

Witness Name: Dr Francis Toolis

Statement No.: WITN3426002

Exhibits: Nil

Dated: 24 October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR FRANCIS TOOLIS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 July 2020.

I, Francis Toolis, will say as follows: -

Preliminary Statement

If I understand correctly the proposed workings of the Inquiry, any statement I make is likely to enter the public domain. Some of the questions posed by the Inquiry in this document raise concerns arising out of patient and colleague privacy and confidentiality issues and potentially of the families of deceased or mentally incapacitated former colleagues. Given, too, the sparsely populated Region served by the hospital in which I worked over the period in question, assigning necessarily very small numbers to patients in a particular category might constitute a breach of patient confidentiality by allowing others to at least guess at their identities. For these reasons, some questions will be answered in general terms or not at all. Please note that I am relying on memories of events that happened many years ago.

Section 1: Introduction

1. Please set out your name, address, date of birth and professional qualifications.

1.1. My name is Francis Toolis.

1.2. My Address is GRO-C

1.3. My professional qualifications were:-

MB.Ch.B (1972), University of Edinburgh

M.R.C.P. (UK): Member of Royal Colleges of Physicians of United Kingdom (1975)

M.R.C.Path: Member of the Royal College of Pathologists (1979)

Fellow of the Royal Colleges of Physicians of Edinburgh (1986), Glasgow (1998) and London (2000)

Fellow of the Royal College of Pathologists (1991)

MBA Health Care Management (1998), University of Stirling.

2. Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates. In particular, please set out, in relation to the period prior to your appointment as a consultant haematologist at Dumfries and Galloway Royal Infirmary ('the Infirmary') in November 1981, where you worked, your roles and responsibilities and your work insofar as it involved the care of patients with bleeding disorders and/or patients with hepatitis.

2.1 I received a standard 4-year training as a haematologist dual-trained in Laboratory and Clinical Haematology at the Haematology Department of the Royal Infirmary of Edinburgh (RIE), with short secondments as a trainee preparing for examination of the Royal College of Pathologists to the Edinburgh and South East Scotland Blood Transfusion Centre (ESESBTC) and the Paediatric Haematology Department at the Royal Hospital for Sick Children, Edinburgh. I participated fully in the usual haematology laboratory service to other clinicians together with inpatient and outpatient care of patients with haematological diseases, including haemophilia. Concerning haemophiliacs, treatment was generally by Outpatient administration of cryoprecipitate for joint bleeds. Transferring patients to home treatment with Factor VIII concentrate

was, as far as I recall, undertaken by Consultant staff in discussion with the patient. My Department did not have any significant role in the management of patients with hepatitis, there being a dedicated Gastroenterology and Liver Unit in RIE.

2.2 Already being in possession of MRCP (UK) qualification and with the gaining of M.R.C.Path in 1979 – the latter commonly seen as an exit examination signifying qualification for a Consultant post – the next step in my career would normally have been application for a Consultant post. Instead, I opted to spend a year as a Clinical Research Fellow with responsibility for running the Cell Separator Unit at ESESBTC. My duties also involved being on the medical rota advising non-haematological clinicians.

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.

3.1 Until I received a copy of the minutes of a meeting of the West of Scotland Consultant Haematologists Group, I did not consider my membership of this group relevant to the Inquiry. I became an ordinary member after my appointment as Consultant Haematologist at Dumfries and Galloway Royal Infirmary (DGRI) and remained so during the life of the Group or until my retiral in 2006.

3.2 For completeness, although the following Societies are primarily academic, I was an ordinary member of -

The Association of Clinical Pathologists
The British Society of Haematology
The European Haematology Association
The American Society of Hematology
I was also a founder member and 1st President of the Scottish Haematology Society.

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, 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.

4.1 I have never been involved in any inquiries, investigations etc relating to blood-borne viruses.

Section 2: Decisions and Actions at the Dumfries and Galloway Royal infirmary

5. Please describe the roles, functions and responsibilities and facilities of the Infirmary during the time that you worked there, insofar as the diagnosis, care and treatment of patients with haematological disorders is concerned.

5.1 With my appointment as Consultant at the end of 1981, the Haematology Department undertook for the first time Inpatient care of patients with haematological disease, principally Acute Leukaemia and Lymphoma. Previously, these patients had come under the care of General Physicians or been transferred 80 - 90 miles to the relevant specialists in Central Belt hospitals in Glasgow and Edinburgh. The Haematology Outpatient service was also expanded to investigate and treat patients with a wider range of diagnoses than before. The diagnostic laboratory service for the Hospital and General Practitioners continued largely unchanged, providing the standard Haematology Laboratory service expected of a District General Hospital.

6. Please identify senior colleagues at the Infirmary and their roles and responsibilities during the time that you worked there.

See Preliminary Statement.

I give my answer to this question, at the insistence of the Inquiry's legal team, under protest. My Preliminary Statement explains my reasons for not giving names of individuals. I regret that the Inquiry's legal team does not accept my reasoning that disclosure of the names of some individuals may cause great harm, without yielding any significant benefit to the Inquiry's workings.

