.

Witness Name: UK Health Security Agency
Statement No.: [WITN7123001]
Exhibits: WITN7123002-WITN7123004 and WITN7123006 - WITN7123018
Dated: 17 August 2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF UK HEALTH SECURITY AGENCY (FORMERLY PUBLIC HEALTH ENGLAND)

Contents

Section 1: Introduction

I, Dr Robert Kyffin, my date of birth is GRO-C, and my professional address is UK Health Security Agency, Noble House, 17 Smith Square, London, SW1 P3JR will say as follows:

1.1. I am the Data and Information Policy and Partnerships Lead in the UKHSA Information Management, Data Governance and Privacy Division of the Data, Analytics and Surveillance Group. I have co-ordinated the response to a request for evidence from the Infected Blood Inquiry pursuant to Rule 9 of the Inquiry Rules 2006 and dated 22 September 2021. The contents of this statement have been provided by the following:

1) Dr Robert Kyffin, Data and Information Policy and Partnerships Lead: led the compilation and editing of the response, and provided the content on the organisation, remit and management of the UKHSA, Public Health England (PHE) and Health Protection Agency (HPA);

2) Dr Helen Harris, Clinical Scientist: provided content on hepatitis C (HCV) reporting;

3) Dr Sema Mandal, Medical Consultant Epidemiologist: provided content on the reporting of hepatitis infections, and the relationship between UKHSA (and its predecessors) and the National Blood Service/NHS Blood and Transplant;

4) Mr Gwyn Morris, Colindale Site, Deputy Director: provided content on the organisation and remit of the Public Health Laboratory Service (PHLS);

5) Dr Katy Sinka: Consultant Epidemiologist / Head of Sexually Transmitted Infections: provided content on notifiable disease reporting and all Creutzfeldt-Jakob Disease (CJD) content;

6) Dr Kate Soldan, Consultant Scientist / Epidemiologist: provided content on the HCV lookback exercise;

7) Dr Claire Reynolds, Senior Scientist, Blood Safety Division: provided content on the HCV lookback exercise.

1.2. I am very grateful to the Inquiry for providing extensions of time for me to respond to this request given the challenges we experienced during the Covid-19 pandemic and as a result of the closure of PHE on 1 October 2021 and the creation of its successor organisation, UKHSA.

1.3. This statement addresses organisation, information management and record keeping at UKHSA and its predecessor organisations.

Section 2: Organisation and Information Management

UKHSA and its Predecessor Organisations

2.1. A summary timeline for the UKHSA and those predecessor organisations which are relevant to the scope of this Rule 9 request is provided below:

1) UK Health Security Agency: 1 October 2021 – onwards (NB. UKHSA was first established in 'shadow', non-operational form on 1 April 2021)

2) Public Health England: 1 April 2013 – 30 September 2021

3) Health Protection Agency: 1 April 2003 – 31 March 2013

4) Public Health Laboratory Service: 1940 – 31 March 2003 (NB. An account of the history of the PHLS is provided below)

Public Health Laboratory Service (PHLS)

2.2. The history of the PHLS dates back to the 1944 White Paper on the NHS and the wartime experience of the Emergency Public Health Laboratory Service, the predecessor to the PHLS established in 1940. The PHLS was initially managed by the Medical Research Council for the Ministry of Health under the National Health Service Act 1946, with this responsibility later delegated to a PHLS Board in 1950. At this stage, the PHLS included the Central Public Health Laboratory in Colindale and a network of laboratories across England and Wales. By 1956, 44 laboratories were part of the PHLS.

2.3. A Statutory Board took on responsibility for oversight of the PHLS on 1 August 1961 under the Public Health Laboratory Service Act 1960. The NHS Act 1977 subsequently incorporated the PHLS and meant it operated in a similar way to Special Health Authorities. The PHLS Act 1979 further allowed the PHLS to incorporate the Centre for Applied Microbiology and Research (CAMR), which was renamed the PHLS Centre for Applied Microbiology and Research.

2.4. The initial remit of the PHLS was to provide a bacteriological service for the control of the spread of infectious diseases. It started as a laboratory only service but increasingly employed epidemiologists. During the 1970s, there was a substantial increase in epidemiology within the PHLS, with the appointment in 1976 of a director for a new Communicable Disease Surveillance Centre. The Centre for Applied Microbiology and Research (CAMR) at Porton was incorporated into the PHLS at this time also. By 1986 there were 52 regional laboratories, and PHLS laboratories increasingly provided a public health as well as an NHS diagnostic service.

2.5. One priority for the PHLS was to ensure that adequate expertise and resources are available to support the investigation and control of outbreaks wherever they occurred, the surveillance of vaccination programmes, the study of new microbial diseases, and other work in the infection field relevant to public health.

2.6. In 1987, a Board Review identified the need for more epidemiological support. Funding was agreed to develop a PHLS AIDS centre at Colindale, which had responsibility for HIV and sexually transmitted infections surveillance.

2.7. In 1994, CAMR moved from the PHLS to the Microbiology Research Authority, reporting to the Department of Health. Alongside the PHLS, CAMR became part of the HPA on 01 April 2003. When the PHLS was disestablished, 8 PHLS laboratories transferred to the HPA, while 32 transferred to local NHS management and 6 to the new National Public Health Service for Wales.

2.8. A collection of the annual reports of the PHLS is held at the UKHSA Colindale site.

2.9. The paper titled 'Communicable disease control: the development of a laboratory associated national epidemiological service in England and Wales' by Galbraith N.S. and Young S.E J. (Community Medicine, 1980(2), 135-143) (WITN7123003) provides a broadly contemporaneous account of the development of the PHLS epidemiological service.

Health Protection Agency (HPA)

2.10. The HPA was the successor organisation to the PHLS. It was first established as a special health authority on 1 April 2003 in advance of the Health Protection Agency Act 2004. This Act brought together the HPA Special Health Authority and the National Radiological Protection Board to become the Health Protection Agency in April 2005 as an executive non-departmental public body. In April 2009 the National Institute for Biological Standards and Control (NIBSC) also

became part of the HPA.

2.11. The HPA's role was to provide an integrated approach to protecting UK public health through the provision of support and advice to the NHS, local authorities, emergency services, other Arm's Length Bodies, the Department of Health and others. Its principle activities in 2012/13 were:

1) providing impartial authoritative information and advice to professionals and the public, and independent advice to the government on public health protection policies and programmes;

2) delivering services to and supporting the National Health Service and other organisations to protect people's health from infectious diseases, chemical hazards and poisons;

3) monitoring and responding to new threats to public health, and providing a rapid response to health protection emergencies, including the deliberate release of poisons, chemicals, or microbiological substances;

4) improving knowledge about health protection through research, development, education, and training.

2.12. A record of the HPA's activities and achievements can be found in its annual reports.[1]

2.13. The HPA was abolished on 1 April 2013 and its functions transferred to PHE, except for those carried out by the NIBSC division, which transferred to the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care (DHSC).

[1] https://webarchive.nationalarchives.gov.uk/ukgwa/20150318223713/http://legacytools.hpa.org.uk/Publications/CorporateReports/AnnualReports/

Public Health England (PHE)

2.14. PHE was established as an operationally autonomous executive agency of the DHSC on 1 April 2013. It brought together more than 5,000 staff from over 70 previously separate sender organisations, including the HPA, the National Treatment Agency for Substance Misuse, the NHS, the public health observatories, the National Cancer Intelligence Network, the Department of Health and Social Care, and others.

