Witness Name: Dr Gary Benson
Statement No.: WITN3082015
Exhibits: WITN3082016 – WITN3082028
Dated: 30 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR GARY BENSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 19 June 2020

I, Dr Gary Benson, will say as follows: -

Section 1: Introduction

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

1) My name is Dr Gary Benson. My professional address is NI Haemophilia Centre, Belfast City Hospital, Lisburn Road, BT9 7AB. My date of birth is GRO-C GRO-C 1976. My professional qualifications are as follows; MB, BCh, BAO, FRCP, FRCPath.

2) I have held the following positions:
   a. JHO Aug 1999-July2000: Altnagelvin Hospital, Western Health and Social Care Trust
   b. SHO Aug 2000-July2001: General Medicine, Altnagelvin Hospital, Western Health and Social Care Trust
   c. SHO Aug 2001-Jan2002: General Medicine, Causeway Hospital, Northern Health and Social Care Trust

d. SHO Feb 2002-July2002: Clinical Oncology, Belvoir Park Hospital, Belfast Health and Social Care Trust.
e. SHO Aug2002-Jan2003: Clinical Haematology, Belfast City Hospital, Belfast health and Social Care Trust.
f. Specialist registrar Feb2003-Jan 2007: Haematology, Belfast City Hospital, Belfast Health and Social Care Trust
g. Specialist registrar Feb2007-Jan2008: Haematology, East of Scotland Haemophilia Comprehensive Care Centre, Royal Infirmary Edinburgh
h. Consultant Haematologist with a specialist interest in disorders of haemostasis: Feb 2008 – present, Belfast City Hospital, Belfast Health and Social Care Trust. This post includes the role of Director for the NI Haemophilia Comprehensive Care Centre in leading and delivering the care to patients in NI with congenital and acquired bleeding disorders. The majority of work revolves around those who attend the adult Centre but also undertake a clinic alongside the paediatric haematologist.
i. I am the laboratory lead for specialty coagulation and run the Regional Specialty Coagulation Laboratory for NI.
j. I am the Clinical Director for Blood Sciences within the Trust.

3) I am a member of the following:
   a. British Society Haematology
   b. Royal College of Physicians
   c. Royal College of Pathologists
   d. Belfast Trust Drugs and Therapeutics Committee
   e. Belfast Trust Transfusion Committee
   f. Regional Haematology Clinical Reference Group
   g. UKHCDO Advisory Committee
   h. Medical advisor UK Haemophilia Society

2. You described your employment history in a statement to the Inquiry dated 13 January 2020 [WITN3082001]. Please review the information you provided and confirm whether you have anything further to add.

4) My employment history is a true and accurate reflection to the posts held.

3. You also set out your membership of a number of committees, associations, societies and groups in your previous statement [WITN3082001] to the Inquiry. Please clarify the dates of your membership and the nature of your involvement for each of them.

5) British Society Haematology. I have been a member of the society since approximately 2006. This is the professional organisation for haematologists and my membership enables me to attend at the annual general meeting and conference as well as to avail of the journal for continuous professional development – British Journal of Haematology.

6) Royal College of Physicians. I have been a member since completing my professional examination in general internal medicine 2002/ 2003. This was a compulsory stage in training prior to embarking upon specialist haematology training. My ongoing membership enables availability to the Medicine journal, and regional and national clinical update meetings, as well as the right to use post nominal awarded by the college.

7) Royal College of Pathologists. Further to successful completion of training in haematology 2007, I automatically became a member of the college and where the majority of my professional time takes place in relation to on line continuous professional development diary recording as well as the right to use the post nominal as awarded by the college.

8) Belfast Trust Drugs and Therapeutics Committee. Further to my appointment to the Trust in 2008, I became a member of the committee and sit to represent mainly anticoagulation related issues and am responsible for the drafting and provision of policies relating to the use of anticoagulants.

9) Belfast Trust Transfusion Committee. I am a committee member as a haematologist as well as the Clinical Director for Blood Sciences and represent the laboratory.

10) Regional Haematology Clinical Reference Group. I am the deputy chair of the group and work alongside the chair person in standardising haematology throughout Northern Ireland as part of the Regional Pathology Network review.

11) UKHCDO Advisory Committee. Part of my post, which I was recruited to, is that of the Haemophilia Centre Director for Northern Ireland. Part of this role nationally, is to represent Northern Ireland on the advisory committee. I am present at each of the committee meetings feeding back any issues, which arise locally, as well as to feed back issues at a national level and seek their application to the local group. I also take part in the national centre audit programme, more recently replaced by the Quality Standard review, as a medical reviewer of other haemophilia centres.

12) Medical advisor UK Haemophilia Society. I was invited to be a part of this group several years back in order to ensure a complete representation of the United Kingdom as well as a support to the society when developing patient information leaflets/ literature.

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 the 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 that you provided.

13) I can confirm that I have not provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to the 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.

Section 2: Decisions and actions of those treating patients with bleeding disorders at the Northern Ireland Haemophilia Centre

5. Please describe the facilities, organisation, roles, functions and responsibilities of the Northern Ireland Haemophilia Comprehensive Care Centre ("the Centre") during the time that you have worked there, and how they have changed over time

14) The Centre is based at the Belfast City Hospital campus of the Belfast Trust, on level C on the Tower Block. It had been at the City Hospital site further to the amalgamation of the haematology services in 2001/2002. On this floor, it is co-located alongside the haematology and oncology outpatient clinics. It is a dedicated space where patients can attend as part of their routine outpatient appointments and acute unscheduled care during the hours of 9-5, Monday to Friday.

15) The out-of-hours service has changed over the time largely driven by the Trust's reconfiguration of the emergency department services. The Belfast City Hospital had an emergency department which patients were directed towards once they had contacted the help line and from which medical assessment was deemed necessary. After the closure of the emergency department, patients still contact the helpline but if assessment is required, this is undertaken through the Royal Victoria Hospital emergency department. Once the helpline is contacted, the haematology specialty registrar is contacted who discusses with the patient and can liaise with the emergency department to ensure treatment available in advance of the consultation. If it is not possible for the patient to attend this emergency department, the registrar will liaise with the local team and direct accordingly as to how best to manage the bleeding disorder. Emergency supply of clotting factor concentrate is held at the Royal Victoria Hospital,

Belfast City Hospital, Royal Belfast Hospital for Sick Children and Altnagelvin Hospital, Londonderry as well as with the patient for those with significant bleeding disorders.

16) The Centre is composed of the Centre Director office/consulting room, specialty doctor office/consulting room, specialty registrar office/consulting room, phlebotomy room, nursing room, resource room, secretary/receptionist office as well as its own waiting area. The specialty coagulation laboratory is in the haematology laboratory at the end of the corridor, alongside the blood bank.

17) The haemophilia service is placed within haematology and oncology service. More latterly this division has been renamed as the Cancer and Specialist Medicine Division. The specialist coagulation laboratory is within the Blood Science division – separate to the clinical.

18) The service is financially supported by the Regional Medical Commissioning Group. The group represents the five health care trusts and is composed of health care representatives from nursing, pharmacy, finance, public health and commissioning. Each Trust contributes an equal proportion to the budget for haemophilia that covers the cost of the treatments. As part of their role, there are regular meetings with myself in relation to the service as a whole and standardisation of care and the ongoing patient needs. This has led to significant additional staffing support over the years. When I started in 2008, the staff break down was the single-handed consultant, two nurses (Band 7 and Band 6), a specialty doctor, and a clinical scientist. Their roles were supported with a secretary, a receptionist, a specialty registrar on rotation and two band 7 biomedical scientists in the specialist coagulation laboratory. As of 2020 the Centre staff are reflected with two consultant haematologists (one vacant post), a specialty doctor, four nurses (one band 7, three band 6 constituting 2 whole time equivalent), a dedicated haemophilia social worker, physiotherapist, social worker, occupational therapist and data manager and two clinical scientists (one vacant post).

19) The role of the Centre and its staff remains to provide care to Northern Irelands adult patients with congenital and acquired bleeding disorders and to support their care should its primary need fall outwith their bleeding issue i.e. obstetrics, orthopaedics etc. This role remains fundamental and is unchanged over time. Whilst the role is unchanged, how this is delivered has adapted in line with the patients' needs.

20) By 2008, the only specialist clinic was that of the HIV service which was undertaken within the haemophilia outpatient clinic.

21) Hepatitis C treatment was made available and provided through the Haemophilia Centre, in line with the then standard of interferon based alongside ribavirin. With the advent of newer treatments, the management for those who had not received previous therapy – through choice or side effect profile, or were refractory to standard therapy, was transferred to the regional hepatology service.

22) The service already had those patients on a hepatoma surveillance programme as well as those patients who had a liver transplant.

23) Subsequent specialist clinics were established from 2008. These included cohorting together patients with haemophilia to organise a dedicated monthly review clinic, facilitating the 'one stop' ethos. Additional clinics were rolled out including the same model for von Willebrand's disease, platelet disorders alongside the routine review service.