In 1981, I replaced the late Dr John Selwyn in post, joining Dr Pauline Bailey. She was an 'old school', almost solely laboratory-trained Haematologist, my training

being as a hybrid Clinical and Laboratory Haematologist. My primary focus for my first 10 years in post was in establishing and providing a clinical, ward-and-outpatient service to patients with haematological disorders. My colleague was Head of Department and focussed primarily on running the Laboratory, although we shared, as far as my ward and clinic duties allowed, equally in providing a diagnostic service to hospital clinicians and GPs sending in blood samples. Please note that Dr Bailey retired in 1990/1991 and is now 88 years old. It has been reported to me that she is GRO-A

Dr Bailey was replaced by Dr Alistair Stark, dual-trained like myself. He became Lead haematologist for our clinical service while I took on the Lead role for the diagnostic laboratory services, although we operated as a team, both participating fully in clinical and diagnostic duties. In time, as our workload expanded and therapeutic regimes for haematological malignancies became more complex, we were joined by a third Consultant colleague, Dr Raymond Dang (I am unsure when, but think it the late 1990s), but the Lead roles remained unchanged, all of us sharing the clinical workload equally, but with the two Leads responsible for the development of their respective services. Sometime in the early 2000s, Dr Dang took up a post elsewhere and was replaced by Dr Ranjit Thomas.

7. Please describe:

- a. your role and responsibilities at the Infirmary and how, if applicable, this changed over time;**
- b. your work at the Infirmary insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

Response to 7(a)

7.1 Given that my Consultant colleague for the first 10 years or so of my tenure was an 'old school', almost solely laboratory-trained Haematologist, my primary focus was on establishing and providing a clinical, ward-and-outpatient service to patients with haematological disorders. For perhaps all of that time, I worked effectively single-handed in that area, preferring as far as possible to do all that

was required myself, a model that (albeit within a rota of other haematologists) I had been used to during my training years. As an example, I stopped junior medical staff undertaking bone marrow aspirate and did this investigation myself wherever indicated throughout the hospital. This was done both for greater patient safety and lesser discomfort and because non-haematologists undertaking few such procedures are more likely to obtain inadequate samples, requiring a repeat procedure.

7.2 Following retiral of my colleague, I was joined in 1991 by a dual-trained haematologist who took Lead position for our clinical service while I took on the Lead role for the laboratory services, although we operated as a team, both participating fully in clinical and diagnostic duties. In time, as our workload expanded and therapeutic regimes for haematological malignancies became more complex, we were joined by a third Consultant colleague, but the Lead roles remained unchanged, all of us sharing the clinical workload equally, but with the two Leads responsible for the development of their respective services.

Response to 7(b)

7.3 Almost all patients treated at DGRI for bleeding disorders had non-hereditary conditions related mainly to auto-immunity, septicaemia or anticoagulant sensitivity. Treatment generally took the form of simple observation, drug therapy and/or the use of blood products such as platelets, plasma or clotting factor concentrates.

7.4 To my knowledge, no patients were infected with HIV or HBV through blood issued by the DGRI Blood Bank during my time in post. Concerning HCV, please see my previous submission WITN3426001, my Preliminary Statement and my response to Q60-64 (NANB Hepatitis/Hepatitis C).

8. Approximately how many patients with bleeding disorders were under the care of the Infirmary when you took up your appointment there in 1981, then

and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

8.1 DGRI is a District General Hospital situated about 80 miles from the nearest Haemophilia Centre. It serves a population of under 150,000 spread over an area of 6,200 Km² (population density 22 persons per Km²). The only towns with a population above 10,000 are Dumfries (33,000) and Stranraer (11,000). By the nature of the Region's rurality and location, families with haemophiliac members were unlikely to move to Dumfries & Galloway unless for a very good social or commercial reason. Accordingly, the number of patients with hereditary bleeding disorders was always going to be very small.

8.2 See Preliminary Statement.

- 9. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated, by the Infirmary, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:**
- a. How, and on what basis, were decisions made about the selection and purchase of blood products?**
 - b. What were the reasons or considerations that led to the choice of one product over another?**
 - c. What role did commercial and/or financial considerations play?**
 - d. What if any involvement did you have?**

Response to 9(a) – (d)

9.1 All Blood and Blood products used in DGRI were supplied by the SNBTS from the West of Scotland Blood Transfusion Service (WSBTS). No commercial products were used, and commercial and financial considerations played no part in selection of blood products. The therapeutic use of a particular blood product or products was determined solely by the clinical needs of each individual patient throughout the hospital, as decided by the patient's clinician,

in consultation with the patient where appropriate. The clinician might be myself or another haematologist. It might, however, be the physician or surgeon in charge of the case, although sometimes requiring agreement or advice by a haematologist, depending on what was being proposed.

10. What particular products were used for treating patients at the Infirmary, over what period of time and for which categories of patients?

10.1. As I recall, there were no such patients with a non-haemophiliac diagnosis such as Von Willebrand's Disease or Christmas Disease (Factor IX Deficiency). Haemophilia treatment consisted of cryoprecipitate until, as indicated in the testimony of the patient of WITN3426001 to the Inquiry, home treatment with Factor VIII Concentrate began sometime in the late 1970s. That is the extent of my recall of treatment of haemophilia at DGRI and of the changes over the period in question.