2.15. As the expert national agency for public health, PHE was responsible for fulfilling the Secretary of State for Health and Social Care's statutory duty to protect health and address inequalities, and executing their power to promote the health and wellbeing of the nation under sections 2A and 2B of the NHS Act 2006, as amended by sections 11 and 12 respectively of the Health and Social Care Act 2012.

2.16. PHE's role and priorities were set out its annual remit letter from the Minister for Public Health (WITN7123007). Its four core functions were:

(1) protecting the public's health from infectious diseases and other hazards to health

(2) improving the public's health and wellbeing and reducing health inequalities

(3) improving population health through sustainable health and care services

(4) building the capability and capacity of the public health system

2.17. A record of its activities and achievements can be found in its annual reports (WITN7123008).

UK Health Security Agency (UKHSA)

2.18. As part of the government's plan to transform the UK public health system (WITN7123009), PHE was disestablished at the end of September 2021 and its functions transferred to the following four receiver organisations:

(1) health protection functions merged with NHS Test and Trace and the Joint Biosecurity Centre, both part of the DHSC, and transferred to UKHSA, a newly established executive agency of the DHSC

(2) health improvement functions transferred to the Office for Health Improvement and Disparities, a new directorate of the DHSC

(3) the national cancer register and national congenital anomaly and rare diseases register transferred to NHS Digital

(4) the national population health screening programmes transferred to NHS England and NHS Improvement

2.19. UKHSA is an operationally autonomous executive agency of the DHSC and exercises the Secretary of State for Health and Social Care's statutory duty to protect health under section 2A of the NHS Act 2006. UKHSA is responsible for planning, preventing and responding to external health threats, and providing intellectual, scientific and operational leadership at national and local level, as well as internationally.

2.20. UKHSA's role and annual priorities are set out in its annual remit letter from the Parliamentary Under Secretary of State for Innovation (WITN7123010). Included in the UKHSA remit is responsibility for infectious disease notifications, management of the national HIV and HCV registers, and epidemiological monitoring of vCJD.

Co-ordination between PHLS Regional Laboratories

2.21. The PHLS regional laboratories were managed as a network, with each laboratory having management accountability to the PHLS director in Colindale and oversight of the network provided by a national management team and an operational committee structure.

2.22. A weekly summary report of infections identified by the PHLS laboratories was published from about 1940. In the 1950s this grew to include reports from non-PHLS laboratories. This became the Communicable Disease Report from 1967. These reports provided epidemiological oversight of infectious diseases in England and Wales. The establishment of the Communicable Disease Surveillance Centre in the PHLS in 1974, as well as regional epidemiology posts made the co- ordination of information more effective, and allowed the report to have a wider distribution. The reports included tabulated data on infections, accounts of epidemics, and analysis and reviews of epidemiological situation.

Working Relationships between UKHSA/PHE and Other Organisations

2.23. As noted above, the UKHSA is the national expert agency for health protection and the successor organisation for the national health protection functions previously provided by PHE.

2.24. To fulfil its remit, UKHSA works in collaboration with a wide range of statutory public bodies at national level, such as NHSE England and NHS Improvement, NHS Digital, NHS Blood and Transplant and the public health agencies in the Devolved Administrations, and at regional and local level, particularly NHS organisations, mayoral and combined authorities, and local authorities. UKHSA works with the royal medical colleagues, university and academic organisations, and other public health organisations on a range of

health protection initiatives and research projects. It also works internationally with the World Health Organisation and organisations such as the European Centre for Disease Control to monitor and respond to global threats to public health.

Executive Authority

2.25. The individuals with executive for UKHSA and its predecessor organisations are listed in the table below. Please note, only the directors and broad years of tenure of the PHLS are provided; for the other organisations, the full list of executive directors and tenure period is provided.

Table 1: Individuals with executive authority for PHLS, HPA, PHE and UKHSA

Name	Role	Date from	Date to
Public Health Laboratory Service (Director only)			
Graham Wilson	Director	1941	1963
James Howie	Director	1963	1973
Robert Williams	Director	1973	1981
Michael Whitehead	Director	1981	1985
Joseph Smith	Director	1985	1992
Diana Walford	Director	1992	2002
Brian Duerden	Director	2002	2003
Health Protection Agency (Executive Board members only)			
Professor Pat Troop	Chief Executive	01/04/2003	06/04/2008
Justin McCracken	Chief Executive	07/04/2008	31/03/2013
Professor Peter Borriello	Director of the Specialist and Reference Microbiology Division and Director of Research and Development (2003/4); Interim Director of	25/09/2003	30/09/2008

.

Name	Role	Date from	Date to
	the Centre for Infections (2004/5); Director of Centre for Infections (2005/6)		
Dr Roger Gilmour	Director of the Business Division (2003/4); Director of the Centre for Emergency Preparedness and Response (2004/5)	25/09/2003	31/10/2004
Dr Nigel Lightfoot	Director of the Emergency Response Division (2003/4)	25/09/2003	31/10/2004
Professor Angus Nicoll	Director of the Communicable Disease Surveillance Centre (2003/4)	25/09/2003	31/10/2004
Dr Mary O'Mahony	Director of Local and Regional Services (2003/4)	25/09/2003	31/10/2004
Dr Tony Sannia	Director of Finance and Resources (2003/4)	01/04/2003	31/03/2013
Dr Roger Cox	Director of the Centre for Radiation, Chemical and Environmental Hazards	01/04/2005	31/05/2009
Paul Cosford	Acting Chief Executive and Accounting Officer; Deputy Chief Executive/ Regional Director of Public Health	15/10/2012	31/03/2013
Duncan Selbie	Acting Chief Executive and Accounting Officer (on secondment from the Department of Health)	01/02/2013	31/03/2013
Public Health England (Management Committee and National Executive members)			
Duncan Selbie	Chief Executive	1/4/2013	19/9/2020
Michael Brodie	Interim Chief Executive	20/8/2020	30/9/2021

.

Name	Role	Date from	Date to
Richard Gleave	Deputy Chief Executive and Chief Operating Officer	1/4/2013	30/9/2021
Lis Birrane	Director of Communications	1/4/2013	24/11/2015
Lee Bailey	Director of Communications	25/10/2016	30/9/2021
Viv Bennett	Chief Nurse	1/4/2013	30/9/2021
Michael Brodie	Finance and Commercial Director	1/4/2013	24/9/2019
Donald Shepherd	Finance and Commercial Director	1/10/2019	30/9/2021
Sir Paul Cosford	Director for Health Protection and Medical Director	1/4/2013	31/12/2019
	Emeritus Medical Director	1/1/2020	4/4/2021
Yvonne Doyle	Director, London	28/7/2015	31/12/2019
	Director for Health Protection and Medical Director	1/1/2020	28/9/2021
Christine McCartney	Director of Microbiology	1/10/2013	31/3/2014
Derrick Crook	Director, National Infection Service	23/5/2017	26/3/2019
Sharon Peacock	Director, National Infection Service	1/6/2019	30/9/2021
Isabel Oliver	Director, National Infection Service	28/7/2020	30/9/2021
Kevin Fenton	Director of Health and Wellbeing	1/4/2013	22/8/2017
	Director, London	5/5/2020	30/9/2021
John Newton	Chief Knowledge Officer	1/4/2014	13/4/2020
	Director of Health Improvement	14/4/2020	28/9/2021

.