24) A combined obstetric haematology clinic was established in April 2008 and is run fortnightly alongside the obstetric team at the Royal Jubilee Maternity Service on the Royal Victoria Hospital campus.

25) Transitional care takes place from around the age of 14 – most commonly around 16. This is a little lower than the rest of the UK but is reflected in the fact that the regional paediatric hospital emergency department does not admit children from their 13th birthday. A combined paediatric clinic was set

up at a time when the paediatric haematologist was a single-handed post and run every other Thursday morning. This has since been stood down further to the successful recruitment of a second paediatric haematologist. Established clinic links continue for those approaching transition.

26) A satellite review service was established for patients living in the Londonderry area, at Altnagelvin Hospital. This had started as myself only attending but has now grown to the whole multiprofessional team attending and reviewing the patients locally.

27) Family educational/ support days were organised and run by the Haemophilia Centre staff in April 2009 Ulster Folk and Transport Museum, September 2012 at the Ulster Museum and May 2016 at Titanic Belfast. These events were attended by over 200 patients and family members.

28) In service training programme was developed and run every third Thursday of the month. Each member of the multiprofessional team delivered some education in relation to recent articles rea or conferences attended.

29) Over the years, a remote telephone review service has been set up and run by the haemophilia nurse specialists for patients with non-severe bleeding disorders. More recently, we have also adopted the use of Microsoft Teams to facilitate virtual consultation, again using the whole multiprofessional team.

30) A significant function in addition to the care of those with known bleeding disorders, is also the investigation and diagnosis of new patients into the service. The regional specialty coagulation laboratory is based at the Belfast City Hospital and undertakes the specialty tests in line with national specifications.

31) The haemophilia centre won the Haemophilia Society Buddy Awards for Best Haemophilia Centre 2016, as voted for by the patients.

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

32) When I took up the post, the staff present within the Centre were Dr O McNulty, specialty doctor and two haemophilia nurse specialists C McAfee and M O'Donnell. The clinical scientist Dr P Winter complimented the service. All members of staff have since retired from the service.

33) Given the increasing number of patients within the Centre, funding was sought and approved for the provision of a second consultant with specialist interest in bleeding disorders. Dr Christopher McCauley was appointed in August 2016 and resigned from post in March 2020.

34) The out of hours care is provided through the leukaemia/ bone marrow transplant team. This is shared with myself as well as Prof MF McMullin, Dr D Finnegan and Dr C Arnold. I am available second on call should I be required as well as being first on call one week in every 4.

7. Please describe your role and responsibilities at the Centre and how they have changed over the years.

35) My job description remains unchanged from that which I had applied to and was successfully appointed. (WITN3082016: job description for Consultant Haematologist with specialist interest in disorders of coagulation).

8. Approximately how many patients with bleeding disorders were under the care of the Centre when you first started working there and have been in subsequent years? Approximately what proportion have been adults and what proportion have been children? If you are able to give exact rather than approximate figures, please do so.

36) The Northern Ireland Haemophilia Centre provides care to those patients who have transitioned from the paediatric service and as such those patients under the care of the Centre are adults only.

37) Adult Database 2008

41 with severe haemophilia A and B

1 with Type 3 von Willebrands

2 with Bernard Soulier

Total: 292 all registered bleeding disorders

38) Adult Database 2020

64 with severe haemophilia A and B

3 with type 3 von Willebrands

6 with Bernard Soulier

1 with Glanzmann thrombasthenia

Total: 596 all registered bleeding disorders

9. Over the years that you have worked at the Centre:

a. What products have predominantly been used for the treatment of patients with bleeding disorders?

39) All patients with haemophilia A from 2008 have been on recombinant factor VIII. All, but one patient, with haemophilia B has been on recombinant factor IX. Patients with congenital haemophilia with inhibitors or those with acquired haemophilia received activated recombinant factor VII to manage bleeding episodes on demand. All patients with von Willebrand's disease receive either DDAVP (documented positive response) or intermediate purity plasma derived clotting factor (with a minimum of two viral inactivation steps adopted in the manufacturing process), depending on the subtype and past documented DDAVP response.

b. Who has been responsible for the selection and purchase of those products?

40) All products are tendered and procured through the national clotting factor tender process via CMU – as per the whole of the UK. As part of the advisory committee role, I support the tender in relation to data provision re total

volume expected to use when the tender was related to volume used as opposed to current model based on a per unit price.

c. How and on what basis have decisions been made about the selection and purchase of the products?

41) As above, the provision of the specific clotting factor concentrates is in line with the national tender model. Switching was maintained at a minimum outwith when a product was withdrawn from the tender process.

d. What, if any, role have financial and/or commercial considerations played?

42) As above, the initial tender process was based on volume of factor used whereby larger volumes pledged would have provided a reduction in the per unit price.

e. What has been the relationship between the Centre and pharmaceutical companies manufacturing/supplying the products, and what, if any, influence has that relationship had on decisions regarding the selection and purchase of products?

43) Pharmaceutical companies provide Centre staff with an update in relation to their products and changes to the licensing and dose/delivery system. They have no influence locally over decisions regarding selection and purchase as these decisions have been taken centrally with a standardised scoring system.

10. What, if any, viruses or infections, other than HIV, HCV and HBV, have been transmitted to patients at the Centre in consequence of the use of blood products during the time that you have worked there? As far as you are aware (from your current knowledge of the patients that you have treated at the Centre over the years), what, if any, viruses or infections, other than

HIV, HCV and HBV, were transmitted to patients at the Centre in consequence of the use of blood products prior to the time you joined the Centre?

44) There have been no cases of viruses or infections transmitted to patients at the Centre in consequence of the use of blood products during the time I have been the lead consultant. I am unaware of any historical transmission of viruses to patients at the Centre outwith HIV, HCV and HBV.

Section 3: Knowledge of, and response to, risk

General

11. When you began work at the Centre, 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 has your knowledge and understanding developed over time?

45) I knew from general education from school, media, as a blood donor, undergraduate medical training of the issues and risks associated with blood borne virus transmission. This was further enhanced through the haematology specialist training programme which I commenced in January 2008 and was admitted to the specialist registrar with the GMC thereafter.

46) The curriculum used at that time covered all aspects of haematology including paediatrics, malignant and benign, coagulation and blood transfusion. (WITN3082018: Specialist haematology training curriculum 2003). This included formal training/teaching in relation to risk of transmission of blood borne viruses, measures adopted to minimise this, as well as tests available to screen donors.

47) I spent a total of three months within the Northern Ireland Blood Transfusion Service (February – April 2005) observing practices and process from blood donor screening through the health questionnaire, virus testing, blood

component processing and storing, releasing and also special requirements. Part 2 of the FRCPath written examination included a written paper dedicated to blood transfusion, coagulation, and general haematology with practical assessment with blood film and bone marrow morphology diagnoses, and data interpretation in blood transfusion and coagulation.

48) As part of routine haematology practice, I continue to require this knowledge to be maintained and kept up to date and this is done so utilising the NHS e-learning system – for both clinical haematology but also blood banks/establishments.

12. When you began work at the Centre, what advisory and decision-making structures were in place, or were put in place, at the Centre and/or within the area covered by the Centre and/or nationally, to consider and/or assess the risks of infection associated with the use of blood and/or blood products? How have these changed over time?

49) Within Northern Ireland, the Northern Ireland Blood Transfusion Service lead in relation to risks of infection posed by the use of blood and/or blood products. Northern Ireland Regional Transfusion Committee lead on many audits in relation to the better use of blood and its components, developing guidelines as well as more recently standardised consent.

Hepatitis

13. When you began work at the Centre, what was your knowledge and understanding of the risks of the transmission of hepatitis, including hepatitis B and hepatitis C, from blood and/or blood products? What were the sources of your knowledge? How has that knowledge and understanding developed over time?

50) As per above and WITN3082018, the transfusion associated infections is covered by the training curriculum and was a core component of training spent at the Northern Ireland Blood Transfusion Service.

HIV and AIDS

14. When you began work at the Centre, what was your knowledge and understanding of HIV and AIDS and in particular of the risks of transmission from blood and blood products? How has your knowledge and understanding developed over time?

51) As per above and WITN3082018, the transfusion associated infections is covered by the training curriculum and was a core component of training spent at the Northern Ireland Blood Transfusion Service.

Section 4: Treatment of patients at the Centre

Provision of information to patients

15. When you began work at the Centre, what information did you provide or cause to be provided (or was, to your knowledge, provided by others at the Centre) to patients 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 has changed over time.

52) I have no knowledge of the nature/type/scope of information provided to patients historically. My own personal practice would be for those patients requiring a commercially available plasma derived clotting factor concentrate, to ensure they understood that it was derived from multiple blood donors and that this had been screened and tested for known viruses, with the inclusion of standard viral inactivation steps, but despite this there remains a small risk of transmission as well as the possible transmission of an as yet unknown pathogen. This would then be balanced in relation to the clinical need for the clotting factor and whether alternatives would be available.

