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INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF MORWENNA CARRINGTON OF DEPARTMENT OF HEALTH AND SOCIAL CARE

Contents

Section 1: Introduction

1.1. I, Morwenna Carrington, have been a Deputy Director in the Department of Health and Social Care ("DHSC") since September 2019. In that time, with the exception of a short period from March to June 2020 when I was seconded to the COVID-19 response as Deputy Strategic Incident Director in the Operational Response Centre ("ORC"), my role has included oversight of blood safety policy and sponsorship of the Advisory Committee on the Safety of Blood, Tissues and Organs ("SaBTO"). The blood safety policy team in DHSC shares responsibility with NHS Blood and Transplant ("NHSBT") for providing the secretariat support for SaBTO. The blood safety policy team in DHSC also oversees two compensation schemes for Creutzfeldt-Jakob disease ("CJD").

1.2. I make this statement in response to a request from the Infected Blood Inquiry ("the Inquiry") to DHSC. I am making this statement as my understanding of the matters referred to in this statement offers the best prospect of providing accurate and helpful evidence to the Inquiry.

1.3. It will be apparent from the introduction to my role set out above that I have no personal knowledge of the events that the Inquiry has asked about before September 2019. My knowledge of these matters, and the content of this statement, is derived from documents, both those supplied by the Inquiry and additional ones that have been located by the DHSC team, including the DHSC legal team. The information that I provide is true to the best of my knowledge and belief, but it is subject to that caveat about its sources. Whilst it provides a general guide to events and applicable guidance, for any areas of specific concern it is not, in my opinion, a true substitute for questions addressed to those who were directly involved at the time, whose perspectives I am not in a position to supply. For example, given the timing of the R9 and its direction to the DHSC, individuals who were directly concerned with many of the decisions made, such as the former CMO Sir Liam Donaldson, have not played a part in the drafting of this statement.

Content of the Statement

1.5. The overall purpose of this Statement is to provide an outline of the role that the Department of Health, subsequently the Department of Health and Social Care ("DH" or "DHSC" in this Statement) had from 2007 to the present with regards to:

- The decontamination of surgical instruments
- The notification and de-notification of highly transfused patients; and
- The MRC Prion Unit's Direct Detection Assay (hereafter "DDA").

1.6. These matters are addressed at, respectively, Section 2 – 5, Section 6 – 7 and Section 8. However, the questions asked under these headings are broader than the post-2007 period only so, where relevant, earlier periods have also been addressed in those sections.

1.7. To answer these questions, the DHSC team has carried out extensive research of the Department records and the Government Legal Department has provided further relevant documentation.

1.8. I will first set out some background on CJD, including:

- Variant Creutzfeldt-Jakob disease ("vCJD"),
- Sporadic Creutzfeldt-Jakob Disease ("sCJD"),
- Iatrogenic Creutzfeldt-Jakob Disease ("ICJD").

1.9. Prion diseases or transmissible spongiform encephalopathies ("TSEs") are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The causative agents of TSEs are believed to be prions. The term "prions" is used to refer to abnormal, pathogenic agents that are transmissible and are able to induce abnormal folding of specific normal cellular proteins called prion proteins ("PrP") that are found most abundantly in the brain. The abnormal folding of the PrPs leads to brain damage and the characteristic signs and symptoms of the diseases. Prion diseases are usually rapidly progressive and always fatal.

1.10. Normal (harmless) PrPs are found at high levels in brain and nerve cells. The exact role of normal PrPs is unknown; however, it is thought they may play a

role in transporting messages between certain brain cells. In CJD, mistakes that occur during protein folding lead to a build-up of misfolded PrPs in the brain. This causes other PrPs to misfold and can ultimately lead to plaques and the development of small holes in the brain, resulting in a sponge-like appearance. CJD leads to progressive neurodegeneration. **[WITN7590150]**

1.11. Sporadic Creutzfeldt-Jakob disease accounts for approximately 8 in every 10 cases of CJD and is usually characterised by a rapidly progressive dementia and neurological symptoms. **[WITN7590002]** These symptoms appear on average between the ages of 60 and 65, and rapidly worsen in the space of a few months. Methionine homozygosity at codon 129 of the PrP gene is a recognised risk factor for the development of sCJD. Between 65% and 81% of sporadic cases have this genotype. **[WITN7590003]** Currently, no other factors have been identified to increase the risk of developing sCJD. In 2020, there were 131 recorded deaths from sCJD in the UK. **[WITN7590004]**

1.12. Familial CJD is a very rare genetic condition where an individual inherits a PrP gene carrying a mutation from their parents, which causes prions to form in their brain during adulthood, triggering the symptoms of CJD. It affects about 1 in every 9 million people in the UK. In 2020, there were 6 deaths from familial CJD and similar inherited prion diseases in the UK. **[WITN7590004]**

1.13. In addition to sporadic and familial CJD, there are two types of acquired Creutzfeldt-Jakob Disease that arise due to exposure to an external source of abnormal PrP. These include ICJD and vCJD.

