Witness Name: Nicholas Phin
Statement No.: WITN7099001
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Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR NICHOLAS PHIN

I provide this statement in response to a request under Rule 9 Request of the Inquiry Rules 2006 dated 18 November 2021

I, Dr Nicholas Phin, Director of Public Health Science and Medical Director at Public Health Scotland, will say as follows: -

Section 1: Introduction

Public Health Scotland (PHS) / NHS National Services Scotland (NSS) Antimicrobial Resistance and Healthcare Associated Infection (ARHAI Scotland) Joint Response to Rule 9 Request of 18 November 2021.

Response informed by existing institutional memory and understanding of events, provided by:

- Dr Anna Molesworth (Consultant Healthcare Scientist, PHS, 11/2020 to present), in relation to time spent at the Health Protection Agency (HPA) between 05/2002 and 03/2006, and at the UK National CJD Research & Surveillance Unit (NCJDRSU) between 08/2010 and 11/2020;

- Dr Hester Ward (Consultant Epidemiologist/in Public Health Medicine, NSS, 11/2009 to present), in relation to time spent at the NCJDRSU with an honorary role with Scottish Centre for Infection and Environmental Health (SCIEH) and with Health Protection Scotland (HPS) between 09/1999 and 11/2009, and with an honorary role with HPS 2014-2019;

- Mrs Annette Rankin, Nurse Consultant Infection Control, HPS/ARHAI Scotland (12/2009 to present);

- Dr Oliver Blatchford, Consultant Epidemiologist/in Public Health Medicine, HPS (11/2008 to 10/2014, retired);

- Dr Martin Donaghy, Medical Director, SCIEH/HPS (01/2003 to 01/2013, retired).

1. **The Inquiry seeks to understand the remit of your organisation in so far as it relates to the Inquiry's Terms of Reference.**

    a. **Please provide an outline of the role, function and responsibility of the SCIEH from 2003 until it became a part of the HPS in 2005**

    (SCIEH, 2003-2005). The SCIEH was established as an NHS body, part of the then Common Services Agency to provide the functions of surveillance of communicable diseases and of the impact of environmental hazards; operational support to public health teams in Health Boards, local authorities and Scottish national agencies; research and development on communicable disease and environmental health, education and training. In relation to vCJD and blood/blood products, the SCIEH was involved in two issues:

    - the risk of vCJD developing in those who had been transfused with blood donated by a person who subsequently was diagnosed with vCJD, and the public health management of such recipients;

    - the risk of vCJD developing in those who had been treated with UK sourced plasma products derived from blood donated by a person who subsequently was diagnosed with vCJD, and the public health management of such patients.

During this time, public health matters relating to vCJD at SCIEH were handled by Martin Donaghy, Medical Director, working closely with Hester Ward as CJD Lead and internal CJD work was aligned closely with the healthcare associated infections (HAI) service. Through them, SCIEH liaised closely with the Scottish Executive Health Department (SEHD), Scottish National Blood Transfusion Service (SNBTS) and Health Board Consultants in Public Health Medicine (CPHMs) as well as the HPA, NCJDRSU and the UK CJD Incidents Panel, of which Hester Ward was a member. This liaison helped discharge SCIEH's role of giving specialist advice on policy, which in relation to CJD was mostly decided at UK level.

b. Additionally, please provide an outline of the role, function and responsibility of the HPS from 2005 until 2020.

(HPS, 2005-2020). In light of growing awareness of infectious and environmental threats to health, and the need for greater local, regional and national cross UK coordination and European working, HPS was established as part of NHS National Services Scotland with an expanded remit to enhance consistency, cohesion and effectiveness in health protection. The functions were:

- Monitoring hazards and exposures and their impact on health;
- Co-ordinating health protection activity in Scotland;
- Facilitating the effective response to outbreaks and incidents;
- Monitoring quality and effectiveness;
- Expert impartial advice;
- Research and development;
- Development of a competent workforce;
- Commissioning National Reference Laboratories.

With regard to vCJD, given the UK-wide population exposure to bovine spongiform encephalopathy and that almost all policy related to vCJD was decided at a UK level, HPS discharged its functions related to vCJD in close relationship and within the framework established by the then HPA (subsequently Public Health England (PHE)). On vCJD and blood/blood product related issues, HPS activities included:

i. development and implementation of UK-wide guidance on CJD incident management, including membership of the UK CJD Incidents Panel (Hester Ward) and working closely with HPA/PHE);

ii. providing advice and support to NHS health boards on reducing transmission risk of CJD in healthcare settings (particularly infection prevention and control in relation to surgical procedures and in incident management), in order to prevent the potential spread of vCJD. This included through membership of the Scottish National CJD Working Group (formerly Scottish CJD Healthcare Delivery Support Group), secretarial support for which was provided by HPS;

iii. long-term public health monitoring of people who have been identified as at increased risk of CJD in Scotland; contributing data to HPA/PHE to inform UK national monitoring of individuals at increased risk;

iv. HPS was involved in the management of three further national incidents, coordinating the notification of patients, and providing information and advice to those at increased vCJD risk and the healthcare professionals involved in their notification and care :

- the risk of vCJD developing in those who had donated blood to a person who subsequently was diagnosed with vCJD, and the public health management of such donors;

- the risk of vCJD developing in other recipients of blood from donors who also donated blood to a person who subsequently was diagnosed with vCJD, and the public health management of such recipients;

- de-notification of vCJD risk, in coordination with the process in England.