Name	Role	Date from	Date to
Jonathan Marron	Director of Strategy	1/4/2013	26/1/2016
Adrian Masters	Director of Strategy	6/7/2016	10/5/2020
Cathy Morgan	Interim Director of Strategy	26/5/2020	30/9/2021
Deborah McKenzie	Director of Organisational and Workforce Development (as of 24/03/2015; Director of Organisational Development previously)	24/2/2015	13/4/2020
	Chief People Officer	14/04/2020	28/9/2021
Tony Vickers-Byrne	Director of Human Resources	1/4/2013	31/3/2014
Jenny Harries	Director, South	1/4/2013	25/6/2019
Paul Johnstone	Director, North - Job title change 14 April 2020 previously Director, North	1/4/2013	13/4/2020
	National Director, Place and Regions	14/4/2020	30/09/21
James Mapstone	Acting Director, South	30/7/2019	24/3/2020
Rashmi Shukla	Director, Midlands and East	28/7/2015	13/4/2020
	National Director, Place and Regions	14/4/2020	18/6/2021
Paul Plant	Acting Director, London	1/7/2019	24/3/2020
Alex Sienkiewicz	Chief of Staff	1/4/2013	1/6/2015
	Director of Corporate Affairs	2/6/2015	30/09/2021
Sally Warren	Director of Programmes	1/4/2013	29/4/2014
Stephen Morris	Development Adviser	1/4/2013	15/7/2014
Neil Squires	Director of Global Public Health	28/7/2020	30/9/2021
Sheree Axon	PHE Transition Director	15/9/2020	30/9/2021

.

Name	Role	Date from	Date to
Alexia Clifford	Director of Marketing	23/3/2021	30/9/2021
UK Health Security Agency (Executive Committee members)			
Dr Jenny Harries OBE	Chief Executive	01/10/2021	-
Rachael Allsop	Chief People Officer Transition Lead	01/10/2021	31/03/2022
Dr Shona Arora	Director of Health Equity Transition Lead	01/10/2021	31/03/2022
Lee Bailey	Director of Communications	01/10/2021	-
Paul Cain	Director General for Health Protection Operations	01/10/2021	-
Sarah Collins	Commercial Director	01/01/2022	-
Jac Gardner	Chief People Officer Transition Lead	11/04/2022	-
Mark Hewlett	Chief Operating Officer Testing	01/10/2021	04/03/2022
Dr Susan Hopkins	Chief Medical Advisor	01/10/2021	-
Sidonie Kingsmill	Customer, Communications & Innovation Transition Lead	01/10/2021	31/03/2022
Scott McPherson	Strategy, Policy & Programmes	01/10/2021	-
Ollie Munn	Chief Operating Officer Testing	17/03/2022	-
Professor Isabel Oliver	Chief Scientific Advisor Transition Lead	01/10/2021	-
Professor Steven Riley	Director General Data & Analytics	01/10/2021	-
Jacqui Rock	Transition Director, Chief Commercial Officer and Head of Corporate Services	01/10/2021	31/12/2021

.

Name	Role	Date from	Date to
Andrew Sanderson	Director General of Finance	01/10/2021	-
Alex Sienkiewicz	Director of Corporate Affairs	01/10/2021	31/03/2022
Adam Wheelwright	Director of Technology Transition Lead	01/10/2021	-

Table notes:

1. A full list of the PHLS senior management team is provided in the printed archive of PHLS annual reports held at the UKHSA Colindale site

2. A full list of the HPA senior management team is provided in the HPA annual reports

3. UKHSA was formally established on 01 April 2021 but become operational on 01 October 2021

Section 3: Reporting and Notifiable diseases

HIV

3.1. The Department of Health published the Health Protection Legislation (England) Guidance 2010 (the '2010 Guidance') on 25 March 2010 to explain the legal notification requirements for registered medical practitioners and laboratories testing human samples, and also the health protection powers available to local authorities and justices of the peace (WITN7123002). These duties and powers are contained within the Public Health (Control of Disease) Act 1984, as amended by the Health and Social Care Act 2008, and the regulations made under the Act, specifically the Health Protection (Notification) Regulations 2010.

3.2. Neither AIDS nor HIV have ever been notifiable in the UK. The 2010 Guidance

notes (WITN7123002 (p15)) that "There are separate mechanisms for notifying and responding to cases of healthcare associated infections, Human Immunodeficiency Virus (HIV)/Sexually Transmitted Infections (STIs) and Creutzfeldt-Jakob Disease (CJD).... Therefore, cases of these diseases should not be reported routinely under this requirement. However, suspected acute infectious hepatitis should be notified even if it is considered to have been acquired through sexual activity...."

Hepatitis

3.3. Viral hepatitis was a notifiable disease between 1987 and April 2010, with Hepatitis A, B, C and 'other' being reported separately. As of 6 April 2010, hepatitis was no longer generally notifiable, except for suspected acute infectious hepatitis which was required to be reported through the statutory notification of infectious diseases (NOIDs) system (WITN7123011). This means that for suspected acute infectious hepatitis, registered medical practitioners should not wait for laboratory confirmation or results of other investigations in order to notify a case. This is to ensure prompt notification so that health protection interventions and control measures can be initiated as soon as possible. Close contacts of acute hepatitis A and hepatitis B cases need rapid post exposure prophylaxis, and urgent notification facilitates prompt laboratory testing. Hepatitis C cases known to be acute need to be followed up rapidly as this may signify recent transmission from a source that might be controlled.

3.4. The statutory notification of hepatitis A, B, C, delta and E viruses (acute and chronic) as causative agents was introduced by the Health Protection (Notification) Regulations 2010. This placed a duty on diagnostic laboratories to notify the UKHSA and its predecessor organisations when they identify evidence of infection caused by hepatitis virus. Reporting by laboratories of

notifiable organisms to UKHSA is managed through the Second Generation Surveillance System (SGSS), a national surveillance system that holds reported test results.

vCJD

3.5. Variant Creutzfeldt-Jakob Disease has never been notifiable in the UK. As noted above, the 2010 Guidance states that there is a separate mechanism for notifying and responding to cases of CJD. Specifically, the 2010 Guidance (WITN7123002 (p19)) explains that "The incidence of Creutzfeldt-Jakob Disease is monitored in the UK by the National CJD Surveillance Unit (NCJDSU) and all suspected cases should be reported to this unit. The unit assists clinicians with the investigation of this disease and works in collaboration with the HPA and the CJD Incidents Panel in the investigation and management of CJD incidents."

Devolved Administrations

3.6. UKHSA understands that the notification requirements for infectious diseases and causative agents are substantively the same across the UK, although there may be some differences in the detail of these requirements, both currently and historically. The Inquiry may wish to contact Public Health Scotland, Public Health Wales and the Public Health Agency Northern Ireland directly for responses on behalf of the Devolved Administrations to this issue.

Processes for reporting notifiable infections Hepatitis

3.7. In the 1990s, hepatitis (A, B and non-A non-B (NANB)) laboratory reports were received from diagnostic laboratories at PHLS Colindale electronically (via the Labbase and predecessor information systems) or through paper notification forms. The latter were reviewed by a consultant epidemiologist and entered into the hepatitis databases stored on secure servers at Colindale. Since around

2000s all laboratory reports are received electronically via Labbase and its replacement, the SGSS.