- The first case of ICJD was reported in 1974. ICJD is caused by accidental transmission of the infection, for example, through medical or surgical treatment. Many cases occurred through the use of human growth hormone to treat children with restricted growth (> 230 cases worldwide). This is because the human growth hormone was manufactured from the pituitary glands of deceased people, some of whom were unknowingly infected with CJD. However, since 1985, the use of pituitary-derived human growth hormone in the UK has been banned and replaced with an artificially manufactured alternative, which has mitigated this risk. **[WITN7080004]**

- Other cases of ICJD have occurred from the transplantation of certain infected human tissues including dura mater (> 230 cases worldwide) and corneas, and through medical procedures involving instruments contaminated with CJD used in neurosurgery **[WITN7080004]**. Increased awareness of these risks means ICJD is now very rare. In 2020, there was 1 death from ICJD in the UK, which occurred in an individual who had been treated with human growth hormone before 1985 **[WITN7590004]**.

- vCJD was first identified in 1996 by the National CJD Surveillance Unit in the UK. In 1996, it was discovered that the consumption of beef or other products from cattle infected with bovine spongiform encephalopathy ("BSE") could cause vCJD. Like other forms of CJD, vCJD is a fatal generative disease that affects the central nervous system. vCJD can be diagnosed by neuropathologic examination of brain tissues. Following the discovery of vCJD in 1996, a number of controls were put in place to prevent BSE from entering the human food chain, culminating in the reinforced feed ban, when mammalian meat and bone meal was banned from all farm animal feed **[WITN7590005]**. The ban was first introduced in 1988, when the cause of BSE was first epidemiologically linked to feed containing meat and bone meal but was reinforced in 1996.

- vCJD has also been transmitted by blood transfusion. Since 1990, there have been 178 deaths from vCJD in total in the UK (including 3 that occurred through transmission following a blood transfusion and 1 death 5 years after transfusion without developing symptoms vCJD but tested positive at post-mortem). The last death from presumed-dietary acquired vCJD occurred in 2016. The last known transmission through blood transfusion occurred in 1999. There is no evidence that vCJD has been transmitted through surgery or surgical instruments to date. **[WITN7034008]**.

1.14. In the early 2000s, there was more focus on vCJD than CJD, as the source of the primary risk was dietary exposure through the consumption of contaminated beef, which could have affected a significant proportion of the population. At this time, the extent of primary transmission due to the consumption of

contaminated beef and the potential for secondary transmission through healthcare exposure were not known. Modelling considered the possibility of very high case numbers of vCJD, although with the emergence of more data, these estimates were subsequently revised downwards. **[WITN7034008]**

1.15. In addition to strict controls in place to prevent BSE from entering the human food chain, since the discovery of vCJD in 1996, many public health precautions were put in place in the following years to minimise the risk of onward vCJD transmission. The leucodepletion of all blood components was introduced in 1999, as well as other measures to reduce transmission through blood, blood products, organ and tissue donation and surgery (including through effective Infection Prevention and Control ("IPC")) **[WITN7080004]**.

1.16. As mentioned above, the DHSC blood safety policy team oversees two compensation schemes for prion disease:

- The DHSC team directly manages the compensation scheme for people infected with CJD following treatment with pituitary-derived human growth hormone from a person infected with CJD. This includes working with GLD to settle legal cases and acting as data controller for the dataset that UK Health Security Agency ("UKHSA") holds and processes.
- Separately, the team oversees the work of the vCJD Trust to deliver a compensation programme that it manages for people that have contracted vCJD as a result of exposure to bovine products purchased in the United Kingdom, or otherwise as a result of exposure in the United Kingdom to BSE or vCJD. As part of that, I met with Trustees of the vCJD Trust in July 2022, to discuss delivery of the Trust's work **[WITN7080004; WITN7590006]**.

1.17. Preventing the transmis sion of CJD and vCJD is difficult. This is because sterilisation methods used to help prevent other types of pathogen, including bacteria and viruses, from spreading are not completely effective against the transmissible PrP that causes the various forms of CJD. However, guidelines on the reuse and decontamination of surgical equipment mean that cases of CJD or vCJD spread through medical treatment are now very rare. The British Society of Gastroenterologists (BSG) noted in its 2020 decontamination

guidance that there had been a dramatic fall in the incidence of vCJD in recent years .The guidance also noted that the Advisory Committee on Dangerous Pathogens ("ACDP") revised its risk assumptions in 2015 to reflect this. Furthermore, following the discovery of vCJD in 1996, strict controls were put in place to prevent BSE from entering the human food chain, thereby preventing further population exposure through the consumption of potentially-contaminated beef or beef products, and limiting the potential pool of people that could be unknowingly incubating the disease **[WITN7080004; WITN7590007]**.