HPS collaborated closely with SNBTS and the SEHD (subsequently the Scottish Government), and internally aligned its work on vCJD and blood with that which was being undertaken by its ARHAI service on the risks of CJD and surgical instruments. Regarding monitoring, expert advice and R&D functions, HPS continued close working relationships with the HPA,

NCJDRSU and UK CJD Incidents Panel. Public health matters relating to CJD were handled by the HPS Infection Control / ARHAI service during this period, overseen by Martin Donaghy and Hester Ward until the end of 2009, then by Oliver Blatchford and then Hester Ward (NSS) again from 2014 until 2019.

c. Lastly, please outline the role, functions and responsibilities of PHS from 2020 to present day.

(PHS, 2020 – present). Following concern that existing organisational arrangements potentially contributed to a lack of public health leadership in Scotland, Public Health Scotland was created on 1 April 2020 to provide a single organisational locus for public health in Scotland. The NSS Public Health and Intelligence business unit, with the exception of NSS ARHAI services, moved from NSS to PHS, together with another organisation called Health Scotland to form Public Health Scotland. NSS ARHAI services remained with NSS, where it discharges the following national functions in Scotland:

- Surveillance and monitoring of HAI and Antimicrobial Resistance (AMR);
- Co-ordinating HAI prevention and AMR containment programmes;
- Giving expert advice and identifying future risks;
- Preparing for and responding to outbreaks and incidents;
- Supporting the development of the infection prevention and control (IPC) workforce;
- Supporting the commissioning of HAI and AMR specialist/reference lab services;
- Performing research and innovation to provide evidence for IPC

The vCJD-related activities that had until 2020 been undertaken by HPS currently remain under the ARHAI programme on Infection Control in the Built Environment and Decontamination within NSS, led by Annette Rankin, Nurse Consultant Infection Control. Within PHS, Anna Molesworth provides a point of contact and general information and triage for health protection.

Section 2: Knowledge of risk of vCJD transmission via blood transfusion and blood products

The Inquiry seeks to gain an understanding as to how knowledge of risk of vCJD developed over time within the UK Government, Blood Services, Haemophilia Centres and other NHS organisations and the adequacy of their response.

Please provide the following:

2. **A chronological summary of the information and knowledge held within your organisation of the key events addressing the risks of vCJD infection and the risk of secondary transmission via blood and blood products.**

   To the best of our recollection, knowledge and understanding, the key events were:

- 1996: a new variant of CJD (vCJD) was identified in the UK. There was no evidence at that time that vCJD would be transmitted by blood, but the possibility that this might occur led to the design and implementation (in 1997) of the "Transfusion Medicine Epidemiological Review (TMER)" study - a collaborative study between the NCJDRSU and National Blood Service, seeking evidence of transmission of CJD through blood transfusion;

- 1997 – 2004: general measures were taken by the UK national blood services to reduce the risk of vCJD transmission through the blood supply. These included the withdrawal and recall of implicated blood components and plasma products (1997), importation of plasma from the USA for fractionation and leucodepletion (1999), importation of fresh frozen plasma for some patients and donor deferral (2004);

- 1999: a risk assessment from Det Norske Veritas (DNV) Consulting, commissioned by the Department of Health (London), considered the risk of vCJD in blood and blood products (updated in 2003);

- 2000: formation of the UK CJD Incidents Panel (CJDIP), reporting to the Advisory Committee on Dangerous Pathogens (ACDP) TSE sub-group and considering the risk of vCJD transmission in the healthcare setting. SCIEH/HPS were represented on the UK CJDIP and supported Health Boards in the public health management of vCJD risk;

- 2003: the first case of possible transfusion transmitted vCJD was detected through the TMER, in a recipient of blood from a donor who later developed vCJD (published 02/2004). Also in 2003, the UK notification of recipients of blood from donors who later developed vCJD proceeded, undertaken in Scotland by SNBTS and the NCJDRSU, with support from SCIEH;

- 2004: second instance of vCJD infection detected by the NCJDRSU in an asymptomatic recipient of blood from a donor who subsequently developed vCJD (published 08/2004);

- 2004: the assessment and international notification of potential exposure of patients to vCJD through their treatment with certain UK sourced plasma products; led by HPA and coordinated in Scotland by SCIEH;

- 2005: the UK notification of donors of blood to people who later developed vCJD proceeded, led by HPA and the national blood services, coordinated in Scotland by HPS working closely with SNBTS;

- 2005: the UK notification of other recipients of blood from donors who also donated blood to a patient who later developed vCJD, led by HPA and the national blood services, jointly undertaken in Scotland by SNBTS and HPS;

- 2006 and 2007: two further cases of vCJD were detected through the TMER mechanism, both linked to the same donor who his/herself went on to develop vCJD;

- 2008: asymptomatic infection detected in a bleeding disorder patient, attributed to their treatment with UK sourced plasma products, 1980-2001 (published 2010);