11. What was the relationship between the Infirmary, you and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Infirmary decisions and actions?

11.1 DGRI, my Department, my colleagues and myself had no relationship with any commercial suppliers of blood products. Our sole supplier was SNBTS.

12. If the responsibility for the selection and purchase of blood products lay with an organisation other than the Infirmary, please specify which organisation and provide as much information as you can about its decision-making.

12.1 I refer to my answer for Q11.

13. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?

13.1 See Answers for Q9 & Q10. Concerning patient choice as to which blood product was used, in the vast majority of cases in DGRI the choice was treatment or no treatment. If active treatment was strongly indicated, a particular deficiency in the blood required a particular product, with generally no satisfactory alternative for most patients.

13.2 One notable exception was the patient pertaining to my draft statement WITN3426001, who switched from outpatient cryoprecipitate to home therapy Factor VIII Concentrate in the 1970s, in consultation with the haematologists then in post. I do not recall ever discussing modalities of therapy with the patient throughout the 1980s, and believe accordingly that my colleague of the time continued the supervision of his case, their professional relationship being longstanding by the time I came into post in late 1981.

14. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders?

14.1 As far as I can recall, there were no alternatives to factor concentrates available in the 1970s or 1980s, with the exception of Fresh Frozen Plasma where volume overload or other medical contraindications were not present. The other exception related to Haemophilia, where cryoprecipitate was available. Intranasal Desmopressin ('DDAVP') was used to treat minor bleeds in Mild Haemophilia and von Willebrand's Disease from the mid-1970's onwards, beginning about the same time that SNBTS Factor VIII Concentrate became available.

14.2 The haematologists then in post at DGRI would have known this and that the patient of WITN3426001 was, by his Factor VIII level, a Mild Haemophiliac. His clinical history of frequent bleeds requiring treatment was, however, more in keeping with a Severe grade. Perhaps for this reason, perhaps because a trial of DDAVP failed or proved intolerable in some way, or for some other reason, the switch from cryoprecipitate to self-administered Factor VIII Concentrate was the chosen therapy. I have an indistinct recollection of discussing the choice

with my colleague soon after I came into post and being satisfied by the explanation.

15. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Infirmary make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

15.1 I refer to my answer for Q14

16. What was the Infirmary's/your policy and approach as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?
a. Did that policy and approach change over time and if so how?
b. How, if at all, was the policy and approach informed by discussions had with external parties?

16.1 I refer to my answer for Q14.

17. In your draft statement WITN3426001, you have described cryoprecipitate as your "favoured modality of therapy at that time". Why was cryoprecipitate your favoured therapy, and over what period of time was this your policy?

17.1 I used cryoprecipitate on the one occasion on which I can remember treating an active joint bleed within my Department. That would have been some time in the 1980s. The advantages to me of cryoprecipitate in an outpatient setting were threefold. It was the anti-haemophiliac product I was most accustomed to administering from my previous post in RIE; it was more convenient to administer, requiring less preparation work; and, most important of all, it was a small-pool product. I cannot say when exactly this event occurred, whether before or after the discovery of HIV transmission by blood and blood products, but have always felt that, as a principle, exposure to potential risk of infection from others should be kept to a minimum. History, including the present Covid-19 pandemic, shows how easily infections can spread through the human population, whether through coughing, touching, sexual intercourse, faecal

contamination of water or through blood. Hence small-pool cryoprecipitate where, I stress, it is possible.

18. What was the Infirmary's/your policy and approach in relation to home treatment? Did the policy and approach change over time and if so how?

18.1 See answers above.

19. What was the Infirmary's/your policy and approach in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

19.1 I refer to my answers to Q13-14.

20. What was the Infirmary's policy and approach in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

20.1 The treatment of children at DGRI was entirely within the remit of the paediatricians. My Department was not involved in any therapeutic decisions. I draw the Inquiry's attention, however, to my response to Question 8 and my Preliminary Statement.

21. To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates?

21.1 See answer to Q14 – 16.

22. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at the Infirmary in consequence of the use of blood products?

22.1 To my knowledge, there were no cases of transmission of HIV or HBV by blood or blood products in DGRI during my time there. Regarding HCV, I was aware of some through the Look-back exercise undertaken by SNBTS but can supply no numbers.

Section 3: Knowledge of, and response to, risk

General

23. When you began work as a Consultant at the Infirmary, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

23.1 Part of my training required an understanding of the risks of blood-borne infection, such knowledge being gained from colleagues, conferences and the medical literature. This learning process continued throughout my career as a Consultant.

24. What advisory and decision-making structures were in place, or were put in place at the Infirmary, to consider and assess the risks of infection associated with the use of blood and/or blood products?

24.1 No formal structures were in place by the Department. Assessment of infection risk was seen as part of the duties of the Consultant Haematologists, who advised clinicians accordingly, monitoring and challenging in particular what they judged to be unnecessary blood transfusion or administration of blood products. There was also a Health Board Infection Control Team run by Bacteriologists and Public Health Specialists, which produced guidance on infection risks and management.

25. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products, and (ii) the use of NHS blood products?