53) Over time, this has not changed in relation to advising patients, albeit selection of the commercially available plasma derived products has developed in relation to viral inactivation steps and always to ensure that, where possible, at least two steps are available.

54) Where plasma derived clotting factor concentrate is the only treatment available, hepatitis A and B vaccination programme was in place and remains.

55) Formalised consent and training is now in place. WITN3082019.

HIV

16. To the best of your knowledge, how many of the Centre's patients, overall, were infected with HIV in consequence of their treatment with blood products? Of those infected,

a. How many had severe haemophilia A?

56) Fifteen

b. How many had moderate haemophilia A?

57) Zero

c. How many had mild haemophilia A?

58) Zero

d. How many had haemophilia B or von Willebrand's disease?

59) One

e. How many were children?

60) The Centre provided care to adult patients only. I am unaware of the ages of individual patients at the time of their HIV diagnosis.

17. To the best of your knowledge, was work undertaken at the Centre to establish the time period during which patients seroconverted? If so, please describe (to the extent that you are able to) what work was done and what, if any, conclusions were reached.

61) In reviewing historical, miscellaneous records, I was able to observe timelines for those patients for whom records were present, of multiple times that testing had been undertaken prior to and further from confirmed diagnosis.

Hepatitis B

18. To the best of your knowledge, how many of the Centre's patients, overall, were infected with hepatitis B in consequence of their treatment with blood products?

62) In reviewing the historical, miscellaneous records, a compiled named list of positive hepatitis C PCR results was uncovered – undated. The same has not been found in relation to hepatitis B outwith a publication [WITN3082021]. 'Questionnaire' forms in relation to jaundice review and hepatitis review were also read – these were sent in centrally to the various working parties at the time but a complete set is not available locally.

Hepatitis C

19. When, to the best of your knowledge, did the Centre begin testing patients for hepatitis C? Over what period of time was testing for hepatitis C carried out after a test became available? How and when were patients told of their diagnosis of hepatitis C? Were they told in person, by letter or by phone?

63) In reviewing the specific miscellaneous records available, the actual dates from which testing was commenced is not known to me. I have no direct knowledge, outwith individual patient feedback, as to how and when they were informed of the results.

20. In the enclosed 15 August 2011 letter to Professor Crane [BHCT0000113, pg.3], you provided a consent letter to enable the liver of a deceased individual to be tested for hepatitis B and hepatitis C. Did you provide such letters for other patients? What was the reason for doing so and what would be done with the results?

64) This specific situation arose further to the changes to the Skipton scheme in relation to financial support to families for patients who had predeceased the establishment of the service. I was approached by one of our patients whose brother was HIV positive, seeking confirmation of whether he had also been hepatitis C positive. Sadly the young man had committed suicide. I worked alongside the virology department in reviewing the historical records as well as the documentation available and referenced above. There was no historical record of a hepatitis C test within the laboratory system. On behalf of the brother, I then approached the Coroners Service to acquire a copy of the death certificate to see whether any annotation was made towards the liver at the time of the post-mortem. The report was nonspecific, making no reference from which a possible hepatitis virus could have been suspected. I further contacted the coroner as to whether any tissue of the liver was available as we had discussed with the laboratory, that there may be a possibility to try to extract DNA from a liver sample. A sample was retained within the Coroner's Office and the patient's brother consented for the tests to be undertaken. The ultimate result was that the testing was negative for hepatitis C virus.

65) The situation was unique and the letters would not have been required for any other family.

21. What information has been provided to patients infected with hepatitis C about the infection, its significance, prognosis, treatment options and management during the time that you have worked at the Centre?

66) The Centre had provided interferon based therapy for patients with hepatitis C infection from the outset. Further to my appointment, those patients who had not received treatment or had partially received treatment had further options discussed – namely pegylated interferon and ribavirin for the standard duration in line with their genotype. Patients were advised as to the risk of chronic hepatitis C and cirrhosis and liver failure/cancer. They were all actively encouraged to consider the treatment at face-to-face outpatient appointments. Around ten patients had been treated during my time as consultant prior to the advent of the non-interferon based treatment. Further to their availability, all patients either treatment naive or refractory have been reviewed, assessed and offered treatment – all but one patient has achieved a sustained virus remission. The one patient who remains hepatitis C PCR positive has opted not to pursue current treatment options.

67) Patients who have developed cirrhosis are managed under the hepatology service hepatoma surveillance programme which is a six-monthly outpatient ultrasound scan as well as a serum alpha fetoprotein screen.

22. To the best of your knowledge, how many of the Centre's patients, overall, were infected with hepatitis C in consequence of their treatment with blood products?

68) In October 2010 it was announced a review of the Skipton fund [WITN3082022] and it was extended to include those who had been infected and predeceased 29th August 2003. I undertook a piece of work to identify those patients, I reviewed historical documents within the Centre and a document was found giving hepatitis C positivity, genotype and patient name [WITN3082023]. This form is undated. Additional patients were identified further and added to this list. There is no accurate tally in relation to those

patients who were hepatitis C PCR negative but hepatitis C antibody positive. As such, the list of those with hepatitis C PCR positive testing is 92.

Delay/public health/other information

23. During the time that you have worked at the Centre, have the results of testing for HIV and hepatitis (of all kinds) been notified to patients promptly, or have there been delays in informing patients of their diagnosis? If there have been delays in informing patients, please explain why.

69) No new cases of hepatitis or HIV have been diagnosed during my time of working at the Centre in relation to patients with bleeding disorders.

24. When you began work at the Centre, to what extent, if at all, did you and/or your colleagues at the Centre take into account the public health implications of HIV, AIDS, hepatitis B and hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients? Please detail whether, and if so how, this has changed over time.

70) In relation to treatment available and provided through the Centre for hepatitis C, public health implications in relation to its transmission as well as teratogenic effect of conceiving while on therapy was highlighted and discussed openly and freely with patients. Partners/wives/family members were able to attend, and did so, for testing if they wished or they attended their family practitioner.

25. When you began work at the Centre, what information was provided to patients about the risks of other infections? Please detail whether, and if so how, this has changed over time.

71) For those patients whose treatment options was limited to commercially available plasma derived clotting factor concentrates, a hepatitis vaccination

programme for A and B remains in place. In line with public health awareness campaign, sexually transmitted infections are highlighted and advice to reduce their risk is discussed. I have observed this is an increasing challenge and have on occasions directed patients to sexual health clinics as well as diagnosing several in the haemophilia clinic.

26. When you began work at the Centre, what information was provided to patients about the risks of infecting others? Please detail whether, and if so how, this has changed over time.

72) I ensured further to starting that this was rediscussed with all patients as opposed to having assumed that this had already been dealt with historically. It continues to be highlighted and discussed.

Consent

27. When you began work at the Centre, how often were blood samples taken from patients attending the Centre and for what purpose(s)? What information was given to patients about the purposes for which blood samples were taken? Were samples stored for prolonged periods and, if so, why? Did the Centre obtain patients' informed consent to the storage and use of those samples? Please detail whether and, if so how, this has changed over time.

73) Patients are routinely tested at each outpatient attendance in relation to the following:

a. Full blood count – assess whether given the bleeding episodes there would be any evidence of anaemia. Platelet count to calculate the AST to platelet ratio for those with hepatitis C. · Renal function
b. Liver function – to assess function and any change from previous test.
c. Clotting factor level and inhibitor screen, in relation to last treatment administered – surrogate marker for pharmacokinetics of the individual factor.

d. Random cholesterol, for those aged over 40 – with ageing population and likely being only health care contact, screen for cardiac disease risk determinant.
e. Prostate specific antigen, for those aged over 50 – well man screen.
f. Genetic samples, if not already known
g. If HIV positive, standard HIV panel in relation to viral load, lymphocyte subset
h. If Hepatitis C PCR positive, AST to platelet ratio index calculator (derived from liver function test, full blood count above)
i. Review previous viral tests re immunity to hepatitis A/B

74) Patients are advised of the tests which are to be checked at the clinic on the day and the reasons for them. Samples are not stored outwith until the test itself is performed and thereafter discarded. The only exception to this is the genetic screening which the patients undergo a signed consent process and the holding of their sample is discussed.

28. During the time that you have worked at the Centre, have patients under its care ever been tested for HIV or for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing? Please detail whether and, if so how, the Centre's approach has changed over time.

75) Patients attending the Centre have never been tested for HIV or hepatitis for any other purpose without their express and informed consent, during my time. All patients are informed of the tests which require to be performed in advance and consent sought.

29. The enclosed 2011 documents [DHNI0000279_001 & DHNI0000279_002] on patient consent for blood/blood transfusion were forwarded to you on behalf of the NIRTC Chair in a 19 January 2012 email [DHNI0000279]. Did the guidance in those documents differ from the approach you/the Centre

were then taking to obtaining consent? Did you/the Centre follow the guidance when it was issued?