- 2009: changes to the pre-surgical assessment for vCJD risk to include certain highly transfused patients; HPS disseminated information about the changes and provided information for patients and clinical information to support Health Boards should patients be identified and notification required, in line with the process in England, led by HPA. Also in 2009, HPS HAI team became responsible for the management of records of those people (excluding Haemophiliacs and PID patients) who were at increased risk of CJD for public health purposes;

- 2011: HPS HAI team commenced annual follow-up of patients at increased risk of CJD resident in Scotland, in collaboration with NHS Boards and the patients' GPs, contributing to the long-term public health monitoring throughout the UK led by UKHSA (previously HPA/PHE);

- 2015: HPS undertook the de-notification of certain patients in Scotland, in coordination with the PHE-led process in England, which followed a revised Department of Health (London) assessment on the risk of vCJD transmission through blood in 2013.

3. **A summary of the steps taken by your organisation to ensure that the Government, Blood Services, NHS bodies, medical profession and patients were informed and educated about the risks of vCJD transmission via blood and blood products. (Please see: NCRU0000143_013, ICHT0000049)**

   We have limited knowledge of the precise steps taken to ensure stakeholders were informed. In general, however, in relation to issues concerning vCJD and blood, SCIEH/HPS liaised and collaborated closely with SNBTS and the SEHD (subsequently the Scottish Government), Health Board Medical Directors and CPHMs, who they supported in public health issues, including the management of incidents in relation to patients at increased risk. SCIEH/HPS also had a close working relationship with HPA/PHE, with whom it aligned its work, and with NCJDRSU and UK CJD Incidents Panel. These liaisons ensured that all parties, including SCIEH/HPS, were kept informed of developments and the risks of vCJD transmission though blood/blood products.

   In terms of patient and clinical communications, SCIEH/HPS discharged its functions within the HPA/PHE led framework. In any notification process, stakeholder groups were identified, involved and consulted, in meetings, teleconferences and by email and telephone. Proposed management strategies for the different patient notifications and the underpinning information were presented to and discussed by the CJD Incidents Panel, amongst whom were lay members and ethicists. In relation to the plasma products notification we also recall attending workshops for extended groups of professional and patient representatives, and strategies were discussed with all stakeholders until consensus was achieved. The proposed approaches were finally endorsed by the CJD Incidents Panel and Department of Health, following which professional, patient and public information materials were developed by SCIEH/HPS with stakeholders, to support the notification processes, using HPA materials which had been drafted with the four nations in mind. These materials included detailed instructions for clinicians regarding the

notification of 'at-risk' patients, draft patient letters and clinical notes to assist in patient consultation, patient information sheets and draft letters for communicating with other clinicians. The materials were tailored for the various professional groups involved in the tracing and notification of patients in Scotland for other groups who would be involved in supporting the process and to address general public information requirements.

In terms of informing the wider public we understand that a range of communications were used in notifications, including the SCIEH weekly health protection report, briefings and presentations to public health teams within Health Boards. SEHD led press releases and media work.

To the best of our knowledge, we are not aware of any further information held by PHS/ARHAI Scotland that may help provide a more definitive response

4. **An account of your organisation's understanding of the relative risks of vCJD infection from the use of domestically sourced blood and blood products and the use of commercially supplied blood products. (Please see: NHBT0001283_003)**

To the best of our knowledge, these decisions were made by the blood services with the advice of experts, drawing also on risk assessments from Det Norske Veritas and the Department of Health (London). SCIEH/HPS were not involved in this process, and we are unable to provide comment on this. We recommend contacting SNBTS, also part of the same common body at the time, NSS, who may be able to provide further understanding on this issue.

Section 3: Actions and Decisions

The Inquiry seeks to understand what actions the Government and other organisations took in response to the risk of vCJD transmission via blood and blood products.

5. **Please provide an outline of any proposals, whether accepted or not, that were made either to or by your organisation in an effort to protect the blood supply from the risk of vCJD.**

Responsibility for protecting the Scottish blood supply from vCJD risk lies with the SNBTS. Beyond our involvement in patient notification and the public health management of those at increased risk, to the best of our knowledge there have been no such proposals made to or by SCIEH, HPS, PHS or ARHAI Scotland.

6. **In addition, please provide the following:**

   a. **Your opinion as to whether the risk of secondary transmission via blood and blood products was adequately mitigated in the UK in line with what was known about the potential risks of vCJD at that time. (Please see: NHBT0001283_003)**

      Based on our knowledge and understanding of this issue and in line with what was known at that time, our view is yes. The UK blood services took a precautionary approach when faced with uncertainty. Regarding vCJD, leucodepletion and the importation of plasma from the USA for fractionation were amongst the measures taken to reduce the risk of vCJD transmission through the blood supply. To the best of our knowledge, no instances of secondary transmission via blood and blood products have been identified since these measures were put in place. In the UK to date there have been four instances of probable transfusion associated transmission of the vCJD agent, all associated with the transfusion of non-leucodepleted blood from asymptomatic donors who subsequently died from vCJD. There has been one additional instance of asymptomatic vCJD infection, reported in 2008, in a patient treated with UK sourced plasma products before 2001.

   b. **Your view as to whether any decisions or actions could and/or should have been made earlier and how this might have impacted the number of individuals considered to be at risk of developing vCJD.**

      The first cases of vCJD had come to the attention of the CJD Surveillance Unit in 1995, only a few years previously, and whilst scientific knowledge was accruing, there was still great uncertainty about the risk of secondary transmission via blood and blood products at that time (1998), and no evidence that this had occurred. Based on our knowledge, understanding and recall of this issue, we believe that decisions were made as soon as they could have been, based on what was known about this new disease and its potential risks. We are not able to know how implementing these decisions earlier would have affected the number of individuals to be later considered at-risk of developing vCJD.