1.18. In the UK, there have been five identified cases of vCJD transmitted by blood transfusion. Steps taken to minimise the risk of transmitting vCJD include:

- Permanent deferral of blood, tissue, and organ donation for those considered at risk of vCJD;
- Permanent deferral of blood donors that had received a blood transfusion in the UK since 1980;
- Removing white blood cells, which may carry the greatest risk of transmitting vCJD, from all blood used for transfusion. This is called leuco-depletion **[WITN7590123]**.

1.19. In order to help contextualise the information contained in the rest of this document, I will now describe the different organisations and decision makers involved in minimising the risk of CJD and vCJD transmission in England.

Role of DHSC

1.20. The Secretary of State has a statutory duty to continue the promotion in England of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis, and treatment of physical illness: National Health Service Act 2006 ("NHS Act 2006"), s.1.

1.21. DHSC is supported by two executive agencies, UKHSA (and its predecessor bodies) and the Medicines and Healthcare products Regulatory Agency ("MHRA"), and partner organisations, for example, NHS England ("NHSE") and NHSBT. These are described in more detail below.

Decision makers and advisers

1.22. The Chief Medical Officer ("CMO") acts as the UK Government's principal medical adviser, and the professional head of all directors of public health ("DPH") in Local Government and the medical profession in government. The CMO provides public health and clinical advice to ministers in DHSC and across government on both communicable and non-communicable diseases. The CMO is an independent position at permanent secretary level. The current post holder is Professor Sir Chris Whitty who took office in October 2019. Professor Sir Liam Donaldson was in post from 1998 to 2010 and Professor Dame Sally Davies was in post from 2010 to 2019.

1.23. The CMO is assisted by Deputy Chief Medical Officers ("DCMOs"), one of whom is specifically responsible for health protection, which includes infectious disease threats. The DCMO for health protection was Professor Sir Jonathan Van Tam from 2017 to 2021. His predecessor was Professor John Watson, from 2013 to 2017, and David Walker (2013 – 2015) before that.

Structure and development of public health services

1.24. From 1 April 2003 to 31 March 2013, responsibility for public health services in England rested primarily with the Health Protection Agency ("HPA"). The HPA was created on 1 April 2003 as a special health authority in England and Wales and was established as a UK-wide non-departmental public body on 1 April 2005 by the Health Protection Agency Act 2004. The HPA brought together expertise and skills from different bodies including:

- The Public Health Laboratory Service ("PHLS") including the Communicable Disease Surveillance Centre, and Central Public Health Laboratory
- The Centre for Applied Microbiology and Research ("CAMR"), which was part of PHLS.
- Functions related to protection from chemicals and poisons including:
    - The National Focus for Chemical Incidents;
    - Regional Service Provider Units that support the management of chemical incidents;

- The National Poisons Information Service

- NHS public health staff responsible for infectious disease control, emergency planning, and other protection support.

1.25. The HPA's functions in relation to health included the protection of the UK public against infectious disease and other dangers to health, and the prevention of the spread of infectious disease. The HPA exercised these functions alongside NHS Primary Care Trusts ("PCTs") who commissioned a range of services to improve or protect the public's health. Policy responsibility for public health services sat with the Secretary of State, supported by DH. The Secretary of State retained the power to direct the HPA to take on other functions in relation to health.

1.26. In 2010, the Government embarked on a health reform programme which included significant changes to public health responsibilities. The Health and Social Care Act 2012 ("HSCA") made significant changes to the NHS Act 2006, including a duty on the Secretary of State for Health to take such steps as the Secretary of State considers appropriate to protect the public in England from disease or other dangers to health (s.2A NHS Act 2006), and a duty for unitary and upper-tier local authorities to take such steps as each considers appropriate for improving the health of the people in its area (s.2B NHS Act 2006). Section 2B also gave the Secretary of State power to take such steps as the Secretary of State might consider appropriate for health improvement. Functions of the HPA, which was abolished, were transferred to the Secretary of State **[WITN7590124]**.

1.27. To support exercise of these new functions, Public Health England ("PHE") was established on 1 April 2013 as an Executive Agency of the Department and operated until 30 September 2021. PHE was the principal route for discharge of the Secretary of State's public health protection duty (s.2A NHS Act 2006), and it also acted under the Secretary of State's public health improvement power (s.2B NHS Act 2006). For the first time, health protection and health improvement responsibilities were combined in the new agency. PHE was a distinct delivery organisation with operational autonomy. It provided government, local government, the NHS, Parliament, industry, public health

professionals and the public with evidence-based professional, scientific and delivery expertise and support, and carried out some statutory functions of the Secretary of State.