76) This was shared to me as a member of the committee and further to a regional piece of work in relation to standardising the consent process prior to transfusion of blood or blood products. The approach did not differ from practice. The regional documentation is followed.

Research

30. Please list all research studies that you have been involved with during your time at the Centre. 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 the steps taken to inform patients of their involvement and seek their informed consent; and

h. Provide details of any publications relating to the research.

Please provide the same details in relation to any epidemiological or similar

studies which you undertook or in which you were involved (insofar as they are relevant to the Terms of Reference).

77) Trial: Pro-pact

Steps to obtain approval: Trial design submitted to trust research and development office for consideration and approval, in line with standard procedure

Personal involvement: principal investigator

Funding source: Novo Nordisk

Number of patients recruited: 1

Consent: in line with standard GCP training**

Publications: Thrombo Res 2012 Dec;130(6):864-70. doi: 10.1016/j.thomres.2012.08.305. Epub 2012 Sep 8.

78) Trial: ONE Registry

Number of patients recruited: 2

Publications: Haemophilia 2013 Jul;19(4):571-7. Doi: 10.1111/hae.12140. Epub 2013 Apr 5.

79) Trial: Explore 5

Other organisations involved: MHRA

Number of patients recruited: 1

Publications: Blood. 2019 Nov 28;134(22):1973-1982. doi: 10.1182/blood.2019001542

80) Trial: Explore 6

Number of patients recruited: 3

Publications: Ongoing

81) Trial: Explore 8

Other organisations involved: MHRA

Number of patients recruited: 4

Publications: Ongoing

82) **Good Clinical Practice (GCP) is the international ethical, scientific and practical standard to which all clinical research is conducted. It is important that everyone involved in research is trained or appropriately experienced to perform the specific tasks they are being asked to undertake. GCP training is a requirement set out in the UK Policy Framework for Health and Social Care Research developed by the Health Research Authority for researchers conducting clinical trials of investigational medicinal products (CTIMPs).

31. What do you understand to be the ethical principles that should guide research? Did you apply those principles to the research and other studies referred to above? If not, why?

83) Training was undertaken, and refreshed regularly, in line with GCP certification (WITN3082024), which is required to be in place by all trial team members ahead of opening the trial.

32. Have patients been involved in research studies without their express consent during the time that you have worked at the Centre? If so, how and why did this occur?

84) No

33. Has patient data (anonymised, de-identified or otherwise) been used for the purpose of research or for any other purpose without their express consent during the time that you have worked at the Centre? If so, what data was used and how and why did this occur?

85) No

34. Has patient data (anonymised, de-identified or otherwise) been shared with third parties (e.g. to UKHCDO) during the time that you have worked at the Centre? If so how and why did this occur and what information was provided and to whom?

86) In line with the annual report for bleeding disorders, information on registered patients is fed back to the UKHCDO. This has been in relation to newly diagnosed patients and their treatments. Evidence of past consent and patient information is evidenced in the medical records of patients – an exercise undertaken by a previous consultant.

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

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96) *The acute management of haemorrhage, surgery and overdose in patients receiving dabigatran.*
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97) *Detection of haemophilia A during quality assurance of fresh frozen plasma.*
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98) *Real-world outcomes with recombinant factor VIIa treatment of acute bleeds in haemophilia patients with inhibitors: results from the international ONE registry.*
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Treatment of patients who were infected with HIV and/or hepatitis

36. How has the care and treatment of patients with HIV/AIDS been managed during the time you have worked at the Centre? In particular:

a. What steps have been taken to arrange for, or refer patients for, specialist care?

b. What treatment options have been offered over the years to those infected with HIV?

c. What information has been provided to patients about the risks and benefits of specific treatments and about side effects?

122) A combined clinic is run alongside the HIV specialist Dr S Quah every 3-4 months for those patients infected with HIV. This was established prior to my appointment and continues. Patients are reviewed with their blood results and medication is provided through the regional specialist pharmacy, based at the Royal Victoria Hospital.

37. What follow-up and/or ongoing monitoring has been arranged in respect of patients who were infected with HIV during the time that you have worked at the Centre?

123) As per above.

38. How has the care and treatment of patients with hepatitis B been managed during the time that you have worked at the Centre? In particular:

a. What steps have been taken to arrange for, or refer patients for, specialist care?

b. What treatment options have been offered over the years?

c. What information has been provided to patients about the risks and benefits of specific treatments and about side effects?

124) No current patients, known to have active hepatitis B infection, are known to the Centre. Historically a total of eleven patients were noted with acute hepatitis B infection (WITN3082020).

39. What follow-up and/or ongoing monitoring has been arranged in respect of patients who were infected with hepatitis B during the time that you have worked at the Centre?

125) No current patients, known to have active hepatitis B infection, are known to the Centre.

40. How has the care and treatment of patients with hepatitis C been managed during the time you have worked at the Centre? In particular:

a. What steps have been taken to arrange for, or refer patients for, specialist care?

b. What treatment options have been offered over the years?

c. What information has been provided to patients about the risks and benefits of specific treatments and about side effects?

d. What if any advice has been given with respect to lifestyle, including but not limited, to the consumption of alcohol and different kinds of food?

126) Historically the Centre has offered and provided interferon based therapy, first line, for patients with hepatitis C, when this was the standard therapy. Advantages and side effects of the treatments had been explained to patients.

127) The regional hepatology service manages all patients post liver transplant, those refractory to first line therapy and those with established cirrhosis maintained on their hepatoma surveillance programme. This programme has undertaken to offer six monthly outpatient ultrasound scans as well as serum alpha fetoprotein quantification. Non-interferon based therapy has been coordinated and provided through the hepatology unit.

128) Routine practice has been to counsel all patients infected with hepatitis C and encourage treatment as well as to monitor, through routine blood tests, their risk of progression or change to cirrhosis.

129) Public health recommendations in relation to diet and alcohol intake is encourage and advocated at all times.

41. What follow-up and/or ongoing monitoring has been arranged in respect of patients who were infected with hepatitis C during the time you have worked at the Centre?

130) Routine attendance at the haemophilia outpatient review clinics has liver function and full blood counts as part of the panel and from which APRI has been utilised as a surrogate marker for cirrhosis.

42. In the enclosed two statements [WITN2778001 & WITN277005] Witness 2778 describes their brother's treatment. You are not asked to comment on the specifics of this patient's care, but to address more broadly the following issues that arise out of the statements:

a. In your previous statement to the Inquiry [WITN3082001], you stated at paragraph 10 that standard practice would have been to discharge patients not attending appointments. Did the practice apply to patients with hepatitis C as well as severe haemophilia? What, if any, attempts would you expect to be made to contact the patient and ascertain the reasons for non-attendance? What steps would you expect to be taken

to encourage a patient (particularly a patient who may be vulnerable and/or who may be at risk of developing a serious or life-threatening condition) to attend appointments and/or undergo tests and/or receive treatment?

131) No patient has been discharged from the haemophilia service with a bleeding disorder and hepatitis C. Patients contact the service on a 4-6 weekly basis to organise a supply of their clotting factor concentrate. Centre staff used this opportunity to discuss ongoing issues with the patients and to ensure things are well with them, if there is anything new that has arisen and also to encourage their routine attendance at the outpatient clinic. Serial non-attendance prompts internal verification of patients' home address against their GP details and on occasions, patient and GP are written to in order to encourage them to attend and ascertain any specific barriers. Availability of treatment and its advantages, and side effects, to receiving continues to be reminded to patients.

b. **You also stated at paragraph 10 [WITN3082001] that an accepted frequency for appointments for patients with severe haemophilia would be every six months. Did the six-month frequency you referred to take into account infection with hepatitis C, including where the patient has been infected for a significant period of time?**

132) The standard of care would be that for a six-monthly review for patients with significant life-threatening bleeding disorders.

c. **At paragraph 17 of the enclosed witness statement [WITN277005], Witness 2778 described being told by Dr McDougall in May 2019 that, where haemophiliacs had been infected with hepatitis C through contaminated blood, the national standard was to undertake an ultrasound and/or fibroscan every six months. Is that the approach currently taken for patients at the Centre? If so, when was it adopted and why? If not, why and what is the current approach?**

133) It is my understanding that the context within which the statement was made was in relation to the hepatoma surveillance programme as and when cirrhosis has been diagnosed. This is a six-monthly abdominal ultrasound scan and blood screening as described. The Fibroscan has become a recently accessible service in routine diagnostic usage utilised for cirrhosis assessment and this is undertaken at the outset of hepatitis C treatment to help determine duration of therapy as well as cirrhosis/ fibrosis assessment. As I understand from letters from the hepatology service, the fibroscan is not offered serially further to the established diagnosis of cirrhosis but that it is the abdominal ultrasound scan.

d. Please describe the tests, scans and other monitoring that you would expect to have been undertaken (and the frequency with which you would expect them to have been undertaken) over the period from 2008 to the present in relation to a patient at the Centre who has been infected with hepatitis C.