Section 4: Screening and Diagnostic Testing

7. **The Inquiry is aware that a prototype test for vCJD is available through the National Prion Clinic. This test is advertised on the NHS' website, please visit: https://www.nhs.uk/conditions/creutzfeldt-jakob-disease-cjd/diagnosis/**

   a. **Is it usual procedure for a prototype to be advertised on the NHS website? Please expand on why this is acceptable or whether this test is an anomaly.**

   Our understanding is that a number of tests may be carried out by neurologists to assist them in making a diagnosis of CJD, and the prototype has been listed amongst these tests. It is outside our knowledge if it is usual NHS practice to list prototypes amongst the range of tests used in clinical diagnostic practice - we have no expertise in this area. We recommend contacting specialist diagnostic services at the NCJDRSU (Edinburgh) and NPC (London) who may be able to provide further information in this respect.

   b. **Are pre-surgery patients and/or blood donors routinely asked about their vCJD notification status? If yes, when was this measure adopted?**

   Pre surgical patients are asked a single question in line with the ACDP's guidance on minimising transmission risk of CJD in healthcare settings, Annex J (available from: ANNEX J - PRE-SURGERY ASSESSMENT TO IDENTIFY PATIENTS WITH, OR AT RISK OF, CJD (publishing.service.gov.uk)). All patients about to undergo any elective or emergency surgical or endoscopic procedure should be asked the question: "Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?" Annex J was published in 2006.

   c. **Has the 2021 vCJD update, re-introducing the use of UK Plasma, had any effect on the questions asked of pre-surgery patients and/or blood donors?**

   Our understanding is not, but full details of this are outside our collective knowledge. The single question in Annex J remains unchanged and therefore NHS Boards are unlikely to have changed the pre surgical question. We recommend contacting the UK blood services regarding donors.

Section 5: Product recalls

The Inquiry is aware of a series of product recalls between 1997-2000 upon instruction from the Medical Controls Agency in relation to concerns of the possible risks of vCJD transmission from the use of vCJD implicated blood products. The Inquiry seeks to gain an understanding as to what, if any, information was relayed to the recipients of blood and blood products which were recalled.

8. **Did SCIEH/PHS have any input into these? If so, please give details and in particular please set out what ethical advice was sought on the issue of whether or not recipients of vCJD implicated blood and blood products should be notified.**

   SCIEH had no involvement. To the best of our knowledge, the 1997-2000 blood product recalls were handled by the UK blood services working with the product manufacturers and their consignees.

Section 6: Notification exercises

The Inquiry has heard evidence of the experiences of a number of infected and affected individuals who were notified of their 'at risk' status of vCJD. The Inquiry seeks to gain an understanding of the rationale behind policy decisions made in elation to notifying at-risk individuals and how this changed over time. (You may be assisted by the following: DHSC0004555_176, NCRU0000143_007, SCGV0000098_125, LOTH0000082_013, NCRU0000143_013, GRAM0000107, ICHT0000049)

9. Please provide the following:

a. **A chronological summary of the knowledge held within your organisation in relation to the issues surrounding notification of risk to individuals deemed to be at risk of vCJD.**

   Please see response to question 2. The rationale behind the policy decisions were discussed by CJDIP; HPA enacted the policy decisions and SCIEH/HPS discharged its functions within the framework established by the HPA/PHE.

b. **A summary of the views, opinions and decisions regarding notification arising from the CDJIP consultation process in 2000.**

This information may be obtained from files held by the HPA, which housed the secretariat for the CJDIP. We do not hold this information at PHS/ARHAI Scotland.

c. **An outline of any policies and practices which were implemented across the U.K. in relation to patient notification and de-notification.**

Pre surgical patients are asked a single question in line with the ACDP's guidance on this (available from: ANNEX J - PRE-SURGERY ASSESSMENT TO IDENTIFY PATIENTS WITH, OR AT RISK OF, CJD (publishing.service.gov.uk)). All patients about to undergo any elective or emergency surgical or endoscopic procedure should be asked the question: "Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?" Annex J was published in 2006.

d. **An account of your organisation's involvement, if any, of those notification exercises between 2003 and 2009**;

- **Recipients of blood from donors who later developed vCJD.** (see supporting document: SCGV0001064_033).

  In 02/2003, SCIEH supported a Health Board in the Board's management of an incident involving a patient who had received a blood transfusion from someone who later developed vCJD SCIEH provided practical advice in this incident but we hold no further information about this incident. The Health Board, SNBTS, NCJDRSU, SEHD and UK CJDIP were also involved and these may have further knowledge or information about this. This incident preceded the formal notification of recipients, which commenced after the first instance of probable transfusion transmitted infection was detected late that year.