25.1 Any blood product sourced from paid donors is, in my view then and now, inherently less safe than from volunteer donors. Although I cannot offhand cite definitive evidence to support my view, it seems likely that paid donors as an

overall group will include those compelled by financial need to donate, and that need may arise from high-risk behaviour. The WHO, International Red Cross and various international and national Blood Transfusion organisations recommend that blood donation should be voluntary and non-remunerated (<https://www.ncbi.nlm.nih.gov/books/NBK305666/>).

25.2 Accordingly, I considered NHS products safer than commercially supplied ones, a view that was strengthened when I learned that much of the commercial plasma imported into England (but not Scotland) came from the United States, sometimes from prison populations (with a presumably greater population of intravenous drug users) and, in the early days of HIV/AIDS, from the Gay community who, ironically, were much more conscientious in donating blood than the general population.

Hepatitis

26. When you began work as a consultant at the Infirmary, what was your knowledge and understanding of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

26.1 See my answer to Q23.

27. What, if any, further enquiries and/or investigations did you and/or the Infirmary carry out or cause to be carried out in respect of the risks of the transmission of hepatitis? What information was obtained as a result?

27.1 I do not understand the relevance of these questions to DGRI. The hospital was, in effect, a passive recipient of the blood and blood products supplied to it by SNBTS. The only mechanism by which the hospital could reduce the risk of blood-borne viral infection was by limiting the use of blood and blood products to the strictly necessary. An example was the 'One Unit' crossmatch. It is axiomatic in Haematology that, except in some rare circumstances, if an adult patient

needs just one unit of blood transfused, he or she does not need any. The policy of transfusing or administering blood products only when necessary was reinforced at every opportunity by the haematologists but, given that only the clinicians in charge of the case were in possession of the full details of a patient's state, channelling every request through a haematologist for permission was impractical as well as potentially dangerous. In the last analysis, the system depended on educated common sense.

28. What, if any, actions did you and/or the Infirmary] take to reduce the risk to patients of being infected with hepatitis (of any kind)?

28.1 I refer to my answer for Q27.

29. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

29.1 As I understood it, until definitive treatments were developed, HIV carried an almost universal mortality rate preceded by very significant morbidity. Hepatitis B did not carry the same morbidity burden and mortality rate, but many patients went on to develop ultimately fatal cirrhosis or hepatocellular cancer. Hepatitis C, by contrast, was considered to be a much less severe infection, with little in the way of morbidity for most patients and with a significant proportion recovering completely without treatment. A relatively small percentage of those with persistent chronic disease were estimated to progress to cirrhosis, but only after decades, and an even smaller proportion progressed further to hepatocellular cancer.

29.2 This knowledge was gained by a general reading of the medical literature, and by occasional conversations with non-haematologist colleagues within whose specialty hepatitis lay. Although hepatitis can be caused by blood transfusion, the medical management of hepatitis itself is not within the competencies of haematologists.

29.3 Over time, the prognosis for HIV improved dramatically. I was less sure what advances were being made in the treatment and management of Hepatitis B. As knowledge of Hepatitis C developed, it came to be seen as less benign than first assessed.

HIV and AIDS

30. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products during your time working at the Infirmary? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

30.1 I was in a peculiar position for a haematologist, having volunteered to become the designated HIV/AIDS Physician for my hospital, in the light of my experience in the medical management of immunosuppressed patients on treatment for acute leukaemia. At that time, treatment for AIDS was essentially 'fire-fighting', dealing with the atypical and often severe infections to which AIDS patients were prone, rather than being able to do much about the underlying viral infection itself. As specialist HIV/AIDS Units developed in the Central Belt, these few patients – all of whom had contracted the disease elsewhere – were transferred to the care of those Units. I played no further part in the management of any patient who might have been found to be HIV positive. If any such diagnoses were made in DGRI, no patient contracted HIV by blood transfusion or blood products at DGRI.

30.2 As part of my initial effort to acquire the necessary skills, I read up on the disease, attended conferences and training courses, and visited St Mary's Hospital and the Middlesex Hospital in London, both by then recognised leading centres in Britain for the management of AIDS. I was also fortunate enough, while on holiday in the United States, to visit San Francisco General Hospital, acknowledged at that time as world leader in HIV/AIDS management. After I relinquished any direct involvement in the care of HIV/AIDS patients, I nevertheless endeavoured to keep up with developments by reading Papers and

Editorials on the subject in the medical journals I subscribed to (*BMJ*, *Lancet*, *Blood*, *British Journal of Haematology* and *Journal of Clinical Pathology*).

31. How and when did you first become aware that there might be an association between AIDS and the use of blood products?

31.1 The potential transmission of HIV by blood transfusion and blood products became an obvious danger as soon as the first cases appeared in intravenous drug users in the mid-1980s.

32. What, if any, enquiries and/or investigations did you and/or the Infirmary carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?

32.1 The minimisation of risk of transmission of HIV in any hospital was the remit of Infection Control Teams and of Blood Transfusion Services. I was never in a position to be able to give any useful information to the Inquiry in response to these questions.

33. What, if any, actions did you and/or the Infirmary take to reduce the risk to your patients of being infected with HIV?