134) As per response to question 27 – routine blood panels in relation to liver function and full blood counts were taken, alongside the other tests, at each outpatient appointment. For those with hepatitis C, the APRI score was calculated as a surrogate marker for cirrhosis. If the score exceeds 1.0 or a change was noted in the liver function from previous attendance, an ultrasound scan of upper abdomen was requested.

e. Please describe what referrals to other clinical services you would expect to have been undertaken over the period from 2008 to the present in relation to a patient at the Centre who has been infected with hepatitis C.

135) Referrals reflected those of their clinical need and were individualised, as opposed to standard. They could include but are not exhausted to clinical psychology, fertility, dentistry, orthopaedics, general surgery, ENT, rheumatology and hepatology.

f. Please describe what advice and information you would expect to have been provided over the period from 2008 to the present in relation to a patient at the Centre who has been infected with hepatitis C.

136) Supportive advice and information in relation to the chronic symptoms and challenges of living with chronic hepatitis. Sign posting available to the regional hepatology service for further discussion and specific information. Additional testing of sexual partners either through the clinic itself or via a local GP service.

g. Please describe the treatments that you would expect to have been offered to a patient at the Centre infected with hepatitis C over the period from 2008 to the present, identifying when you would expect those treatments to have been offered.

137) Treatments were rediscussed and updated at each outpatient appointment and included any newer agents. Many patients will have had some historical treatment based on interferon and for them no alternative treatment was available outwith clinical trials (none available/organised locally) until the newer treatments. Patients were advised of these therapies and details shared with the hepatology service who were leading on their adoption and use in line with Northern Ireland's implementation of the NICE guidance. All patients have been offered treatment for their hepatitis C infection and one patient remains PCR positive, having currently declined the treatment.

h. In what circumstances would you recommend, or would you have recommended in the past, antidepressants to a patient proposing to undertake hepatitis C treatment?

138) From personal observation of the interferon related treatments, depression was a common side effect and I would have personally recommended and prescribed antidepressant therapy alongside their hepatitis C treatment.

i. **In the enclosed 24 November 2014 letter to Dr Leeson [WITN2778004], you stated that the brother of Witness 2778 was hepatitis C positive and was "treatment naïve due to his on-going trouble with alcohol." Again, without asking you to discuss the particular circumstances of the patient's care, to what extent and why would alcohol consumption be a reason for patients not undergoing treatment for hepatitis C during the period from 2008 to the present?**

139) Ongoing alcohol consumption has been reported to decrease the rate of response to antiviral therapy of hepatitis C. Alcohol may affect the outcome of therapy by decreasing adherence or interfering with the antiviral actions of interferon-based therapy. Interferon acts both as an antiviral agent and an immune modulator (enhancer). Alcohol is known to blunt immune responses. Depression, irritability, and anxiety that occurs in 20% to 30% of patients treated with interferon based therapies. The rate of successful response being reduced and balanced against the side effects, the margin is minimal. Standard advice followed at the time would always be to encourage abstinence from alcohol when considering interferon based therapies.

43. **At paragraph 43 of the enclosed statement [WITN3320001], Dr McCorry commented that it was "of course deeply regrettable that the RVH Liver Unit were not in a position to offer [the patient] modern, effective hepatitis C therapy at a time point before he developed liver cirrhosis and hepatoma". What do you understand Dr McCorry to have meant by "modern, effective hepatitis C therapy"? When did such therapy become available at the Royal Victoria Hospital? In your view, was the availability of modern, effective hepatitis C therapy delayed for patients at the Centre relative to other parts of the United Kingdom? If so, please explain your understanding of the reasons for the delay and its effect on the Centre's patients.**

140) I believe the term 'modern, effective hepatitis C therapy' is applied to the non-interferon based treatment.

141) The specifics surrounding the availability, adoption, and prioritisation relating to these treatments, as well as the waiting times to acquire them, is best answered by the hepatology team as their timelines and possible challenges are not known to me.

44. During the time that you have worked at the Centre, do you consider that the care and treatment available for patients with hepatitis C has been more limited than for patients in other parts of the United Kingdom? If so, please explain your understanding of the reasons for the difference; how it has changed over time; and what if anything you/the Centre/Belfast Health and Social Care Trust have done in response.

142) I have no knowledge of the systems in place in relation to hepatitis C treatment within the rest of the United Kingdom. Again, the specialist knowledge with regards to these newer agents is best addressed to the hepatology department.

45. There are two witness statements from Witness 2339 [WITN2339001 & WITN2339002] which refer to hepatitis C treatment he received following your recommendation. You are not asked to comment on the specifics of Witness 2339's care, but to address more broadly the following issues that arise out of his statement.

a. Were there or have there been delays or other difficulties in patients in Northern Ireland receiving treatment for hepatitis C? If so, please describe them and what you understand their causes to be.

143) In order for a minimal delay in starting interferon-based therapy, this was offered through the haemophilia service from the outset. As for the non-interferon based therapies, this was overseen by the hepatology service which would be best placed to answer this.

b. Did those delays or difficulties result in you making referrals for hepatitis C treatment for patients under the Centre's care?

144) No

c. What were the arrangements for referring patients under the Centre's care for hepatitis C treatment at the time of Witness 2339's treatment? What are the arrangements now?

145) All patients were referred at the time when non-interferon based therapies were available and reviewed by the hepatology team. Prior to this, as and when a patient was willing and able to receive the interferon-based treatment this was made immediately available. All patients have been referred and offered the new treatment, with one patient remaining PCR positive having declined current treatment offer.

d. Were there (or are there now) any tensions or disagreement between you/the Centre and hepatology services/other clinicians in relation to the care and treatment of patients with hepatitis C? If so please explain why or how they occurred and whether they have been resolved.

146) The specifics of the question have arisen in relation to a single patient. The differences of opinions arose between the hepatology specialists with one – Hepatologist A, having advocated consideration towards switching the brand of interferon and continuing the treatment for 12 months as opposed to the standard 6 months. This option was not supported by Hepatologist B. Given that no other alternative therapy was available outwith this, and given the patients willingness to accept a low chance of response, the plan as set forward by Hepatologist A was prescribed and delivered through the Haemophilia Centre.

46. At paragraph 53 of the enclosed witness statement [WITN1383001], Witness 1383 stated that you informed him he would not need to declare

his haemophilia or hepatitis C when applying for life insurance. Do you recall providing this information to patients? If so please describe the advice that you gave them.

147) This is not my recollection of the discussion, which took place with the patient. At all times, patients are informed to complete such applications fully and completely given the risk of failure to pay out owed monies, should they be needed, if at a later date a falsehood is uncovered.

148) I have never informed a patient to lie on an application form. This behaviour goes totally against both my professional and personal conduct. As I recollect the discussion, this was in relation to answering questions and openness and honesty. The question of do you have hepatitis C versus have you had hepatitis C prompts differing answers. Patient was encouraged to answer the question as asked and that additional medical information was available when required by the insurance under writer.

47. What if any involvement have you and/or colleagues at the Centre had with any clinical trials in relation to treatments for HIV and hepatitis C? Please provide details.

149) I have not been involved in clinical trials in relation to treatments for hepatitis C or HIV.

48. What if any arrangements have been made at or through the Centre to provide patients infected through blood products with counselling, psychological support, social work support and/or other support during the time that you have worked there?

150) From my appointment, patients and their families have had an open access in relation to psychology support services through the trust Psychology department. This was not a dedicated service but a general one. Over the years, I have made such referrals. Further to the appointment of a

dedicated social worker, and more latterly dedicated psychology support, this service has developed greatly with clear and open signposting in place.

49. During the time that you have worked there, has the Centre been allocated, whether by government or another source, any funding to help with counselling of patients infected with HIV or HBV or HCV? If so please provide details.

151) Counselling services, as detailed above, have been available in relation to patients with bleeding disorders whether infected or otherwise to avail of support. The appointment of the haemophilia social worker aimed to also provide psychosocial input.

152) A dedicated psychology service has been in place from the outset of the inquiry, and both the psychologist and social worker collaborate closely in relation to the affected and infected families.

50. What kind of counselling if any has been made available to patients during the time that you have worked at the Centre?

153) As per responses to 49 and 50 above.

51. What, if any, difficulties have you/the Centre encountered in obtaining sufficient funding for the treatment of people who have been infected with HIV and/or hepatitis C?

154) No restriction or limitation has ever been encountered in relation to funding in relation to funding for the treatment of people who have been infected with HIV and/ or hepatitis C.

Records

52. What has the Centre's policy or practice been as regards recording information on death certificates when a patient had been infected with HIV or hepatitis during the time that you have worked there?