  The formal notification of recipients of blood from donors who later developed vCJD commenced in the UK in 12/2003. To the best of our understanding, in Scotland the notification was led and undertaken by SNBTS and the NCJDRSU, in coordination with the UK framework and process led by HPA in England. SCIEH was involved in producing information literature in conjunction with HPA and NCJDRSU, as well as

supporting the public health management of the recipients, but not in the notification of the recipients. We are not aware of any further information held by PHS/ARHAI Scotland that can provide further information about this.

- **Patients treated with UK sourced plasma products derived from blood donated by a person who subsequently was diagnosed with vCJD.** (see supporting documents: PHEN0000810, PHEN0000138, HCDO0000651, LOTH0000546).

  The notification of those who had been treated with UK sourced plasma products derived from blood donated by a person who subsequently was diagnosed with vCJD, commenced in 09/2004. In this process SCIEH worked closely with SNBTS and SEHD within the framework established by the HPA in England. Whilst SNBTS had responsibility for the tracing of and policy on blood donations, SCIEH was responsible for co-ordinating the notification of patients, epidemiological follow-up and incident management.

  SCIEH had no direct contact with patients, instead the approach taken was, with the exception of haemophilia doctors who were contacted by the UKHCDO, for SCIEH to notify the healthcare professionals who were in charge of patient care, asking them to identify and contact patients at increased risk. SCIEH provided information, advice and support to healthcare professionals, in case this was needed. These materials were drafted by HPA together with UK national blood services, CJD experts and clinical and patient representatives, and modified for Scotland by SCIEH, approved by the Scottish Executive and issued to the target audiences by NHS organisations.

- **Donors of blood to people who later developed vCJD.** (see supporting documents: PHEN0000130, NHBT0031747, NHBT0031744, SCGV0001022_008 page 44, page 39, page 49, page 1, SCGV0001022_007, PHEN0000124, PHEN0000025)

  The notification of donors of blood to people who later developed vCJD commenced in Scotland in 07/2005 and was coordinated in Scotland by HPS, within the UK framework established by the HPA. HPS was not involved in directly notifying patients, but was involved in producing information literature for donors and clinical information in conjunction with HPA, and liaised with SNBTS on the joint formulation

of the letters to donors, which were sent by the Medical Director SNBTS. HPS also liaised with the Information Services Division on the identification of donors' GPs, the GPs were briefed by HPS so that they were prepared when the patients were informed and for purposes of incident management.

- **Other recipients of blood from donors who also donated blood to a patient who later developed vCJD.** (see supporting documents: PHEN0000080, PHEN0000079, NHBT0031744, NHBT0031741, NHBT0031739_006, PHEN0000076, NHBT0031745, page 3, WITN7099002, WITN7099003, NHBT0031739_005)

  The notification of other recipients of blood from donors who also donated blood to a patient who later developed vCJD commenced in Scotland 12/2005. This notification was jointly undertaken by SNBTS and HPS, within the UK framework established by the HPA. HPS was involved in producing information literature for recipients and clinical information in conjunction with HPA, and liaised with SNBTS on the joint formulation of the SNBTS letters to recipients and GPs. SNBTS then informed patients of their possible exposure and the actions they need to take. This was communicated either directly by SNBTS to the recipient by letter, with SNBTS notifying the GPs on or a few days before the patient was notified, or to the patient via their GPs. GPs were briefed by SNBTS so that they were prepared when the patient was informed and for purposes of incident management (NHBT0031744, SCGV0001022_008 page 44, SCGV0001022_008 page 39, and NHBT0031741, NHBT0031739_006, and PHEN0000076). In a very few instances, patients were contacted directly by HPS. As part of its role in national coordination of health protection activity, HPS notified CPHMs in the relevant patient's Health Boards on the same date or shortly after SNBTS had informed the recipients' GPs, for the purposes of local public health management of the incident.

e. An account of your organisation's involvement, if any, in any de-notification exercises post 2013 or earlier.

HPS was involved in one de-notification exercise. This was carried out in late 10/2015 for a single patient who had previously been informed they were at increased risk due to a high number of blood transfusions since 1980.

The background to this de-notification is as follows: In 07/2009 HPS informed Health Boards of changes to pre-surgical assessment for vCJD risks (Annex J of the ACDP TSE infection control guidance) in relation to certain highly transfused patients. Patients due to have high risk surgery or neuro-endoscopy were to be asked if they had received transfusions of blood or blood components from 80 or more donors since 1980. This differed from previous notifications, in that risk was not linked directly to a known case of vCJD but to exposure to a sufficient risk, based on risk assessment, to recommend that public health precautions were taken. HPS asked Health Boards to inform these patients of their increased risk through the patient GP, and provided information for patients and clinical information, in line with the HPA-led UK framework (see supporting document: WITN7099004). Subsequently three patients were identified by hospitals at pre-surgical assessment and notified by the Health Board of their increased risk in 2009, 2010 and 2012.