HIV

3.8. UKHSA and its predecessor organisations undertake infectious disease surveillance for England, including for HIV/AIDS and mortality related to HIV/AIDS. The way disease surveillance has operated has changed over time. From the early 1980s, data was collected through paper forms that were stored securely onsite. These have since been scanned and electronically archived and the paper forms securely destroyed. In around 2000, data collection transitioned from paper-based to electronic reporting, with HIV data received from or through:

3.8.1. NHS laboratories diagnosing HIV infection;

3.8.2. clinician reports of new diagnoses and of AIDS (collected through an electronic reporting form from around 2010);

3.8.3. Office of National Statistics data on deaths where HIV or AIDS are mentioned among the causes of death;

3.8.4. SOPHID (survey of prevalent HIV infections diagnosed), an annual electronic return of the latest HIV patient attendance within a calendar year (2000 to 2013);

3.8.5. HARS (HIV and AIDS reporting system), a quarterly electronic return of all HIV outpatient attendances (2013 to present);

3.8.6. CD4 surveillance scheme, an annual electronic laboratory survey collecting markers of immune suppression among people living with HIV;

3.8.7. RITA (recent HIV infection testing algorithm), used to measure recently acquired HIV infection;

3.8.8. Positive Voices, a largely anonymized (see next paragraph) survey of people living diagnosed HIV infection to gain understanding of patient experience, co-morbidities and other measures of health.

3.9. Infected patients may be reported through any or all of these sources and a process of matching (using a soundex code pseudonym) is in place to enable de-duplication so that recording of HIV infections is accurate and not overestimated. Direct patient identifiers, including patient name or NHS number, are not collected. An online guide to HIV surveillance systems has been published by UKHSA/PHE (www.gov.uk/guidance/hiv-surveillance-systems).

3.10. There may be several clinical and academic organisations collecting patient-level hepatitis data for research and audit purposes. The Inquiry may wish to contact the National Institute for Health Research and the Medical Research Council (MRC) for information on any hepatitis-related research and audit they are funding. UKHSA is aware of the STOP-HCV and HCV Research UK programmes as staff from PHE were on the steering committees for these initiatives. STOP-HCV is a MRC-funded consortium which aims to use patient information to establish the most effective and cost effective treatments for patients with HCV (www.expmedndm.ox.ac.uk/stop-hcv). HCV Research UK is a consortium of UK clinical and scientific researchers with specific interest in HCV (https://gut.bmj.com/content/61/Suppl_2/A147.3).

3.11. With regard to AIDS/HIV, other UK organisations that UKHSA is aware of that are currently collecting, or have in the past collected, patient-level data include:

3.11.1. Public Health Scotland, which undertakes HIV surveillance for Scotland[2] (WITN7123012 and WITN7123013);

[2] www.hps.scot.nhs.uk/a-to-z-of-topics/hiv/#data

3.11.2. UK Haemophilia Doctors Organisation, which runs the national haemophilia database for individuals with bleeding disorders;[3]

3.11.3. University College London Institute of Child Health, which undertakes surveillance of HIV in pregnancy and childhood;[4]

3.11.4. University College London UK Collaborative HIV Cohort Study, which investigates the clinical outcomes and response to treatment of HIV patients;[5]

Relationship between UKHSA and NHSBT

3.12. With regard to the relationship between UKHSA and NHS Blood and Transplant (NHSBT), a joint scientist post to work on the surveillance and epidemiology of transfusion transmissible infections was first established between NBS and PHLS in late 1994. This scientist post, and the larger unit that developed subsequently, worked collaboratively for some years on the surveillance of infections in blood donors. A Steering Group was put in place to oversee and advise the work of the scientist post, and included staff from PHLS with relevant expertise in blood borne infections including HIV, hepatitis and bacterial infections, as well as staff from NBS.

3.13. In late 1995, a joint NHSBT/UKHSA (previously NBA and PHLS) epidemiology unit was set up, whose function was to run UK-wide surveillance scheme for blood donation testing (for monitoring incidence and prevalence of blood borne infections in donors) and confirmed positive donors, and continues to collect data in a systematic way to monitor blood safety and to inform policy more widely. Surveillance has also been performed by the joint epidemiology unit to

[3] www.ukhcdo.org/nhd
[4] https://www.ucl.ac.uk/integrated-screening-outcomes-surveillance/
[5] https://www.ucl.ac.uk/global-health/research/z-research/uk-collaborative-hiv-cohort-uk-chic-study

monitor the incidence of transfusion transmitted infections in recipients since 1996, and to horizon-scan for new and emerging threats to blood safety since 2007. The joint epidemiology unit helped ensure that expertise in infectious disease epidemiology was feeding into the national blood service, and helped develop exclusion, deferral and testing policy. The data from the blood service also formed an integral part of surveillance of infections of public health importance, including but not limited to HBV, HCV, HIV and HTLV. A joint steering group has been in place since the late 1990s, with chairing and membership from both agencies, initially reporting to the HPA Hepatitis Programme Board, but governance arrangements have changed over successive reorganisations. The collaboration was successful and the joint team was gradually expanded and took on key areas of work such as estimation of the residual risk, natural history studies in infected individuals and surveys of donor risks. A consultant in public health was appointed into the Blood Service to oversee the joint work in 2008.

3.14. As well as collaborating with UKHSA on surveillance, NHSBT has worked closely with the blood-borne virus unit (BBVU) and has funded a package of research and development work within the unit.[6] The BBVU undertakes surveillance, research and development activities for hepatitis A through to hepatitis E virus, and also for pathogens that impact on blood safety. Since 2010, a work programme of blood safety has been delivered collaboratively by UKHSA (and its predecessors) and NHSBT.

3.15. The broad strategic direction of this programme has been as follows: to be responsive to current and emerging microbiological threats to the safety of blood, tissues, cells and organs; to generate the evidence and provide scientific support

[6] https://www.gov.uk/guidance/blood-borne-viruses-unit-bbvu-services

that informs donor screening policies and operational strategic decisions; and maintain a programme of technology development and transfer. The programme has been overseen by a joint NHSBT/UKHSA steering group. The programme has undertaken the development of assays, generating novel reagents to support these areas of work. Seroepidemiology studies, evaluations and investigations in specific at-risk groups have also been carried out to address data gaps and to inform policy. Of note, the programme generated data on the prevalence of HEV virus in blood components, reporting on transmissions rates and outcome in recipients. This study led to policy change with UK blood services implementing screening in blood, tissue, organ and cell donors.

3.16. The NHSBT-funded work programme ended in March 2022 but the BBVU continues to work in collaboration with NHSBT and the University of Oxford and University College London as part of the National Institute for Health Research Blood Transfusion Research Unit (BTRU) on transfusion and transplantation transmitted infections. The BTRU programme of work is called 'Genomics to Enhance Microbiology Screening'.

3.17. UKHSA laboratories may be used by NHSBT for investigation of potential transfusion transmitted infections where additional genotyping is required. Outside of the sequencing of HCV infected donors, there were no additional work streams undertaken by the programme specifically on HCV.

Section 4: Record Keeping for infection following Transfusions or Blood Product use

Identification of HCV Infections not included in English HCV Lookback

4.1. In the 2002 article by K. Soldan (PRSE0000620), at page 588, an attempt was

made to estimate the likely number of infections due to transfusion of blood components issued by the English National Blood Service (NBS) that were not identified during the English HCV Lookback. The estimated infections were not, and could not be, notified because there was no information to identify each potentially infected component and link this to a known recipient. These estimated unidentified HCV infections were not included in notifications or counts of HCV infected individuals at the time by PHLS or subsequently by its successor organisations. Under the Public Health (Control of Diseases) Act 1984, notification is required for cases or suspected cases of infection for the purpose of disease control and does not apply to estimates of infections among unidentified individuals.

4.2. The responses provided describe the actions taken by PHLS and its successor organisations to identify HCV infections among transfusion recipients who were not identified by the English HCV Lookback based on the level of understanding of the probability of unidentified infections, the deficiencies in the English HCV Lookback, and the threat to public health of undiagnosed HCV infections.