155) Doctors certifying deaths do so as a statutory duty under the Births and Deaths Registration (Northern Ireland) Order 1976 Section 25(2) which holds that,

"Where any person dies as a result of any natural illness for which he has been treated by a registered medical practitioner within twenty-eight days prior to the date of his death, that practitioner shall sign and give forthwith to a qualified informant a certificate in the prescribed form stating to the best of his knowledge and belief the cause of death, together with such other particulars as may be prescribed."

156) During the time I have worked here, one patient has died under our direct inpatient care who was hepatitis C PCR positive at the time. This was duly recorded on the death certificate.

53. What have the retention policies of the Centre been in regards to medical records during the time that you have worked there?

157) It is my understanding that medical record retention has been in line with standard trust policy, from the time of my appointment.

54. The enclosed 7 June 2011 note of a call between you and Karen Simpson [DHNI0000334] recorded that the Belfast Trust destroyed patient records after 8 years. Has this policy applied to the Centre throughout the time that you have worked there? If so, has it applied to all categories of medical records? Please provide details.

158) Medical record retention has been in line with standard trust policy available at that time.

55. Have you maintained separate files for some or all patients? If so, why; where were those files located; and where are those files now?

159) I have not maintained separate files for some or all patients.

56. Have you kept 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 Centre? If so, why, what information and where is that information held now?

160) I have not kept records or information about any of the patients at my home or anywhere other than the Centre.

57. The Inquiry has heard from a number of individuals who asked to be provided with their own or their relative's medical records. Some of them have described facing difficulties or a reluctance to provide the records; others have commented on the help you gave them to obtain records after facing difficulties elsewhere. What has been your policy on the disclosure of medical records to patients and their family members during the time that you have worked at the Centre? Has it ever differed from the policy adopted by others at the Centre, or by other parts of Belfast Health and Social Care Trust? If so, please explain how and why.

161) All requests for medical record release are signed promptly and marked for full disclosure by myself and no other team member.

162) I am aware of a specific case, which came to light at the start of the Inquiry meeting in Belfast. The witness contacted me, as she had wanted to discuss how she was feeling at the time. The Trust 'Inquiry Team' made up of senior management – medical, nursing and administration as well as myself, had had a recent meeting going through the requests for medical records and their ongoing searches. It was clear that whilst initial searches may have proved fruitless, on subsequent research which involved a slight change in the name of the patient e.g. reversing the first and the middle name or using the name

as given on the birth certificate rather than the name called, had resulted in more records being located. It was one such volume that had been mentioned at this meeting. The witness had called and stated the paperwork, which she had received seemed lighter than I had expected for something referred to as a 'volume'. I advised the witness that I would confirm with the team that I had understood correctly. I confirmed that it was as I had understood and that an additional volume of notes had been recently found. There was no reluctance to declare to the Inquiry.

163) The whole team and I remain fully committed to the provision of patient relative medical records.

Section 5: Blood services and NIBTS

58. Please outline the interactions and dealings you have had with the NIBTS (and with any other blood services, whether on a regional or national level), during the time that you have worked at the Centre.

164) The treatment budget for the Haemophilia Centre resides with the NIBTS. As such regular meetings take place between myself and the accountant for the service. Budget preparation and subsequent allocation is worked on closely.

165) Clinically we work closely with the transfusion consultants in relation to specialist cases whereby HLA matched platelets are required or HPA1a negative platelets for the maternity patients with FMAIT.

166) I have assisted the transfusion consultants, on occasions, when faced with staffing shortages and have covered out of hour shifts.

167) Regular meetings are shared in our attendances relating to the Regional transfusion Committee meetings as well as the Belfast Trust Transfusion committee.

59. Please describe the system at the Centre for keeping records of the blood or blood products that have been used during the time that you have worked there.

168) All blood and blood products, including recombinant clotting factor concentrates, are recorded and dispensed through the blood bank lab centre system. This has been in place throughout the time I have worked at the Centre.

Section 6: UKHCDO

60. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups).

169) As Centre Director, I am a member of the advisory committee and more latterly have joined the working party relating to comorbidities.

61. During the period that you have been involved with UKHCDO, please outline:

a. The purpose, functions and responsibilities of UKHCDO, as you have understood them;

170) The United Kingdom Haemophilia Centre Doctors' Organisation is an association of medical practitioners who work within the Haemophilia Centres of England, Scotland, Northern Ireland or Wales; and have an interest in the care of people with Haemophilia or other inherited bleeding disorders

i) to preserve, protect and relieve persons suffering from haemophilia and other inherited bleeding disorders;

ii) to advance the education of the medical profession, the nursing profession, professions allied to medicine and the general public in the knowledge of haemophilia and other inherited bleeding disorders and their treatment;

iii) to promote or assist in the promotion of audit and research into the causes, prevention, alleviation and management of haemophilia and other inherited bleeding disorders and to disseminate the useful results of such research.

b. The structure, composition and role of its various committees or working groups;

171) Specific clinical and research areas are dealt with by relevant Working Parties. These produce published clinical guidelines, conduct research and data collection.

172) Current committees and working groups cover the following:
Advisory Committee
Data Management Working Party
Co-Morbidities Working Party
Data Analysis Group
Genetics Working Party
Gynaecology Task Force
Laboratory Working Party
Peer Review Working Party
Prophylaxis Task Force
Inhibitor Working Party
Paediatric Working Party
Musculoskeletal Working Party
Von Willebrand Disease Working Party

c. The relationships between UKHCDO and pharmaceutical companies;

173) Full members shall be required, as a condition of their continuing in membership, to declare personal and non-personal interests in the pharmaceutical industry, or in any commercial company linked with the care

of people with inherited bleeding disorders, as described in the Standing Order agreed by the members.

d. How decisions have been taken by UKHCDO;

174) An Executive Committee made up of elected officers and advised by a 34-person committee directs UKHCDO. The Executive Committee meets monthly via conference. The Advisory Committee meets with the Executive Committee three times a year (usually in London). The Executive Committee interacts directly with the DoH on a regular basis, as required.

e. How information or advice has been disseminated by UKHCDO and to whom;

175) Specific clinical and research areas are dealt with by relevant Working Parties. These produce published clinical guidelines, conduct research and data collection and share this openly through their website.

176) An Annual General Meeting of all the membership is held in November of each year.

f. Any policies, guidance, actions or decisions of UKHCDO in which you have been involved and which relate to:

- **i. the risks of infection associated with the use of blood products;**
- **ii. the sharing of information about such risks with patients and/or their families;**
- **iii. obtaining consent from patients for the testing and storage of their blood, for treatment and for research;**
- **iv. vCJD exposure; and**
- **v. treatments for HIV and hepatitis C.**

177) I have had no involvement in relation to the development these policies/guidance as they have predated my appointment.

62. The Inquiry understands that you became a member of the Scotland and Northern Ireland Haemophilia Directors Group in April 2008. Please describe your involvement with the Group insofar as relevant to the Inquiry's Terms of Reference.

178) This was an historic relationship dating back to a working relationship between clinicians in haemophilia and the Northern Ireland and Scottish Blood Transfusion Service relating to Scottish plasma fractionation. Time had marched on and no further relationship existed with SNBTS as clotting factor fractionation had ceased as well as devolved government and health care infrastructure was such that little overlap was justifiable. As such, and further to discussion with the team, I stood down the role for the Northern Ireland service to attend.

Section 7: Pharmaceutical companies/medical research/clinical trials

63. 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 (including dates) of the advisory or consultancy services that you provided.

179) I have not ever provided advice or consultancy services to any pharmaceutical company.

64. 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.

180) No

65. 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 (including dates) and of any financial or other remuneration you received.

181) No

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

182) No

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

183) No

68. 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.

184) No

69. What regulations or requirements or guidelines have been in place concerning declaratory procedures for involvement with a pharmaceutical company during the time that you have worked at the Centre? If you have been so involved, have you followed these regulations, requirements and guidelines and what steps have you taken to comply with them?

185) Conflict of interests are completed further to my role on the trusts Drugs and Therapeutics Committee as well as UKHCDO.

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

186) No

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

187) No

72. If you have ever received funding from pharmaceutical companies for medical research, have you declared the fact that you were receiving funding and the source of the funding to your employing organisation?

188) I have not received funding from pharmaceutical companies for medical research but I have participated in medical research, which has been sponsored by pharmaceutical companies in relation to new product development.

Section 8: vCJD

73. 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?

189) Through the training time 2003- 2008, the risk of transmission of vCJD was part of the role elements of the curriculum. Additional information was sought and delivered through specific conference teaching on the subject and its implication both to the patient as well as public health.

74. How and by whom were decisions taken (either nationally or locally or both) as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?

190) This exercise predated my appointment but reflected and followed the position taken by the UKHCDO at that time.

75. What was the process at the Centre for informing patients about possible exposure to vCJD?

191) This exercise predated my appointment but I was assured of the patient identification and the write out process as well as face to face discussions further to consideration for further write out which arose around 2009/ 2010.