33.1 I refer to my answer to Q32.

34. In the Minutes of a meeting of the West Scotland Consultant Haematologists Group held on 22 November 1984 (attached), which you attended, it is noted at paragraph 17 that Dr Mitchell outlined 'moves to prevent dissemination of AIDS by blood products'. It is further noted that 'This programme appears to be progressing satisfactorily and to date no cases have been reported resulting from infusions of products from the Scottish Protein Fractionation Centre.' What efforts were made to prevent dissemination? What if any, efforts were made by the Infirmary in particular?

34.1 My Department received all its blood and blood products from our Regional Blood Transfusion Centre, and responded as appropriately to demand for blood and blood products as indicated by clinical need, challenging requests where they seemed unnecessary or inappropriate, within the limitations of clinical urgency. Of necessity, we otherwise depended on the efforts of SNBTS to minimise risk of transmission of HIV.

**35. How often did the West Scotland Consultant Haematologists Group meet?
What was the purpose of its meetings?**

35.1 I cannot recall how often the West of Scotland Haematologists Group met. Perhaps 2 – 4 times a year. The purpose of the Group, as shown by the Agenda submitted to the Inquiry, was to coordinate haematological services in the West of Scotland. After this length of time, I can recall no details on any meeting of the Group I attended. See my answer to Q34 concerning prevention of dissemination of HIV.

36. Did the Infirmary continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

36.1 DGRI did continue to use certain blood products for which there was no satisfactory substitute. Concerning the use of Factor VIII concentrate, I do not recall whether this was continued at this time or the patient was advised to switch to another therapy.

Response to Risk

**37. Did you or your colleagues at the Infirmary take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV?
If so, what steps?**

37.1 Clinicians in the hospital would have been aware of the risk of blood-borne viral infections, although the message that blood is dangerous – I remember using that phrase many times – would have been reinforced repeatedly by my

colleague and myself. By that phrase, I meant that blood transfusion and its derivatives has always, does now and will continue to pose potential infective risk to recipients. As each blood-borne infective agent is discovered and excluded from blood donations, the risk still remains of other unknown and undetectable agents present in some donors.

37.2 The risk of hepatitis and HIV was discussed with the haemophiliac patient under the care of DGRI Haematology.

38. When did the Infirmary begin to use heat treated factor products and for which categories of patients?

38.1 I cannot answer when DGRI began to use heat-treated factor products except to state that it would have been as soon as such was supplied by SNBTS.

39. Do you consider that heat-treated products should have been made available earlier? If not, why?

39.1 The decision as to when SNBTS switched to heat-treated products is one upon which I am not qualified to offer an informed opinion.

40. Did you or your colleagues at the Infirmary revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

40.1 See my answer to Q36.

41. Do you consider that your decisions and actions, and those of the Infirmary? in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

41.1 I think that the decisions and actions taken by myself and the Infirmary in general were adequate and appropriate in the light of the then current knowledge, practice and therapeutic armamentarium. Even now, I cannot see what we could have done differently. The alternative was not to treat a clinical need.

42. Looking back now, what decisions or actions by you and/or by the Infirmary could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

42.1 The alternative to not using blood products of the time was no treatment, with inevitable morbidity and deaths. Letting someone bleed to death or be crippled now to prevent possible viral disease later is not a choice.

43. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

43.1 I do not feel qualified to offer any opinion on these questions.

44. Do you consider that greater efforts could and/or should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

44.1 Again, I am not qualified to offer an opinion on what greater efforts should have been made to neutralise viral contamination of blood and blood products.

Section 4: Treatment of patients at DGR

Provision of Information to patients.

45. What information did you provide or cause to be provided (or was, to your

knowledge, provided by others) to patients at the Infirmary with a bleeding disorder about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

45.1 See my answers to Q14 – 16 and Q37.

46. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients about alternatives to treatment with factor concentrates? Please detail whether, and if so, how this changed over time.

46.1 I refer to my answers for Q14, Q15, Q16 and Q37

47. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients before they began home treatment/home therapy?

47.1 I refer to my answers for Q14, Q15, Q16 and Q37

HIV

48. When did you first discuss AIDS or HIV (HTLV-III) with any of your patients?

48.1 To my knowledge, no patient in DGRI contracted HIV through blood.

49. Please describe how and when you learned that patients under your care/the care of the Infirmary had been infected with HIV.

49.1 I refer to my answer for Q48.

50. What if any arrangements were made at the Infirmary for pre-test

counselling?

50.1 I refer to my answer for Q48.

51. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by phone? Were they seen individually or in groups? What if any involvement did you have in this process?

51.1 I refer to my answer for Q48.

52. What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret?

52.1 I refer to my answer for Q48.

53. What was the Infirmary/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?

53.1 I refer to my answer for Q48.

54. What, if any, information or advice was provided by you or colleagues at the Infirmary to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

54.1 I refer to my answer for Q48.

55. What if any arrangements were made at the Infirmary for post-test counselling?

55.1 I refer to my answer for Q48.

56. How many patients at the Infirmary were infected with HIV? Of those

infected,

- a. How many had severe haemophilia A?
- b. How many had moderate haemophilia A?
- c. How many had mild haemophilia A?
- d. How many had haemophilia B?
- e. How many had von Willebrand's disease?
- f. How many were children?