4.3. The following information about known causes of death for those who died is provided in the collaborative paper titled 'The English National Blood Service HCV Lookback Collation Collaborators. Probability of receiving testing in a national lookback programme: the English experience' (Transfusion 2002 Sep;42(9):1140-5): (NHBT0097156_005)

1) "Some free text about the cause of death was reported for 44 percent (1199) of those known to have died. Of these, 5 percent mentioned liver-related conditions. For 26 recipients with liver conditions, and 10 with gastrointestinal bleeds, involvement of HCV infection, if acquired at their time of transfusion, could not be excluded (cases with cause stated as alcohol or other non-HCV cause, and cases with death known to have

occurred within 4 years of transfusion, were excluded). Of these, three in the liver group and one in the gastrointestinal bleed group received their lookback transfusion whilst in the care of gastroenterologists and therefore may well have had pre-existing liver or gastrointestinal disease. For 32 of the 36 suspect deaths, the date of death was not known, so may have been soon after transfusion."

4.4. The names, date of birth and date of death of recipients identified during the English HCV Lookback were collected by the NBS. This information was not held at the time by PHLS or subsequently by its successor organisations.

4.5. Donors tested by the NBS whose test result was indeterminate were recorded as such (i.e. as "indeterminate") in PHLS and NBS surveillance reports on testing outcomes. The NBS was responsible for contacting and counselling these individuals, and for notification as required by the Act. Clinicians caring for patients hold the responsibility for notification of infections covered by the Act, but indeterminate test results would not likely be considered to indicate "an individual suffering from hepatitis C" and therefore would not normally have led to statutory notification when HCV became notifiable in 1998. The PHLS and its successor organisations did not include indeterminate test results in counts of identified infections.

4.6. Indeterminate HCV test results for donors (as referred to in Annex A of the Chief Medical Officer letter dated 3 April 1995) (DHSC0027764_001) were recorded and deferred from blood donation. The English HCV Lookback included previous donations from some donors found to be of indeterminate anti-HCV status that was thought likely to be predictive of true HCV infection at some time. These were defined as donors with a 3+, or stronger, band to either c22 or NS3[c33c] on recombinant immunoblot assay (RIBA) testing and reactivity in accordance with the manufacturer's instructions on at least one enzyme

immunoassay (EIA) without negative results by an alternative EIA. PHLS and its successor organisations did not undertake any follow-up of donors with indeterminate (or positive) test results; this was managed by the NBS with referrals into appropriate care.

4.7. Indeterminate HCV test results were not included in the monitoring of HCV incidence and prevalence by the PHLS and its successor organisations. The implications of an indeterminate result would depend on the assay characteristics and the understanding of the natural history of HCV at the time, so PHLS staff would defer to expert microbiological staff in the NBS.

An Account of the 1995 HCV Lookback

4.8. Explanations of the methods, results and findings of the 1995 HCV Lookback exercise for England are provided below. Information for the Devolved Administrations is not held by UKHSA. The Inquiry may wish to contact Public Health Scotland, Public Health Wales and the Public Health Agency Northern Ireland directly for responses on behalf of the Devolved Administrations regarding this matter.

4.9. A detailed explanation of the process used to gather information by the 1995 Lookback is described in the paper 'Transfusion transmission of HCV infection before anti-HCV testing of blood donations in England: results of the national HCV lookback program' (Transfusion. 2002 Sep;42(9):1146-53 (NHBT0097156_004). This paper describes the methods for identifying components for the lookback, identification and testing of recipients, national collation of data, and the analyses of the lookback data set.

4.10. Blood products were not included in the English 1995 HCV Lookback.

4.11. 669 people were identified as HCV infected after receiving a transfusion with a

component included in the lookback exercise.

4.12. The paper cited above (NHBT0097156_004) notes that of 14 regional transfusion centres in England, 12 contributed data to the lookback data set about all donors, components and identified recipients. From this sub-set, p1148 of the paper notes:

1) "Recipients were identified for 97 percent (4432/4586) of transfused components, and 39 percent (1713) of these were not known to be dead. Fifteen percent (651) did not proceed for testing either because they were not traced or because their clinician indicated they were unsuitable for testing (the justification applied to each case was not reported). Twenty-four percent (1062) of identified recipients were tested. Of all tested recipients, 50 percent (669/1333) had evidence of HCV infection and 68 percent (456) of these were shown to be viremic."

4.13. The number of people notified should be between the number identified and not known to be dead and the number tested. National recording did not include details of all communications with patients and their families from the 12 centres who provided detailed tracing data for the 1995 Lookback.

4.14. 1,333 people were tested for HCV as a result of being notified that they were at risk.

4.15. 669 people tested positive for HCV following notification.

4.16. 488 people tested negative for HCV following notification.

4.17. 52 people tested indeterminate for HCV. For a further 124 people there were insufficient test results to classify their infection status.

4.18. The information reported from the 12 participating centres included 651 people who were reported as not known to be dead and as not tested. These 651 did

not proceed for testing either because they were not traced or because their clinician indicated they were unsuitable for testing (the justification applied to each case was not reported). In cases where the clinician indicated they were unsuitable for testing, UKHSA and its predecessor organisations does not hold information on whether the patient or family members were consulted.

4.19. The UKHSA and its predecessor organisations does not hold information on how many times clinicians tried to notify their patients.

4.20. UKHSA and its predecessor organisations does not have information on the numbers of tested patients who were counselled. The UKHSA understanding is that the NBS protocol was to provide counselling to all tested patients; it is also possible that some patients who were not tested would have received counselling and decided not to proceed to testing.

4.21. The 1995 Lookback exercise focused on recipients of blood components, not recipients of blood products such as haemophiliacs, so individuals who had been identified by places such as Oxford Haemophilia Centre as testing positive for Non-A Non-B hepatitis (NANBH) due to liver functions test results were not included.

4.22. The PHLS reported infections in repeat donors separately and conducted extra investigations and analyses to inform both blood safety and epidemiology of these infections. An example of this reporting is provided by the paper 'Incidence of seroconversion to positivity for hepatitis C antibody in repeat blood donors in England, 1993-5' by Soldan K, Barbara JA, Heptonstall J (BMJ, 1998 May 9;316(7142):1413-7 (HSOC0009903). The protocols for managing repeat donors and their prior donations were the responsibility of the NBS; the PHLS contributed advice to inform this management when consulted.

4.23. With regard to the other Public Health Bodies, the PHLS and its successor

organisations in England were not recipients of information gathered by the Devolved Administrations, and data was not shared or held centrally by PHLS and its successors.

Actions Post-1995 Lookback

4.24. The aim of the work described in the 2002 paper titled 'The contribution of transfusion to HCV infection in England' by K. Soldan (PRSE0000620) was to attempt to estimate the likely number of infections due to transfusion of blood components issued by the English NBS that were not, for various reasons, identified during the English 1995 HCV Lookback.

4.25. The number of not-identified infections estimated in the 2002 paper by K. Soldan were not included in published statistics of HCV at the time by PHLS or subsequently by its successor organisations.

4.26. Please note that a response is provided by UKHSA and its predecessor organisations for England only. The Inquiry may wish to contact Public Health Scotland, Public Health Wales and the Public Health Agency Northern Ireland directly for responses on behalf of the Devolved Administrations to this matter.

4.27. In England, no direct response was made to the Penrose recommendation on testing for HCV as a variety of initiatives were in place to help find individuals at risk of undiagnosed HCV infection.