A single, highly transfused, patient was de-notified in late 2015, following a change in criterion that raised the number and timing of donor exposures considered to put an individual at increased risk to 300 or more donors since 1990. De-notifications across all four nations were informed in coordination with the process in England, led by PHE. In Scotland the de-notification was led by HPS, who asked the patient's GP to inform the patient that they were no longer considered to be at increased risk, and to inform the local hospitals so that any special infection control measures implemented in respect of the patient, were no longer necessary.

f. Details as to whether your organisation was aware of any circumstances where individuals were not informed of their risk status or only informed at a later date and if so why;

We are aware of an instance, in 2006, in a recipient of blood from a donor who also donated blood to a patient who later developed vCJD, where the GP did not wish to inform the patient due to mental capacity issues. Clinicians were asked to liaise with their patient's GP to agree the best way to inform each patient, ensuring the patient had adequate time to discuss issues and arranging ongoing support. It is possible that some individuals were not informed by their GP/clinician if it was anticipated that this might have harmed their patient.

g. **An account of what, how, when and where patients were told that they might have been exposed to a greater risk of vCJD.**

- **Recipients of blood from donors who later developed vCJD.** (see supporting document: SCGV0001064_033).

  In 02/2003 a patient in a Health Board was informed by the Consultant Haematologist that they had previously received a blood transfusion from someone who later developed vCJD. This predated the 2003 decision by CJDIP to notify patients at risk and we hold no information relating to this beyond the Health Board report of the incident review.

  Regarding the later recipient notification, which commenced in the UK in 12/2003, to the best of our knowledge/our records indicate the notification was led and undertaken by SNBTS and the NCJDRSU. We have identified no further information regarding this, and are unable to provide any further detail.

- **Patients treated with UK sourced plasma products derived from blood donated by a person who subsequently was diagnosed with vCJD.** (see supporting documents: PHEN0000810, PHEN0000138, HCDO0000651, LOTH0000546).

  Patients were given information about vCJD, the reasons for their being notified, how this affected them and where they could go for further information and advice. They were asked not to donate blood, tissues or organs, and to tell whoever was treating them that they were at increased risk, so that appropriate precautions could be taken, if needed, for the instruments used. They were advised also to tell their families, in case of emergency surgery in the future.

  Notification of patients with bleeding disorders in Scotland was made by haemophilia doctors; for patients with primary immunodeficiency in Scotland by lead immunologists. For other patients in Scotland notification was by the clinician responsible for patient care, via the medical directors of NHS health boards. GPs were also informed.

  i. Patients with bleeding disorders: haemophilia doctors were asked by UKHCDO to notify all patients with bleeding disorders on an agreed date in

September. A template letter to patients and patient information leaflet were recommended by HPA for this purpose, agreed by UKHCDO and patient representatives. SCIEH Medical Director liaised with the Scottish Lead Haemophilia Director regarding the production of the Haemophilia Centre Director's letter.

ii. Patients with primary immunodeficiency: immunologists were asked by SCIEH (based on advice from CJDIP/ HPA/PHE) to make individual risk assessments of their patients before the agreed September patient notification date, when both those patients assessed to be at risk, and all other primary immunodeficiency patients would be informed. The clinician was asked to liaise with the patient's GP to agree the best way to inform each patient, ensuring patients had adequate time to discuss issues and arranging ongoing support. Template letters were provided to immunologists that could be used.

iii. Other patients: medical directors of the Health Boards were asked by SCIEH that, where possible, they traced batches to individual patients and sent patient exposure details to SCIEH for onward to HPA for confirmation of at-risk status and next steps (requested by end Oct 04). The clinician responsible for the care of that patient would then be asked to liaise with the patient's GP to agree the best way to inform each patient, advise them of the special public health precautions required, and arrange for on-going support.

- **Donors of blood to people who later developed vCJD.** (see supporting documents: PHEN0000130, NHBT0031747, NHBT0031744, SCGV0001022_008 page 44, page 39, page 49, page 1, SCGV0001022_007, PHEN0000124, PHEN0000025)

  A summary of the notification was written by NBS and HPA, and including information relating to Scotland. All donors were notified in 07/2005 in writing by the Medical Director of SNBTS (SCGV0001022_008, page 1 and SCGV0001022_007). HPS also wrote to the donors' GPs, so that the GPs were informed and could support their patients.

- **Other recipients of blood from donors who also donated blood to a patient who later developed vCJD.** (see supporting documents: PHEN0000080, PHEN0000079, NHBT0031744, NHBT0031741, NHBT0031739_006, PHEN0000076, NHBT0031745, page 3, WITN7099002, WITN7099003, NHBT0031739_005)

  The notification of Scottish recipients took place between 12/2005 and 05/2006 and involved multiple Health Boards. The letters and information provided to patients are included in the supporting documents.

h. A summary of information or advice given to partners or family members of patients who were at risk of infection with vCJD.

We are not aware of separate information being prepared for partners or family members. Clinicians were asked to make local decisions regarding how patients were best informed about their additional risk; if the patients were children or lacked capacity then this clinical decision may have involved the family members/carers.

Section 7: Scale of exposure

The Inquiry seeks to gain an understanding as to the number of people who have been exposed to vCJD and the extent to which this can be assessed and quantified.

