sub-populations at risk of infection and once these data are available a decision will be made on the value and scope of a campaign.

Question 9 - Please set out your view as to how successful the elimination programme has been in identifying those infected with hepatitis C through blood and blood products

18. Data from the hepatitis C treatment registry indicates that 3,498 people with a risk factor of receipt of infected blood have been treated (5.3% of the total treated) (**WITN3042005**). Note that the registry collects data on 'people who acquired hepatitis C via non-occupational contact with blood in healthcare setting' which will include people infected by contaminated blood administered outside England. The attached figure indicates that the number and proportion of such individuals has reduced over the last few years which we believe indicates that the majority of such people have been treated. In the absence of accurate information describing the number of people in England who are alive and have hepatitis C infection as a result of receipt of blood and blood products it is not possible to say whether or not this represents an acceptable proportion of the population at risk. It is my personal opinion that we are likely to have treated the majority of this population but the studies outlined above will test this opinion.

Question 10 - Please set out what services, including testing and treatment, are offered to those identified via the elimination programme. What is the uptake of these services?

19. Services for people with hepatitis C are provided by the operational delivery networks who receive funding to provide all necessary support to those identified as infected. The support offered depends upon local circumstances but involves an assessment of liver fibrosis by a non-invasive modality and NHSE has provided a Fibroscan device to all of the hepatitis C networks to ensure that this assessment is universally available. All patients who are infected with hepatitis C are expected

to have their treatment needs discussed at a multi-disciplinary meeting which is attended by a clinician, pharmacist, nurse and virologist, all of whom must have experience in this area. Following discussion of the patient's needs antiviral therapy is made available in an appropriate format. This may involve attendance at the hospital, review in a community setting (e.g. an addiction service), therapy in a mobile unit (Mark Gillyon-Powell confirms that there are 14 treatment vans that have been funded by NHSE to promote community treatment and that there are further vans which are being commissioned, including some of those in partnership with the Cancer Programme) and, where appropriate, involves support from a peer trained and provided by The Hepatitis C Trust. The Hepatitis C Trust peers are provided to each network and all have lived experience of hepatitis C and provide support to patients at all stages of the treatment pathway.

Question 11 - Please set out any barriers there are to identifying those infected with hepatitis C via blood and blood products through the elimination programme

20. In my opinion there are no barriers to testing and treatment for people infected with blood and blood products in the NHSE elimination program. However, there is a lack of data on how many people remain infected and in the absence of such data an informed program to identify such people is impossible. The work set out above to assess unidentified infection will allow an accurate estimate of the number of such patients that have not yet been identified.

Question 12 - Please set out your view as to additional steps that could be taken to identify people infected through blood and blood products.

21. In my opinion the number of people infected by blood or blood products in England who have not yet been offered treatment is likely to be low. I do not believe that additional steps to identify such patients would be a cost-effective use of NHSE resources. However, as noted above, NHSE has a number of on-going programs to identify 'unmet need' and the outcomes from this work will determine whether or not a cohort of 'unidentified infected' people exists. Once these data are available decisions on the most appropriate strategy to find such people can be undertaken.

Section 3: Your work as NHS England and NHS Improvement's Clinical Lead for HCV

Question 13 - The Inquiry understands from paragraph 16 of the statement of Claire Foreman [WITN3953053] that all hepatology services are expected to have in place all necessary links and referral pathways so patients can access psychological care should they need it. During your time as clinical lead for HCV, was any work done in auditing whether such links and pathways were in place and were operating effectively? If so, what was the outcome of this?

22. No work has been undertaken to assess access to psychological care. However, support for infected patients is provided by NHS England funded hepatitis C peers. Mark Gillyon-Powell has informed me that peers provided for both prisons and in the community are funded from NHS England's hepatitis C elimination budget. Some NHS Trusts have then added additional funds to recruit more peers, and a few are funded by Pharmaceutical industry partners as a part of the strategic procurement with NHS England. A review of the program showed an increase in treatments by 12% in networks that, at the time of the study, had deployed peers. This suggests that support by the peer program has assisted patients in accessing care.

Question 14 - It is understood that currently England does not provide specialist counselling for those with HCV unlike in Northern Ireland, Wales and Scotland. Was any consideration given during your time as clinical lead for HCV for establishing such a specialised service? If so, what was the outcome. If not, why not?

23. Specialist counselling for people with hepatitis C has not been provided in England and decisions on the support required for patients has been devolved to the individual networks. NHSE has provided a network of specially trained peers with lived experience of hepatitis C to support patients who are infected (see **RLIT0001728**). This program ensures that every patient with hepatitis C has access to individuals with lived experience of the infection who can provide appropriate support. Patients with particular needs are usually referred to the peers by the hepatitis C team and provide assistance as required.

Question 15 - One of the Inquiry's core participants has submitted to the Inquiry that such a service for psychological support could be delivered through NHS England, via the regional Operational Delivery Networks (ODNs). Do you view this recommendation as practical within the current framework and structure of the elimination programme and NHS at large? What obstacles could arise in delivering specialist counselling services in England?

24. As noted above significant psychological support is provided by the NHSE funded network of peers. It is not clear to me whether further support, and at what level is required and I do not know whether sufficient trained counsellors are available. If there was a clear demonstration of need and if sufficient counsellors were available it would be possible to set up a support network via the ODNs but given the large geographies served by the network a considerable number of counsellors would be required to avoid inequity of access.

Question 16 - One of the issues that has been raised with the Inquiry by core participants is the lack of consistency in clinical practice across the UK in terms of the surveillance that is offered to those with current HCV infection, and those who have cleared their HCV infection. The Inquiry understands from the statement of Claire Foreman [WITN3953053 at paragraphs 30 - 37] this inconsistency is because the decision as to what follow up is appropriate is one for the local treating physician in conjunction with the

patient. As to this:
(i) Is there any guidance as to appropriate follow up? If not, should there be?
(ii) Are there, to your knowledge, any plans to standardise follow up arrangements for those either currently infected or who have cleared their HCV infections? If so, please give details.
(iii) Is there anything you would wish to add to what is set out in paragraphs 30 - 37 of Ms Foreman's statement on this issue?

25. There are European guidelines on the management of hepatitis C that include recommendations on appropriate follow up (**RLIT0001729**). In my clinical experience patients differ greatly in their desire to undergo long-term follow up with some preferring to accept a low risk of future complications rather than to attend for regular scanning and others wishing to undergo regular review, even though the long-term risk is negligible. It is my opinion that these decisions are best made during consultations between the patient and the local medical team and that the European guidelines meets the need for appropriate evidence based guidance. We have no plans to standardise guidance further as best practice is to develop an individualised approach in consultation with the patient.

26. I have nothing to add to Ms Foreman's statement

Statement of Truth

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

GRO-C

Signed _____

Dated _28 September 2022_____

Table of exhibits:-

Date	Notes/ Description	Exhibit number
N/A	Chart - Treatments to people who acquire Hepatitis C via non-occupational contact with blood in healthcare setting	WITN3042005
20/09/2022	Hepatitis C Trust – Community Peer Programme	RLIT0001728

01/01/2018	EASL Recommendations on Treatment of Hepatitis C 2018	RLIT0001729
18/02/2020	Second written statement of Claire Foreman	WITN3953053