56.1 A small number of individuals who had contracted HIV elsewhere returned or moved to the Region. See Preliminary Statement and my answer to Q30.

57. Was work undertaken at the Infirmary to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

57.1 I know of no patient who seroconverted to HIV at the Infirmary.

Hepatitis B

58. Were patients infected with hepatitis B informed of their infection and if so, how? What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?

58.1 No patients under my care were infected with Hepatitis B. I have no knowledge of any DGRl patient with Hepatitis B.

59. How many patients at the Infirmary were infected with hepatitis B?

59.1 I refer to my answer to Q58.

NANB Hepatitis/Hepatitis C

60. Were patients infected with NANB hepatitis informed of their infection and if so, how and by whom? What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?

60.1 I was not involved in the identification of patients with NANB or their subsequent management.

61. When did the Infirmary begin testing patients for hepatitis C? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What if any involvement did you have in this process?

61.1 The test for HCV became available to DGRI in 1990 or 1991 when it began to be provided via a reference Microbiology Laboratory, either at the Western General or Royal Infirmary in Glasgow. Other than the patient forming the subject of my previous submission WITN 3426002 and those identified by SNBTS's Look-back exercise, I had no involvement in any other patients who might have been identified by other clinicians as HCV positive. Concerning the Look-back patients, I cannot recall how they were normally informed of the result and the offer of follow-up, although I think it might have been by a letter template provided by WSBTS.

62. What information was provided to patients infected with hepatitis C about their infection, its significance, prognosis, treatment options and management?

62.1 The information provided and management of those patients found to be HCV positive by Look-back was undertaken by WSBTS, without further involvement by myself or my Department.

63. When a test for HCV became available, what if any steps were taken by

the Centre and/or by you to ensure that all patients who had received blood products were traced and invited to be tested?

63.1 WSBTS provided me with a list of units of blood previously donated by donors subsequently found to be HCV positive, these units of blood having been sent to DGRI. My Department identified the patients who had received any of these units. As I recall, a letter prepared by WSBTS was sent by me to each patient, requesting in effect that they attend DGRI for a HCV test.

64. How many patients at the Infirmary were infected with hepatitis C?

64.1 See SNBTS Look-back statistics.

Delay/public health/other information

65. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

65.1 I can answer only for those patients with haematological disorders under the care of myself and my haematologist colleagues. Thankfully, none of those patients where HIV or Hepatitis testing was indicated medically yielded positive results, and I would think they were informed by telephone as soon as the result was received. The exceptions were any identified by Look-back (see Answer to Q61) and the patient of WITN3426001.

66. To what extent, if at all, did you/your colleagues take into account the public health implications of HIV, AIDS, hepatitis B, NANB hepatitis and hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?

66.1 I refer to my answer for Q65.

67. What information was provided to patients about the risks of other infections?

67.1 I refer to my answer for Q65.

68. What information was provided to patients about the risks of infecting others?

68.1 I refer to my answer for Q65.

Consent.

69. How often were blood samples taken from patients attending the Infirmary and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so how and where?

69.1 In relation to DGRI in general, no answer is possible for the questions posed here. Concerning patients under the direct care of the Haematologists, it was taken for granted that patients attending a Blood Clinic so named or admitted as a haematology inpatient had given tacit consent to have blood samples taken. With the exception of patients considered in answer to Q71 below, the provision of information concerning the purpose of the blood samples would have been minimal unless specifically asked. Consent was never recorded nor, unless challenged by the patient (if such had ever happened), would there be any kind of procedure akin to pre-operative Consent. To do such would have been extremely disruptive to the running of Clinics and inpatient care. The blood samples taken were not for storage, and were retained for at most a few days after initial analysis in case repeat analysis might be required.

70. Were patients under your care or under the care of your colleagues at the Infirmary treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur?

What was your approach to obtaining consent to treatment? Was their consent recorded and if so how and where?

70.1 I cannot answer for DGRI in general, but cannot conceive that any patient other than the comatose would have been given blood or blood products without being informed of this and of the need for it, with acceptance by the patient. To suggest otherwise is to propose that a doctor or nurse walks up to a patient's bed and connects up a unit of blood or infuses/injects a blood product into an intravenous line without speaking of it to the patient.

70.2 In relation to haematology patients, where factor concentrates or other blood products were given, patient consent was generally assumed after an explanation of the need for such treatment, and where there was no objection expressed or otherwise indicated. I can recall no instance where consent was recorded. Fully informed Patient Counselling and Consent (similar to that done before surgical procedures) before administration of each of the many thousands of units of blood and blood products issued annually by DGRI's Blood Bank was not practical.

71. Were patients under your care tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing? Was their consent recorded and if so how and where?

71.1 See my answer to Q30 concerning my training in the management of HIV/AIDS patients. One subject that had repeatedly arisen, engendered by patients' fear of stigmatisation, was the ethics of testing and the mandatory careful consent process preceding it, all under strict confidence. Accordingly, I was very aware of the sensitive importance of seeking informed consent to test for HIV and again of promptly informing the patient of the result, whether good or bad. Given the similar potential fears and risks of stigmatisation with HBV and HCV, I followed exactly the same procedure regarding their testing and confidentiality in the same way as I would have with HIV. Consent was not formally recorded, as I

remember. Such would not have been my standard practice: the patient's word and mine had always seemed sufficient.