4.28. For example, in addition to the national HCV lookback programme in England, PHLS staff supported Health Promotion England, on behalf of the Department of Health, in providing four regional conferences for health care professionals across England to help raise awareness of hepatitis C infection in 2002. Further conferences were subsequently organised by Health Promotion England.

4.29. In 2004, PHLS/HPA supported the Department of Health to provide an externally commissioned campaign aimed at healthcare professionals and the public called 'FaCe It', which sought to raise awareness of hepatitis C infection in support of the government's Hepatitis C Action Plan for England. This included poster campaigns and displays as well as advertorials and commissioned pieces for print and radio targeting groups at risk of HCV infection.

4.30. In addition, in partnership with stakeholders, a variety of initiatives and resources have been developed by the PHLS and its successor organisations to help raise awareness of HCV and increase the numbers of people diagnosed. These include initiatives to support healthcare providers, commissioners and others to improve case-finding and testing in both the general population and among risk groups.

4.31. These initiatives and resources include the following:

1) A suite of resources is available to encourage people at risk of infection to seek a HCV test.[7] This includes an online testing quiz, which has been completed by more than 2,000 people (as at April 2021).[8] Also provided are posters, videos and banners for social media in multiple languages which are co-branded with the World Hepatitis Alliance, the British Liver Trust and the Hepatitis C Trust.

2) A Hepatitis C re-engagement exercise is being undertaken to support the NHS to identify people registered with a GP who have been diagnosed with HCV in the past but who may not have cleared their infections.[9] The NHS is in the process of contacting these patients to

[7] https://publichealthengland-immunisati.app.box.com/s/iptxtlziu57evyejw8zgvhimh0pjwa05
[8] http://www.hepctrust.org.uk/quiz
[9] https://www.gov.uk/government/publications/hepatitis-c-patient-re-engagement-exercise

offer testing so that those with chronic infection can be referred for assessment for treatment. Data from the NHS England Hepatitis C Patient Registry and Treatment Outcome System suggests that at least 326 individuals have already been identified and accessed treatment via this exercise as of 23 June 2021.

3) The NHS hepatitis elimination programme is supporting a testing initiative in primary care which is developing a software tool for installation in participating general practice electronic patient management systems to identify and offer testing to those who have risk factors for infection.

4) A Royal College of General Practitioners (RCGP) training course on hepatitis B and C is available to help raise awareness in primary care and among other professionals working with groups at high risk of viral hepatitis infection.[10] As of February 2017, 2,800 individuals had completed the e-learning module. In November 2018 and again in August 2021, the course was updated; as of April 2021, 500 individuals had completed the updated version. Other downloadable training resources are also available, such as those accessible via the International Network on Health and Hepatitis in Substance Users, that have been developed by PHE/UKHSA, the NHS, the RCGP and academic organisations for use in primary care and drug treatment services.[11]

5) PHE/UKHSA has published an evidence review highlighting interventions that are effective in increasing case-finding and linkage to care for patients with HCV (WITN7123014). This was produced to

[10] https://elearning.rcgp.org.uk/course/search.php?search=Hepatitis+B%26C
[11] https://www.inhsu.org/what-we-do/education/united-kingdom/

support commissioners and health care providers in making decisions on prioritisation of resources and the commissioning of services.

6) HCV Action has produced a Hepatitis C Commissioning Toolkit which outlines the importance of effective commissioning in eliminating hepatitis C (WITN7123015).

7) As part of the NHS England-funded hepatitis elimination initiatives, a pilot project led by Bristol University in collaboration with PHE/UKHSA is underway to provide primary care-based testing for HCV among individuals aged 40 to 65 who have not been identified as being at risk of HCV via other means.

Guidance and Advice to Medical Professionals

4.32. In England, in addition to the list of online training and resources provided in this statement, the following guidance has been provided to medical professionals to help them identify patients in need of HCV testing because they were at risk of infection from a blood transfusion:

1) Information on hepatitis C for General Practitioners (WITN7123016).

2) UK standards for microbiology investigations: screening for hepatitis C infection (WITN7123017).

3) Guidance on the investigation and management of occupational exposure to hepatitis C (ABHB0000097).

4) Information for General Practitioners, for their patients, on hepatitis C and the Infected Blood Inquiry (RLIT0000790).

5) A suite of resources and information about the NHS England and PHE/UKHSA initiative to support finding and treating diagnosed patients

who may not have accessed the latest curative treatments.[12]

6) Guidance on management of potential exposure to blood-borne viruses in emergency workers for occupational health service providers and frontline staff (WITN7123018).

HCV Positive Blood Donors tested since September 1991 (introduction of routine screening for HCV)

4.33. Data on the number of new and repeat blood donors who were confirmed positive for HCV are produced by the joint NHSBT/ UKHSA Epidemiology Unit for the years 1991 to 2021 as detailed in the table below.

4.34. Table 1: Numbers of new and repeat blood donors confirmed positive for HCV, by month, 1991 to 2022 (WITN7123006)

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
	A. Number of new donors												
1991	-	-	-	-	-	-	-	-	-	-	-	-	**94**
1992	-	-	-	-	-	-	-	-	-	-	-	-	**289**
1993	-	-	-	-	-	-	-	-	-	-	-	-	**252**
1994	-	-	-	-	-	-	-	-	-	-	-	-	**254**
1995	-	-	-	-	-	-	-	-	-	33	19	17	**249**
1996	22	14	16	18	13	13	30	11	6	13	15	14	**185**
1997	17	17	8	9	11	15	11	16	14	17	14	11	**160**
1998	8	10	11	6	13	6	11	7	9	9	9	6	**105**
1999	10	13	13	14	10	18	7	8	15	8	17	12	**145**
2000	10	16	15	7	17	10	14	9	14	8	4	8	**132**

[12] https://www.gov.uk/government/publications/hepatitis-c-patient-re-engagement-exercise

.

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
2001	10	11	10	6	8	8	13	8	12	8	16	5	**115**
2002	13	10	11	7	3	10	7	10	10	10	6	5	**102**
2003	11	6	8	6	10	5	7	10	6	6	8	8	**91**
2004	5	6	5	5	6	10	5	4	16	2	8	5	**77**
2005	8	7	6	4	0	7	10	6	3	3	0	7	**61**
2006	10	5	7	4	2	6	9	4	8	5	2	2	**64**
2007	5	3	8	5	3	5	4	2	4	6	4	4	**53**
2008	5	4	7	5	5	5	7	3	4	10	5	2	62
2009	8	1	5	5	4	6	9	5	6	5	4	7	65
2010	5	4	5	2	6	8	9	5	4	5	2	4	59
2011	7	4	7	11	6	6	6	3	3	2	7	4	66
2012	6	12	7	3	2	4	2	3	3	6	1	2	51
2013	2	5	9	4	5	2	3	5	1	1	2	1	40
2014	0	1	1	3	1	2	4	3	0	5	2	2	24
2015	3	6	5	3	2	3	4	5	4	3	2	2	42
2016	3	1	2	1	2	1	4	2	3	6	2	1	28
2017	2	2	0	2	2	2	2	5	2	2	2	3	26
2018	0	2	4	5	1	3	1	0	2	1	0	2	21
2019	2	1	4	6	3	2	1	2	1	1	3	5	31
2020	4	1	2	2	1	4	0	3	1	2	1	2	23
2021	4	5	3	4	1	5	0	2	2	2	4	2	34
2022	1	2	6	3	2	-	-	-	-	-	-	-	**14**
	B. Number of repeat donors												
1991	-	-	-	-	-	-	-	-	-	-	-	-	**438**
1992	-	-	-	-	-	-	-	-	-	-	-	-	**518**
1993	-	-	-	-	-	-	-	-	-	-	-	-	**204**

.