76. How and when were patients told of possible exposure to vCJD?

192) Documented records are filed within patients notes reflecting of two separate letters which were sent out in September 2004 – one to the patient and another to the patients registered general practitioner, by Dr Frank Jones. As this exercise took place prior to my appointment, I have no further knowledge.

77. What information was provided to patients about the risks of vCJD?

193) The letter to the patients referenced 'enclosed' material (not filed) for those who wish to discuss their own situation including whether or not they had received any such batches. A reply form and stamped addressed envelope was provided with the reply form at the back of the 'six page letter to patients' – a copy of has not been filed so I am unaware as to its contents.

78. The enclosed minutes of the 24 March 2009 Scotland and Northern Ireland Haemophilia Directors Group meeting [GGCL000222_001] record that all present expressed concern about the process for a vCJD notification exercise. They also record particular concerns that you expressed. Please describe the concerns expressed by you and others in the group in more detail, with particular reference to their impact on Northern Ireland/patients at the Centre.

194) The vCJD letters and notifications, continue to this day to cause great distress to many of the patients. They often reflect during the consultation how they felt and how many may not have been affected by HIV and hepatitis but that this was alarming, affecting all aspects of their health care. My personal concern was in line with repeating the write out exercise again to the patients affected. Subsequent discussion with the team who had been present at the previous write out, were able to provide assurance of the robust system employed to identify and inform all patients within the service. Given the adoption of recombinant clotting factors and leucodepletion of blood transfusions, there was no additional patients identified between the two time points and a such the distress was inevitable and therefore subsequent repeat correspondence was not considered appropriate at the time.

79. In the enclosed 24 August 2009 letter to Dr Paige [WITN2340013, pg.46-47], which resulted from the cancellation of a patient's ophthalmological operation, you stated that the patient's vCJD risk was theoretical as he had not been exposed to a plasma product from which a donor had subsequently died of vCJD. You also stated that the risk was similarly theoretical for all of your patients. Did you discuss this issue with your patients? If so please provide details. What were the consequences for your patients of being regarded as at risk? How do you think patients in respect of whom the risk is, as you describe it, "theoretical", should be and should have been treated?

195) As part of the notification letters, patients were identified and informed, as a whole, based on them having received factor concentrates from UK blood donors between 1980 and 2001. In discussion with the team and records available at the time, it was known that the specific patient had not received any concentrate/product which was identified as having been from a patient who subsequently died from vCJD. Moreover the explanation of infective risk of different tissues required clarification as the blanket risk is not all procedures but only those with a high infective risk such as the posterior chamber of the eye, lymph nodes and spinal cord/brain.

80. In the enclosed 6 June 2009 email [DHNI0000145], Dr Heather Livingston recorded a conversation she had with you about issuing letters to patients about vCJD risks. She stated that HPA letters [DHNI0000145_001 & DHNI0000145_002] were not being sent out on the basis that all patients had already received verbal information and that the same approach had been taken to previous letters in February 2009. Does the email accurately record the reasons for not providing these letters to the Centre's patients? If it does, when were patients provided with verbal information, what were they told and what was the information based on? Does the reference to patients being told about "their risks" mean that the risk had been assessed for particular patients rather than assessed for categories of patients? If so, how was the risk for each patient assessed?

196) Reasons for not sending out further letters are as per above 78 + 79.

81. The Inquiry has heard from patients at the Centre who described receiving letters informing them about risk from vCJD prior to 2009, for example, in 2004 and 2006. Please see enclosed an example of such a letter [WITN1383002]. Were such letters sent by the Centre or by other organisations or bodies? If they were provided by the Centre, why did letters stop being sent in 2009?

197) Letters were sent by the Centre. Further letters in 2009 were not deemed required as there was nothing new or different from what the patients and their GPs had already been informed. Also no additional new patients had been identified due to the adoption of recombinant clotting factor concentrate.

82. What counselling, support and/or advice was offered to patients who were informed that they might have been exposed to vCJD?

198) The letter had stated if face-to-face consultation and discussion was required to self-report to the service. I am unaware as to whether this service was availed of by any patients. Further to my own appointment, open discussion in relation to vCJD and its impact is discussed. Ongoing support is available through social worker and psychology meetings as well as clinical clarity from the Centre as and when queries arise.

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

199) The Trust had established a vCJD group to manage a work list to identify patients at risk ahead of surgical procedures, including endoscopy, to best manage patients and ensure no delay in health access occurred. As part of the group, it was agreed that I would be the contact person within the Trust, based on the assumption that the majority of patients would fall with the congenital bleeding cohort.

Section 9: Involvement with the financial support schemes

84. What if any involvement have you had 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?

200) My involvement has been the completion of relevant paperwork for the patient and/or their families and supporting them in the process. I have had no additional contact outwith this area.

85. To the extent that you had any involvement with the trusts or funds or with the applications made by patients for assistance, please answer the following questions in respect of the time that you have worked at the Centre:

a. To what extent did the Centre and its staff (including you) inform patients about these different trusts or funds?

201) Patients attending the Centre were openly advised in relation to these services. In discussion with the local handling of the financial scheme, further to its sign over, and cross checking patients and/or families infected – there is complete concordance.

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

202) I am unaware as to whether a policy or guideline existed.

c. What kind of information did the Centre (whether through you or otherwise) provide to the trusts and funds about or on behalf of patients who were seeking assistance from the trusts and funds?

203) Standard application forms were provided, completed and returned on behalf of the patient and/or families.

d. Did the Centre, or any of its staff (including you), 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.

204) I have not acted as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance outwith providing confirmatory medical information in line with the scheme.

e. Was the Centre or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

205) I was not involved in determining applications made by patients for assistance from the trusts or funds.

f. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of the Centre's 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?

206) I am unaware of any negative feedback from any patient in relation to how the trusts and funds were run. I understand an exercise is currently underway by the local scheme, seeking patient feedback. I am aware of a patient who was turned down for Part 2 Skipton Fund financial support due to failure to prove that cirrhosis was caused purely by past hepatitis C infection and not also by body mass index and alcohol intake.

The Skipton Fund

86. The enclosed 21 February 2011 email [DHNI0000331] records that you had recently met with Ms Simpson and Dr Elizabeth Mitchell in relation to the Skipton Fund. What was the context of and reason for the meeting and your continued correspondence with Ms Simpson? Also enclosed is a 24 March 2011 email [DHNI0000431] from Ms Simpson forwarding a DHSSPS press release regarding new financial support measures in Northern Ireland.

207) I had met to discuss my concern in relation to the exercise undertaken in October 2010 in relation to the inclusion of patients who predeceased August 2003 Skipton scheme and the meetings of families face to face. Given the ask in having to provide evidence to support the application of confirmed

hepatitis C PCR, I was worried in raising an expectation only to let the families down.

208) Ms Simpson was tasked with all things relating to the contaminated blood patients, hence ongoing close working.

87. In the enclosed 18 September 2011 email to Ms Simpson and Dr Mitchell [DHNI0000974], you provided an update on the progress of haemophilia patients in accessing the Skipton Fund. Please provide some further context to the email and describe your/the Centre's involvement. In doing so, please explain your references to "working through" and "tracing" patients, as well as your involvement in obtaining supporting information. You also recommended the appointment of a social worker and a data manager. Please explain further why you made those recommendations, and whether either of them was ever implemented.

209) Both social worker and data manager have been funded, recruited and appointed to post.

210) Further to the changes in the Skipton fund now including patients who had predeceased the inception of the fund, I required to review all records available to me and review information available to help support families. Many of these families no longer had ongoing contact with the Centre due to the death of the relative. In advance of writing out to them, as and when an address was available, I wanted to ensure that all of the correct information was to hand to fully support the applications. I undertook this work alongside colleagues with their memory of the patients at that time as well as the virology department in reviewing local records in relation to hepatitis C PCR testing and results.

88. In the enclosed 21 September 2011 response to your email [DHNI0000974], Ms Simpson noted that only a very limited amount of money was available for counselling services.

a. Did you suggest any ways it could be used?

211) I advised seeking full time funding for a social worker with a desired background in psychosocial work. This was taken forward and fully funded and appointed by the Special Medical Commissioning Group.

b. Ms Simpson also stated that the posts you had recommended would have to be taken forward by the Belfast HSC Trust with the Health and Social Care Board. Were they?

212) As per above 87 – both posts were funded, advertised and recruited to further to discussion with the Specialty medical Commissioning Group.

c. Were any additional resources found to fund counselling, a social worker and/or a data manager? If not, what was the impact of the lack of funding?

213) As per above 87 – both social worker and data manager were fully fund as whole time equivalents.