72. Please detail all decisions and actions taken at the Infirmary by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

72.1 I am unfamiliar with the term PUPS (previously untreated patients).

Research

73. Please list all research studies that you were involved with during your time as a consultant at the Infirmary. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:

- a. Describe the purpose of the research.**
- b. Explain the steps that were taken to obtain approval for the research.**
- c. Explain what your involvement was.**
- d. Identify what other organisations or bodies were involved in the research.**
- e. State how the research was funded and from whom the funds came.**
- f. State the number of patients involved.**
- g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.**
- h. Provide details of any publications relating to the research.**

73.1 My Department undertook routine blood monitoring (Full Blood Counts and perhaps Clotting Screens) in a number of studies being undertaken by clinicians in DGRI and the neighbouring Crichton Royal (Psychiatric) Hospital. I cannot name any of these studies and my Department was not involved further in them. None, however, required administration of any blood products. Treatment of patients with haematological malignancies such as Leukaemia, Lymphoma and Myeloma was, as far as possible, by informed admission to the appropriate

Clinical Trial run by the Medical Research Council or similar body, and appropriate samples were taken as required by the Trial. All medical studies undertaken in the Region required the prior permission of the local or a national Research Ethical Committee, which ensured adherence to the issues specified in these questions (e.g. consent, anonymisation, etc). My own personal research interest was in temporal and geographic clustering of Acute Leukaemia cases, this being entirely a statistical analysis of existing data, not relevant to the Inquiry.

74. Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

74.1 I refer to my answer for Q73.

75. Were patients involved in research studies without their express consent? If so, how and why did this occur?

75.1 I refer to my answer for Q73.

76. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express consent? If so, what data was used and how and why did this occur?

76.1 I refer to my answer for Q73.

77. Was patient data (anonymised, de-identified or otherwise) shared with third parties without their express consent? If so how, and why did this occur, and what information was provided to whom?

77.1 I refer to my answer for Q73.

78. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference.

78.1 I refer to my answer for Q73.

Treatment of patients who had been infected with HIV and/or Hepatitis

79. How was the care and treatment of patients with HIV/AIDS managed at the Infirmary? In particular:

- a. What steps were taken to arrange for, or refer patients for, specialist care?**
- b. What treatment options were offered over the years to those infected with HIV?**
- c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

79.1 See my answer to Q30.

80. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

80.1 I refer to my answer for Q30.

81. How was the care and treatment of patients with hepatitis B managed at the Infirmary? In particular:

- a. What steps were taken to arrange for, or refer patients for, specialist care?**
- b. What treatment options were offered over the years?**
- c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

81.1 I had no involvement or knowledge of patients with Hepatitis B, NANB or Hepatitis C (with the exception of those identified by Look-back and the patient of WITN3426002). If there were any other such patients under the care of DGRI, that care was provided by General Physicians and, from 1998 onwards, a newly-appointed Infectious Diseases Consultant. If there were any infected children,

they would have come under the care of the local Paediatricians and/or the Royal Hospital for Sick Children, Glasgow.

82. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis B?

82.1 I refer to my answer for Q81.

83. How was the care and treatment of patients with NANB hepatitis managed at the Infirmary? In particular:

- a. What steps were taken to arrange for, or refer patients for, specialist care?**
- b. What treatment options were offered over the years?**
- c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

83.1 I refer to my answer for Q81.

84. How was the care and treatment of patients with hepatitis C managed at the Infirmary? In particular:

- a. What steps were taken to arrange for, or refer patients for, specialist care?**
- b. What treatment options were offered over the years?**
- c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

84.1 I refer to my answer for Q81.

85. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis C?

85.1 I refer to my answer for Q81.

86. What arrangements were made for the care and treatment of children

infected with HIV or hepatitis? How did those arrangements differ (if at all) from the arrangements made for adults?

86.1 I refer to my answer for Q81.

87. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

87.1 See my answers to Q81– 86 and any Answers relating to Look-back.

88. Did the Infirmary receive funding from the government or from any other source to help with the counselling of patients infected with HIV?

88.1 I was unaware of any specific funding given to DGRI in relation to HIV-positive patients, but point out that, apart from the few referred to in Answer 30, it seems unlikely to me that DGRI had any HIV-positive patients as their care would be undertaken by Central Belt specialist Units. Other than briefly through Look-back and the one patient previously alluded to, I had no involvement with any patients with hepatitis.

89. What (if any) difficulties did you/the Infirmary encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

89.1 I refer to my answer for Q88.

90. What if any involvement did you, the Infirmary or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

90.1 I refer to my answer for Q88.

Records

91. What was the Infirmary's policy with regard to recording information on death certificates when a patient had been infected with HIV or hepatitis?