10. Please provide the following:

a. A summary of any research studies or papers, reports, recommendations, look back exercises and databases, which PHS has been involved in, which have addressed the prevalence of the transmission of vCJD in blood and blood products. (Please see: ICHT0000049)

In 2009, the HPS HAI team took responsibility for managing a register of patients (excluding those with a bleeding disorder or primary immunodeficiency) who had been notified they were at increased risk of CJD. Public health information about these patients had previously been held at NCJDRSU which held the details for all UK patients. The information passed to the HPS HAI team would have been for Scottish residents only. In 2011 the HPS HAI service commenced the annual follow-up of these patients contributing to long-term public health monitoring throughout the UK. This continues to present. Individuals who have been identified

as 'at increased risk' of CJD and informed of this, are followed up annually to help determine whether they develop CJD (see supporting document WITN7099005). Public health monitoring and follow up activities include GP updates covering deaths, the development of any dementia or other neurological conditions, and other patient concerns. Clinical review and, where autopsy has been undertaken, post-mortem investigation, are undertaken in collaboration with NCJDRSU. This enhanced surveillance activity is UKHSA led and currently managed in Scotland by ARHAI Scotland.

To the best of our knowledge SCIEH/HPS/PHS/ARHAI Scotland have not been involved in other activities to address the occurrence of transmission of vCJD in blood and blood products.

b. Your view on the effectiveness of any look back studies you are aware of, to trace recipients of vCJD infected blood and blood products

A number of studies have considered this and provide direct follow-up and investigation of patients exposed to a potential additional risk of vCJD through blood and blood products. To the best of our knowledge these are as follows:

i. The TMER study, which started in 1997 looking for evidence of transmission of vCJD through blood transfusion, even though at that time there was no evidence to suggest that this would occur. The TMER mechanism was prompt in identifying possible transfusion associated transmission in late 2003, and has continued to be effective in its investigation of all known cases of vCJD for evidence of transmission through blood. Since inception and continuing to present, the study has been conducted jointly by the NCJDRSU and NHSBT, and has not involved SCIEH/HPS/PHS/ARHAI Scotland. We recommend contacting the NCJDRSU for further information (see The Transfusion Medicine Epidemiology Review (TMER) | CJD).

ii. Enhanced surveillance of patients at increased risk of CJD due to healthcare associated exposures (excluding Haemophiliacs and PID patients), is led by UKHSA and has been conducted in Scotland since 2011 by NHS NSS ARHAI.

The surveillance contributes to the long-term public health monitoring of healthcare associated CJD risks throughout the UK, and thereby the generation of knowledge and evidence about these risks. (see Creutzfeldt-Jakob disease (CJD) surveillance: biannual updates - GOV.UK (www.gov.uk)

iii. Prion surveillance in primary immunodeficiency patients is undertaken by the NCJDRSU and looks for evidence of infection in antibody deficient patients who received certain UK-sourced immunoglobulin products between 1996 and 2000. We recommend contacting NCJDRSU for further information. The surveillance conducts effective follow-up and clinical monitoring of subjects. A paper has been published discussing the study (see No evidence of asymptomatic variant CJD infection in immunodeficiency patients treated with UK-sourced immunoglobulin - PubMed (nih.gov)).

iv. A database was established by UKHCDO to enable the monitoring of patients with bleeding disorders who were at-risk of vCJD. For further information, we recommend you contact the UKHCDO (see NHD – UKHCDO.)

c. Details of any studies which provide a regional comparison of the prevalence of vCJD in the UK. A breakdown of the prevalence figures, geographically among the devolved nations.

To date there have been four studies of the prevalence of the vCJD-related prion protein prevalence in the UK, none of which have provided regional comparisons:

i. MRC tonsil and appendix study (published 2004, Prevalence of lymphoreticular prion protein accumulation in UK tissue samples - PubMed (nih.gov));

ii. National anonymous tonsil study (published 2009, Prevalence of disease related prion protein in anonymous tonsil specimens in Britain: cross sectional opportunistic survey - PubMed (nih.gov));

iii. Appendix 2 (published 2013, Prevalent abnormal prion protein in human appendixes after bovine spongiform encephalopathy epizootic: large scale survey - PubMed (nih.gov);

iv. Appendix 3 (published 2020, Prevalence in Britain of abnormal prion protein in human appendices before and after exposure to the cattle BSE epizootic - PubMed (nih.gov));

The NCJDRSU publishes information on the geographical distribution of vCJD, with regional comparisons of cases and incidence across the UK, in their annual report (see Data and Reports | CJD (ed.ac.uk)).

d. An outline of the system of recording the cause of death from vCJD infection from blood or blood products in the UK. Please provide your views on the accuracy of information captured about the cause of death and any areas of weakness or failures in this system to investigate, certify or record the cause of death where it was potentially linked to vCJD.

To the best of our understanding, all deaths reported from vCJD in the UK are investigated by the NCJDRSU. Deaths from vCJD in any donors to, or recipients of blood from vCJD cases are identified through the TMER mechanism. Additionally, deaths in any at-risk individuals are reported to ARHAI Scotland through their annual GP follow-up and flag this with the NCJDRSU, the latter whom undertake a clinical review of the patient and/or their medical notes to look for evidence of vCJD. If a post-mortem has been conducted, the NCJDRSU is also asked to investigate any available tissues, for evidence of vCJD. No surveillance system is complete, however, and there is likely to have been some underreporting of vCJD cases to the NCJDRSU, as well as of some deaths in at-risk patients in Scotland, the latter which is reliant on GP updates.