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
1994	-	-	-	-	-	-	-	-	-	-	-	-	**125**
1995	-	-	-	-	-	-	-	-	-	2	5	2	**105**
1996	11	5	4	4	4	5	5	4	4	5	7	5	**63**
1997	1	4	9	2	4	2	5	6	4	5	5	5	**52**
1998	8	7	6	4	2	6	4	4	4	1	11	1	**58**
1999	1	1	2	3	1	3	1	7	3	3	9	3	**37**
2000	3	0	2	2	3	6	3	2	2	2	2	1	**28**
2001	6	4	0	1	4	4	1	2	1	0	0	3	**26**
2002	2	2	2	1	3	2	2	4	2	0	3	2	**25**
2003	0	2	2	2	1	0	2	4	0	0	2	0	**15**
2004	2	3	3	4	0	1	1	1	2	1	1	0	**19**
2005	0	1	1	0	0	1	0	1	0	0	0	1	**5**
2006	1	1	1	0	0	1	0	0	0	0	0	0	**4**
2007	0	1	1	1	0	0	0	0	0	0	0	0	**3**
2008	0	0	0	0	0	0	2	0	0	0	0	0	**2**
2009	0	0	0	0	0	0	1	0	0	0	0	1	**2**
2010	0	0	2	0	1	0	2	1	0	0	0	2	**8**
2011	0	1	0	1	1	1	0	1	0	0	0	0	**5**
2012	0	1	1	0	0	0	2	1	0	1	0	0	**6**
2013	0	0	0	0	0	0	0	2	0	0	0	0	**2**
2014	0	0	0	0	0	0	0	0	0	0	1	0	**1**
2015	0	0	0	0	0	0	1	0	0	0	0	0	**1**
2016	0	0	0	0	0	0	0	0	0	0	0	0	**0**
2017	1	0	1	0	0	0	0	0	1	1	0	0	**4**
2018	0	0	0	0	0	0	0	0	0	0	0	0	**0**
2019	1	0	0	0	0	0	0	0	0	0	0	0	**1**

.

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
2020	1	1	0	0	0	0	0	0	0	0	0	0	**2**
2021	0	0	0	1	0	0	0	0	0	0	0	0	**1**
2022	0	0	0	0	0	-	-	-	-	-	-	-	**0**

4.35. Table notes:

1) Repeat donors may include donors newly tested for HCV infection, particularly after routine screening was introduced.

2) 1991-1995 figures include data from England (from NHS Blood and Transplant) and Wales (from Welsh Blood Service); NHS Blood and Transplant figures include data from North Wales up until April 2016.

3) 1991 data is partial year data covering 1 September 1991 to 31 December 1991 inclusive.

4) 2020 data excludes 9 HCV positive new convalescent plasma donors.

5) 2021 data excludes 5 HCV positive new convalescent plasma donors and 4 HCV positive new plasma for medicine donors, see working tab.

6) 2022 data is preliminary and does not currently exclude Plasma for Medicine donors.

7) 2021 data is preliminary to 4 November 2021; it excludes 4 HCV positive new convalescent plasma donors but includes 2 new plasma for medicine donors.

4.36. Blood donations that are found to be repeatedly reactive for HCV according to the criteria specified by the manufacturer of the test used are referred for further confirmatory testing according to the algorithm in place in the testing laboratory concerned. Please note that these algorithms are not specified at

national level by UKHSA or its predecessor organisations.

4.37. There are no data prior to the commencement of routine testing known to the NHSBT/UKHSA Epidemiology Unit. UKHSA contacted NHSBT to ascertain whether that organisation had access to monthly data for the period September 1991 to September 1995 inclusive. NHSBT staff confirmed that neither the NHSBT library nor the NHSBT confirmatory laboratory was able to locate old reports or original data that might provide monthly counts for this period.

HCV Positive Transfusion Recipients tested or diagnosed since September 1991

4.38. Between 1992 and 2004, a total of 49,819 confirmed hepatitis C infections were reported to the PHLS/HPA by laboratories in England and Wales. The annual number of reports increased from 241 in 1992 to 8,149 in 2004 (reference: U. Gungabissoon, M. A. Balogun and M. E. Ramsay. Hepatitis C Virus: Laboratory Surveillance in England and Wales, 1992-2004; Epidemiology and Infection 2007 May; 135(4): 541–548). (WITN7123004) (Information relating to risk factors was present in 28.5% (14,221/49,819) of the reports received; of these, 303 reports were attributed to blood transfusion, 26 of which reported as having acquiring infection while abroad.

4.39. Prior to this, a survey of anti-HCV tests performed in public health laboratories between 1990 and 1993 identified that 548 of 3,315 tests undertaken had a HCV acquisition risk described as having acquired hepatitis C through receipt of blood or blood products. Of these tests, 189 (34.4%) were positive for anti-HCV. (reference: Ramsay ME, Balogun MA, Collins M, Balraj V. Laboratory surveillance of hepatitis C virus infection in England and Wales: 1992 to 1996; Communicable Disease and Public Health 1998 Jun; 1(2): 89–94) (RLIT0000319).

vCJD Lookback

4.40. Between 2003 and 2013, the HPA provided the secretariat function for the CJD Incidents Panel, which had UK-wide coverage and included representatives from the Devolved Administrations. The Panel provided advice on the actions to take following incidents where potential healthcare exposures to prions had occurred. Where these were surgical exposures, the NHS trust where the surgery occurred was involved in the follow up and management of the incident, including identifying any patients that the panel advised should be informed.

4.41. UKHSA currently undertakes, as its predecessor organisations did previously, long term follow up of certain individuals with an increased risk of developing CJD as a consequence of a healthcare exposure. This includes some individuals from the Devolved Administrations, although Public Health Scotland undertakes its own follow up and does not routinely share patient identifiable information with UKHSA.

4.42. The National CJD Research and Surveillance Unit (NCJDRSU) undertakes surveillance of clinical cases of CJD. As part of public health follow up, individuals with an increased risk of CJD were cross-checked against the NCJDRSU register twice a year to detect whether any may have developed the condition. This cross checking has not taken place since 2019 due to reductions in capacity in UKHSA resulting from the combined pressures of responding to the COVID-19 public health emergency and overall headcount reductions and staff turnover in the UKHSA CJD team. However, this change in practice is not considered to have reduced the completeness of CJD surveillance as there continues to be case matching to mortality records and follow-up by the NCJDRSU of any relevant past healthcare exposures for new CJD diagnoses. UKHSA and NCJDRSU receive enquiries relating to CJD and infection control relating to CJD and may refer these to each other

or seek information to help respond directly.

4.43. The main documentary records held by the UKHSA and its predecessor organisations regarding vCJD commence in 2003/04 when the HPA was established and assumed responsibility for providing the secretariat function for the CJD Incidents Panel. UKHSA is not aware of its predecessor organisation having received any documents concerning a lookback in 1998, or other contextual information to enable a deduction of the purpose, scope or operation of any lookback at that time.

4.44. The UKHSA does hold records of three exercises where individuals were identified as having a potential risk of variant CJD and informed of this risk. The first exercise focused on recipients of blood from donors who later developed vCJD for the following time periods:

- December 2003 – January 2004: Living recipients from 16 blood donors who had later developed vCJD;
- July 2005: Living recipients from 16 blood donors who had later developed vCJD.