91.1 I am unaware of any DGRI policy concerning death certification of patients with HIV or hepatitis, nor do I know anything about its retention policies for medical records. With two exceptions, neither I nor my Department kept separate files on any patients. The first of these was a (paper) ledger record of the issue of blood and blood products to patients, held during my time in post in the Department's Blood Bank. The second was charts plotting out serial Blood Counts, and blood/blood products and drug administrations to haematology patients with malignant disease on active cytotoxic therapy. The charts gave a visual picture of a patient's treatment over time to aid clinical management.

92. What were the retention policies of the Infirmary in regards to medical records during the time you were practising there?

92.1 I refer to my answer for Q91.

93. Did you maintain separate files for some or all patients? If so, why; where were those files located; and where are those files now?

93.1 I refer to my answer for Q91.

94. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the Infirmary? If so, why, what information and where is that information held now?

94.1 I refer to my answer for Q91.

95. Do you still hold records or information about any of your patients? If so, explain why and identify the records or information that you still hold.

95.1 I do not hold any records or information about my former patients.

Section 5: United Kingdom Haemophilia Centre Directors Organisation

96. To what extent did you receive and/or rely upon information from the UKHCO about blood products, risk of infection, hepatitis and HIV? What other sources of information or advice did you have?

96.1 I had no involvement with UKHCO. My sources of information relating to blood-borne viral infection were the medical literature, academic meetings I attended and advice sought from or guidance given by those I judged expert in their fields.

97. During the period that you were involved with UKHCDO, please outline:

- a. The purpose, functions and responsibilities of UKHCDO, as you understood them.
- b. The structure, composition and role of its various committees or working groups.
- c. The relationships between UKHCDO and pharmaceutical companies.
- d. How decisions were taken by UKHCDO.
- e. How information or advice was disseminated by UKHCDO and to whom.
- f. Any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to:
 - the importation, purchase and selection of blood products;
 - the manufacture of blood products;
 - self-sufficiency;
 - alternative treatments to factor products for patients with bleeding disorders;
 - the risks of infection associated with the use of blood products;
 - the sharing of information about such risks with patients and/or their families;
 - obtaining consent from patients for the testing and storage of their blood, for treatment and for research;

- heat treatment;
- other measures to reduce risk;
- vCJD exposure; and
- treatments for HIV and hepatitis C.

97.1 I refer to my answer for Q96.

Section 6: Pharmaceutical companies/medical research/clinical trials

98. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.

98.1 Neither I nor my Department had any involvement with commercial companies related to blood products, or undertook research or clinical trials for them.

99. Have you ever received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

99.1 I refer to my answer to Q98.

100. Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details of your involvement and of any financial or other remuneration you received.

100.1 I refer to my answer to Q98.

101. Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

101.1 I refer to my answer to Q98.

102. Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

102.1 I refer to my answer to Q98.

103. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

103.1 I refer to my answer to Q98.

104. What regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

104.1 I refer to my answer to Q98.

105. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

105.1 I refer to my answer to Q98.

106. Have you ever provided a pharmaceutical company with results from medical research studies that you have undertaken? If so, please provide details.

106.1 I refer to my answer to Q98.

107. If you did receive funding from pharmaceutical companies for medical research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

107.1 I refer to my answer to Q98.

Section 7: vCJD

108. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?

108.1 I became aware of vCJD and its risk of transmission of vCJD via the medical literature, Government announcements and reports in the Media, although these related principally to population-wide risk from meat consumption. The theoretical possibility of transmission by blood of a virus contracted by food but able to travel through the bloodstream to the brain was, however, immediately obvious. Thereafter, I relied on the medical literature and WSBTS for guidance. As far as I am aware, no blood or blood product from a donor later found to have vCJD was ever delivered to my Department's Blood Bank. Accordingly, the need to inform, counsel and support patients at risk did not arise.

109. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so please answer the following questions:

- a. What steps were taken put in place a process at the Infirmary for informing patients about possible exposure to vCJD?**
- b. What steps were taken to tell patients of possible exposure to vCJD?**
- c. What steps were taken to provide information to patients about the risks of vCJD?**
- d. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?**

109.1 I refer to my answer to Q108.

110. What measures were put in place at the Infirmary, from a public health perspective, in relation to the care and treatment of patients?

110.1 I refer to my answer to Q108.

Section 8: The Financial Support Schemes

111. What if any involvement did you have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) which were set up to provide financial support to people who had been infected?

111.1 I had no involvement with any relevant Trust or Fund, and have no knowledge of how DGRl might have dealt with them.

112. To what extent, during your time at the Infirmary, did staff (including you) inform patients about the different trusts or funds?

112.1 I refer to my answer to Q111.

113. Did the Infirmary have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

113.1 I refer to my answer to Q111.

114. What kind of information did the Infirmary provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

114.1 I refer to my answer to Q111.

115. Did the Infirmary, or any of their staff, act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

115.1 I refer to my answer to Q111.

116. Was the Infirmary or any of its staff involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

116.1 I refer to my answer to Q111.

117. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your patients in relation to the trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

117.1 I refer to my answer to Q111.

Section 9: Other Issues.

117.2 Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

117.3 No complaints.

117.4 Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

117.5 Nothing to add.

Statement of Truth

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

Signed

GRO-C

Dated

26th October 2020