Section 8: Impact

The Inquiry seeks to gain an understanding as to what impact a diagnosis of or classification of being at risk of developing vCJD has had on individuals and families.

11. Please provide details of your knowledge relating to:

a. The impact of the various notification and de-notification processes 2003-2013, the information conveyed, the adequacy of such information, follow up or lack of. (Please see: LOTH0000082_013, GRAM0000107)

PHS/ARHAI Scotland do not hold information or knowledge to determine the full impact of the notifications and de-notification in Scotland. The report of the 02.2003 incident review indicated that the patient concerned had not undergone a medical procedure because of their potential exposure to vCJD and, anecdotally, we are aware of other instances of possible stigma and/or concern amongst the cohort of patients at increased risk. However in the annual HPS at-risk surveillance a question is included to identify if the patient has raised any concerns relating to their at-risk status. ARHAI Scotland confirm that no concerns have been reported by GPs to date.

We are aware that the National Blood Service conducted a survey of donors that we understand considered the impact of notification and adequacy of information provided (see supporting document PHEN0000025). HPA also conducted a qualitative study involving a small number of donors at increased risk of vCJD (Impact of being placed at risk of Creutzfeldt-Jakob disease: a qualitative study of blood donors to variant CJD cases and patients potentially surgically exposed to CJD - PubMed (nih.gov)). We are not aware of any systematic approaches to follow-up in other notification groups.

b. Any formal complaints made by patients in relation to stigma received insofar as the denial of surgical/medical treatment due to individuals being categorised as 'at risk' to vCJD.

We are not aware of any formal complaints having been made to SCIEH/HPS/PHS/ARHAI Scotland.

Section 9: Other Issues

None.

Statement of Truth

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

Signed GRO-C NICHOLAS PHIN

Dated – 11th May 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
22 April 2003	Report of Incident Review, entitled "*Incident in Dumfries and Galloway arising in February 2003 from a patient who received blood from a vCJD case*"	SCGV0001064_033
28 May 2004	Note of meeting to dicuss CJD incidents involving management of risks from blood products and plasma derivatives potentially contaminated with vCJD agent	PHEN0000810
7 September 2004	vCJD and Plasma Products: Summary of Patient Notification Exercise	PHEN0000138
9 September 2004	vCJD and Plasma Products: Information for Patients	HCDO0000651
September 2004	Briefing Pack re Plasma Product Notification - vCJD	LOTH0000546
2005	vCJD and Blood Donors Summary of Donor Notification Process: Scotland 2005	PHEN0000130
20 July 2005	CJD Incidents Panel Recommendations on "*Assessment of the risk of vCJD implied by donation of blood to a patient who later develops vCJD*"	NHBT0031747
July 2005	vCJD and Blood Donors: Clinical Information	NHBT0031744
19 July 2005	Letter to NHS Highland GPs, entitled "*vCJD and Blood Donors*"	SCGV0001022_008, page 44
19 July 2005	Letter to NHS Tayside GPs, entitled "vCJD and Blood Donors"	SCGV0001022_008, page 39
15 July 2005	vCJD and Blood Donors : GP Report Form	SCGV0001022_008, page 49
19 July 2005	SNBTS letter to Highland Donors re vCJD notification	SCGV0001022_008, page 1
19 July 2005	SNBTS letter to Tayside Donors re vCJD notification	SCGV0001022_007
July 2005	vCJD and Blood Donors: Information for Donors to vCJD cases	PHEN0000124

July 2005	NBS Summary on vCJD Donor Notification Exercise	PHEN0000025
November 2005	vCJD and Blood Transfusions : Summary of notification of recipients of blood donated by donors wo also donated to a patient wo later developed vCJD (UK)	PHEN0000080
November 2005	CJD Incidents Panel Recommendations on "*Assessment of the risk of vCJD due to receipt of blood from a donor who also donated blood to a patient who later developed vCJD*"	PHEN0000079
November 2005	vCJD and Blood Transfusions : Clinical Information	NHBT0031744
2005	SNBTS letter to GP re GP notifying patients	NHBT0031741
2005	SNBTS letter to GP re SNBTS notifying patients	NHBT0031739_006
December 2005	Actions to be taken by GP for notifying patients of vCJD and blood transfusion	PHEN0000076
December 2005	vCJD and Blood Transfusion GP Report Form	NHBT0031745, page 3
14 December 2005	Example letter to Health Boards re vCJD and Blood Transfusion	WITN7099002
2005	SNBTS notification letter to patient re vCJD and blood transfusion	WITN7099003
November 2005	vCJD and Blood Transfusions : Information for Patients Leaflet	NHBT0031739_005
12 July 2009	E-mail correspondence entitled "*Pre-surgical assessment for variant Creutzfeldt-Jakob Disease (vCJD) risk - Scottish Documentation*" and attachments	WITN7099004
2011	CJD Annual Surveillance GP report form	WITN7099005