4.45. In December 2003, following the conclusion that an individual who had died from variant CJD in autumn that year could have acquired the infection leading to the development of this disease from a blood transfusion, the HPA was asked by the Department of Health to work with the NBS to coordinate the contacting, informing and supporting of 15 infected individuals in England and Wales. The Scottish Health Department developed separate arrangements for informing two recipients living in Scotland. In January 2004, the HPA was informed by the NBS of a further donor who had subsequently developed vCJD. One recipient of blood from this individual was notified at this time. A fuller explanation of this

exercise is contained in the HPA 'Interim report on incident involving blood components and vCJD and the patient notification exercise conducted from December 2003 to January 2004', a copy of which has been provided previously to the Inquiry.

4.46. In 2005, following the diagnosis of vCJD in two more former donors, a further 10 living recipients of implicated blood components had been traced, notified and asked to take special public health precautions. This made a total of 27 living blood transfusion recipients who have been notified. Further information is provided in the minutes of the CJD Incidents Panel Meeting that took place on 7 September 2005 (PHEN0000629).

4.47. The second exercise focused on donors of blood to individuals who later developed v CJD and other recipients of blood from these donors covering the following time periods:

1) July to October 2005: Blood donors identified whose blood was transfused to 3 recipients who later developed vCJD;

2) November 2005: Other recipients of the blood from 2 of above donors;

3) January 2010: Donors whose blood was transfused to 3 recipients who later developed vCJD;

4) April 2010: Other recipients of the blood from these donors.

4.48. The risk assessment, papers and record of the meetings concerning whether to inform donors to individuals who later developed vCJD, and the other recipients of these donors, are contained within the papers, minutes and associated correspondence of a subgroup of the CJD Incidents Panel that took place in 2005. Copies of these documents were provided by PHE to the Infected Blood Inquiry in 2019.

4.49. There were two occurrences in which this type of notification was undertaken: one in 2005 and one in 2010. These followed the recommendation from the CJD Incidents Panel in June and September 2005 respectively to the Chief Medical Officer that donors to individuals who later developed vCJD and other recipients of blood from these donors should be deferred from donating organs and tissues, including blood. The notification to donors and other recipients was done by the National Blood Services in England, Scotland and Wales, supported by the HPA and Health Protection Scotland, which provided information resources and communications to health professionals.

4.50. Further information is provided in the papers of the CJD Incidents Panel meetings that took place in May 2005, September 2005, May 2009 and September 2009. Copies of these documents were provided by PHE to the Infected Blood Inquiry in 2019.

4.51. The third exercise focused on recipients of UK sourced plasma products (1980-2001). The background, rationale and process followed for this notification exercise is described in the report 'Notification of potential exposure to variant Creutzfeldt- Jacob Disease through plasma products - Report to the CJD Incidents Panel by the Health Protection Agency January 2005' (PHEN0000721). The consideration and discussion that led to the notification exercise is recorded in the papers of the CJD Incidents Panel Technical Subgroup that took place in April 2004 and the papers of the CJD Incidents Panel that took place in May 2004. Copies of these documents were provided by PHE to the Inquiry.

.

Statement of Truth

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

Signed: GRO-C

Dated: 17 August 2022

.

INFECTED BLOOD INQUIRY

INDEX TABLE TO WITNESS STATEMENT OF DR ROBERT KYFFIN

Document	URN	Date	Description
1	WITN7123002	25/03/2010	Department of Health - Health Protection Legislation Guidance 2010
2	WITN7123003	1980	Galbraith N-Communicable Disease Control-Community Medicine 1980(2) 135-143 "Communicable disease control: the development of a laboratory associated national epidemiological service in England and Wales"
3	WITN7123004	2007	Gungabissoon M-Hepatitis C Virus Laboratory Surveillance Epidemiology and Infection 2007 135(4) 541-548. Hepatitis C virus: laboratory surveillance in England and Wales, 1992-2004"
4	NHBT0097156_005	16/06/199	HCV Lookback Collaborators-Probability of receiving testing-Transfusion 2002 42(9) 1 140-1145 "Probability of receiving testing in a national lookback program: the English HCV experience".

.

5	NHBT0097156_004	01/07/2002	HCV Lookback Collaborators Transfusion transmission of HCV infection-Transfusion 2002 42(9) 1146-1153"Transfusion transmission of HCV infection before anti-HCV testing of blood donations in England: results of the national HCV lookback..."
6	RLIT0000319	1998	Ramsay M-Laboratory surveillance of hepatitis C virus-Comm Disease and Public Health 1998 1 (2) 89-94 "Laboratory surveillance of hepatitis C virus infection in England and Wales: 1992 to 1996"
7	HSOC0009903	09/05/1998	Soldan K-incidence of seroconversion to positivity for hepatitis C-BMJ 1998 316 1413-1417 "Incidence of seroconversion to positivity for hepatitis C antibody in repeat blood donors in England, 19935"
8	PRSE0000620	13/08/2002	'The contribution of transfusion to HCV infection in England' by K. Soldan et al.
9	DHSC0027764_001	03/04/1995	Letter from Dr. Kenneth C. Calman, Department of Health, to All Doctors, re: hepatitis C and Blood Transfusion Lookback
10	PHEN0000721	07/01/2005	Notification of potential exposure to variant Creutzfeldt-Jacob Disease through plasma products - Report to the CJD Incidents Panel by the Health Protection Agency January 2005

.

11	PHEN0000629	07/09/2005	CJDIP Meeting minutes September 2005
12	WITN7123006	18/07/2022	UKHSA- HCV Positive Blood Donors By Month 1991-2022
13	WITN7123007	13/07/2021	Letter from Jo Churchill to Michael Brodie, Chief Executive, Public Health England (PHE), re: Public Health England strategic remit and priorities
14	WITN7123008	31/01/2022	Public Health England, Annual Report and Accounts, 2020-2021
15	WITN7123009	29/03/2021	Policy paper, 'Transforming the public health system: reforming the public health system for the challenges of our times'
16	WITN7123010	13/07/2021	Letter from Lord Bethell to Dr Jenny Harries, UKHSA chief executive
17	WITN7123011	07/06/2022	Guidance, 'Notifiable diseases and causative organisms: how to report', by the UK Heath Security Agency (UKHSA)
18	WITN7123012	27/08/2019	Surveillance report, 'HIV treatment and care in Scotland: summary report to 31 December 2018', by BL Cullen, RL Cameron, D Henderson, LA Wallace and DJ Goldberg
19	WITN7123013	23/06/2020	Report, 'HIV in Scotland: update to 31 December 2019', by Public Health Scotland
20	WITN7123014	2019	'Hepatitis C: interventions for patient case-finding and linkage

.

			to care evidence review' by Public Health England
21	WITN7123015	01/09/2018	'Hepatitis C Commissioning Toolkit', by HCV Action
22	WITN7123016	25/11/2020	'Hepatitis C: information for GPs'
23	WITN7123017	01/08/2017	'UK Standards for Microbiology Investigations'
24	WITN7123018	01/09/2019	'Guidance on management of potential exposure to blood-borne viruses in emergency workers For occupational health service providers and frontline staff' by Public Health England
25	RLIT0000790	01/07/2019	Information for patients on the Infected Blood Inquiry
26	ABHB0000097	01/12/1999	'Guidance on the Investigations and Management of Occupational Exposure to Hepatitis C' by Dr Mary Ramsay, PHLS Communicable Disease Surveillance Centre