Infected Blood Payment Scheme for Northern Ireland

89. The Inquiry understands that you were involved in the creation of the Infected Blood Payment Scheme for Northern Ireland, established in October 2017. In particular, the Inquiry understands that you were asked about the scope of the scheme before it was set up, that you completed the medical aspects of the applications and that you were consulted about the appeals process (in particular, assisting with the choice of an expert for the appeal panel). Is that correct? If so, please provide details of your involvement on each of those elements of the scheme, as well as any other involvement you have had with it.

214) I was not involved in the creation of the Infected Blood Payment Scheme for Northern Ireland.

215) I was not asked about the scope of the Scheme before it was set up.

216) I was not consulted about the appeals process nor did I assist with the choice of an expert for the appeal panel.

217) I complete the paperwork in relation to patients applying to the scheme alongside the hepatology team.

90. The Inquiry understands that you have provided supporting letters for discretionary payments for individuals accepted onto the scheme. If that is correct, please describe the nature of your involvement and the kind of information you have provided.

218) I have been asked to submit information in confirming an individual's eligibility to apply ie that they have been infected.

91. Based on your own dealings with the scheme and/or based on your knowledge of the experiences of the Centre's patients in relation to the scheme, do you consider that it is well run? Do you consider that it is achieving its purpose? Are there difficulties or shortcomings in the way in which it operates or in its dealings with applicants for assistance?

219) I have only had positive dealings fed back to me from patients who have accessed the local scheme and the team handling it.

<u>Section 10: Current haemophilia care and treatment</u>

92. The questions in this section are aimed at enabling the Inquiry to understand how haemophilia care is currently provided and how the provision of care and treatment and the approach to patients may have changed over the years. Please describe:

a. How the provision of care and treatment for bleeding disorders is currently organised at the Centre; and

b. Your current roles and responsibilities at the Centre.

220) Care and treatment are followed through using national standards from the UKHCDO and the Haemophilia Alliance service specification. Unlike England, the NHS does not subscribe to CQUINN and/or quality standard dashboard.

221) The service is externally reviewed in line with all other Haemophilia Comprehensive Care Centres throughout the UK. The most recent having been last year, and part of the West Midlands quality review process. (WITN3082025, WITN3082026, WITN3082027, WITN3082028).

222) The service is funded through the Regional Specialty Commissioning Group who meet the cost of the clotting factor concentrates and have worked alongside the service in providing funding and support for additional roles including physiotherapist, social worker, data manager, nursing, additional consultant and a second clinical scientist and a dedicated occupational therapist – the only one in the UK.

223) My roles and responsibilities within the Centre remain unchanged from my original job description (WITN3082016).

93. Please outline the treatments currently provided to patients with bleeding disorders at the Centre.

224) Treatments provided are in line with the national tender process for recombinant factor VIII and IX as well as the framework for all other clotting factor concentrates.

225) For the rare platelet disorders – Bernard Soullier syndrome/Glanzmann thrombasthenia/Hermansky, Pudlak syndrome, the only available therapy is

apheresis platelet transfusions on demand which are provided through the blood transfusion service.

94. Please describe how you typically obtain your patients' consent to treatment. In particular:

a. What information do you give patients about the risks of the treatment?

b. What information do you give patients about the side-effects of the treatment?

c. What information do you give patients about the risks of not having the treatment?

d. What information do you give patients about the benefits of having the treatment?

226) Risks/side effects specific to the individual products and in line with their clinical trial licensing data. Risks/side effects such as inhibitor/antibody development, anaphylaxis, loss of efficacy, virus transmission for plasma derived concentrates – known and as yet unknown.

227) Risks of not having treatment are dependent on the nature of the bleeding disorder and the bleeding episode encountered – e.g. spontaneous or further to surgery. Delay in achieving haemostasis and impaired wound healing, increased risk of blood transfusion due to prolonged bleeding. Discuss alternatives, if available.

228) Bleeding risk for surgery becomes the same as another patient having the procedure who does not have a bleeding disorder. Less likelihood of needing a blood transfusion. Improved wound healing.

95. Please describe how you typically record your patients' consent to treatment.

229) Consent is recorded verbally as part of the consultation process ahead of providing factor concentrate/blood products. Patients concerns are noted and discussed.

230) Treatment escalation plan explored and discussed.

96. Do you routinely take blood samples from patients attending the Centre? If so, what information do you provide to patients about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so how and is that recorded?

231) This is answered earlier, 27.

97. Please describe how you typically (a) obtain and (b) record your patients' consent to testing of any kind.

232) Blood tests are discussed at each consultation as to the type of tests needed and the reason behind these. Verbal consent is provided.

98. How many current patients at the Centre were:

a. Infected with HIV through blood products;

233) Three

b. Infected with hepatitis C through blood products;

234) From the original cohort, one remains positive.

c. Infected with hepatitis B through blood products;

235) Zero

d. Co-infected with HIV and hepatitis C through blood products?

236) All three, but are hepatitis C PCR negative

99. What, if any, involvement do you have/does the Centre have now in the treatment of the Centre's patients for HIV and/or hepatitis C and/or hepatitis B? Are there multidisciplinary clinics (e.g. haematology and hepatology), and if not would such arrangements be feasible and beneficial?

237) A combined clinic is run for those infected with HIV.

238) Patients on the hepatoma surveillance programme are followed up through the hepatology department.

239) Currently one patient remains hepatitis C PCR positive. Treatment has been offered but currently the patient has declined. He continues under active review in the Haemophilia Centre and has an open review at the hepatology service for as and when treatment is accepted.

100. What, if any, psychological services are available at the Centre? Do you have a psychologist as part of the staff team? Is there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

240) A psychologist and social worker are available to patients and families infected and affected by the consequence of infected blood products.

101. What, if any, other support services are available at the Centre?

241) Physiotherapy, occupational therapy, nursing.

102. What has been the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. Upon patients at the Centre (without identifying any individual patient);

b. The ways in which decisions about treatment and care are taken, and treatment and care are provided, at the Centre?

242) The impact upon the families infected and affected has been significant in relation to the down stream effects of the loss of a brother, husband, son and father. I have seen how families have lost a second income coming into the home necessitating moving house and lost opportunities in education and forming relationships during vital formative teenage years due to fear of disclosure.

243) Northern Ireland is a very small place and families have kept infections secret not just from the communities in which they live but also from other family members, due to the stigma which they had witnessed during the 1980s and 1990s.

244) More latterly since the start-up of the Inquiry, the hurt and distress voiced and shared by the patient group has been overwhelming – more so now than it was ever in the recent past of which I have a memory.

245) It has best been described to me by the wife of an infected patient as "it all feels life is like a snow globe. For many years it sat, settled and undisturbed. Now someone has picked it up and given it shake and the snow is whirling all around – chaotic and control has been lost."

103. Has the infection of patients with HIV and/or hepatitis B and/or hepatitis C through blood products:

a. Changed or influenced your professional practice and approach and if so, how?

246) It has had a profound effect on my professional practice. The service is not just consultant lead but also consultant delivered. I have got to know each and every one of the patients and their families over the years that I have been the Centre Director.

b. Changed or influenced the practice and approach of your colleagues and if so, how?

247) It is not a topic or subject that I have ever spoken to any of my consultant colleagues about.

c. Changed or influenced the way in which haemophilia care is now provided and if so, how?

248) Because of what happened, haemophilia care is unrecognisable today in Northern Ireland. Beyond the provision of products, the assembled team are available to look at patients as people as opposed to being defined by their bleeding disorder. This holistic approach has had a positive impact on how patients view themselves and have moved the focus from what they are not able to do because of their bleeding disorder, towards a perspective of what they can do.

Section 11: Other issues

104. 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 Northern Ireland Public Services Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

249) As part of annual appraisal, complaints are reviewed annually. I can confirm that no complaints have been registered against me, either with the employer, the General Medical Council, to the Northern Ireland Public Services

Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

105. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry.

250) I believe that the questions and my responses as set out above, cover the whole range of issues covered by the terms of reference of the inquiry.

Statement of Truth

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

Signed GRO-C

Dated 30-11-2020

Table of exhibits:

Notes/ Description	**Exhibit number**
Job description	WITN3082016
General registrar training curriculum 2003	WITN3082017
Specialist registrar training curriculum 2003	WITN3082018
LBT transfusion certificate	WITN3082019
The Ulster Medical Journal, Volume 60, No. 1, pp. 63-74, April 1991. Human immunodeficiency virus infection in Northern Ireland 1980-1989	WITN3082020
The Ulster Medical Journal, Volume 58, No. 1, pp. 72- 82,	WITN3082021

April 1989. Hepatitis B virus infection in Northern Ireland 1970- 1987	
Contaminated blood sufferers with hepatitis C benefit from new payment scheme	WITN3082022
Patient list	WITN3082023
GCP e learning certificate	WITN3082024
Belfast Adults UKHCDO Audit 2006/7	WITN3082025
Belfast Adults UKHCDO Audit 2008	WITN3082026
Belfast Adults UKHCDO Audit 2012	WITN3082027
IABD Quality Review Belfast Adults 2019	WITN3082028