1.28. The UKHSA officially operationalised on 1 October 2021, replacing the health protection responsibilities of PHE. It is an executive agency of DHSC with operational autonomy. UKHSA is the Department's permanent standing capacity to prepare for, prevent and respond to threats to health. Its responsibilities are for England, across the UK on reserved health matters, and in partnership with lead agencies in Scotland, Wales, and Northern Ireland on devolved issues, where relevant. It provides national leadership on health security and health protection and ensures a cohesive response across public health functions. UKHSA embeds effective clinical, scientific, and operational functions in the public health system. Today, UKHSA carries out surveillance of patients at increased risk of vCJD. The National CJD Research and Surveillance Unit, funded by DHSC, reports case numbers.

1.29. NHSBT provides blood and transplantation services to the NHS, looking after blood donation services in England and transplant services across the UK. This includes managing donation, storage and transplantation of blood, organs, tissues, bone marrow and stem cells, and researching new treatments and processes **[WITN7590008; WITN7590141]**. All blood donations go through a process of leucodepletion. This is mandatory in the UK as white blood cells in donated blood often have no benefit to recipients but can carry pathogens and cause adverse reactions **[WITN7590009].** NHSBT tests each blood donation for syphilis, Hepatitis B virus (HBV), Human immunodeficiency virus (HIV), Hepatitis C virus (HCV), Hepatitis E Virus (HEV), and Human T-lymphotropic virus (HTLV). Extra tests may be carried out, dependent on a donor's individual circumstance, with a particular focus on travel or skin piercing, to test for Malaria, T-cruzi, West Nile Virus (WNV) and Cytomegalovirus (CMV). Any blood donation that reacts to initial tests, will not be used. Further tests are carried out to confirm whether the result indicates a true infection.

1.30. The Medical Devices Agency ("MDA") merged with the Medicines Control Agency ("MCA") in 2003 to form the MHRA **[WITN7590010]**. The MDA was

responsible for regulating medical devices in the UK. As Professor Don Jeffries (St Bartholomew's Hospital) stated during the Microbiological Safety of Blood and Tissues for Transplantation vCJD Subgroup meeting on Tuesday 8 April 2003 **[DHSC0004526_142]**, the creation of MHRA came into effect from 1 April 2003. Dame June Raine outlined this change, as well as the merger of the National Institute for Biological Standards and Control with MHRA in April 2013, in her statement **[WITN7135001]**.

National Institute for Health and Care Research ("NIHR")

1.31. The NIHR is part of the DHSC. It is the nation's biggest public funder of health and care research. Its mission is to improve the health and wealth of the nation through research. It does this by: funding high quality, timely research that benefits the NHS, public health and social care; investing in world-class expertise, facilities, and a skilled delivery workforce to translate discoveries into improved treatments and services; partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research; attracting, training and supporting the best researchers to tackle complex health and social care challenges; and collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system **[WITN7590125; WITN7590011]**.

1.32. DHSC commissions independent research through the NIHR. The Science, Research and Evidence (SRE) Directorate senior management team provides executive leadership for the NIHR within DHSC. The DHSC Chief Scientific Advisor ("CSA") is the Chief Executive Officer of the NIHR. The NIHR was established in 2006. Its remit was to "*create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public*" **[WITN7590012]**. Since that time, the NIHR has transformed research in and for the NHS and helped to shape the health research landscape more broadly, for example in public health and social care.

Expert and Advisory Committees

1.33. The Department played a role in a number of organisations that were responsible for assessing the risk of CJD and vCJD transmission through the

use of surgical instruments and setting out guidance for the health sector to minimise this risk. Published records illustrate that the Spongiform Encephalopathy Advisory Committee ("SEAC"), which was established 3 April 1990, was the government's overarching committee for advising on the science of transmissible spongiform encephalopathies and assessing the risk to the public **[WITN7590013]**. The Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathies working group ("ACDP TSE"), the CJD Incidents Panel, and the Engineering and Science Advisory Committee ("ESAC") were responsible for the development of practical advice on this, including minimising the risk of CJD and vCJD transmission through contaminated surgical instruments. I will now provide a short description of the roles of these and other groups.

1.34. The **Advisory Committee on Dangerous Pathogens** ("ACDP"), established in 1981, is a DHSC scientific advisory committee with an independent chair. Its work cuts across a number of organisations, including the Health and Safety Executive ("HSE"), UKHSA and Department of Environment, Food and Rural Affairs ("Defra"). The Committee's purpose is to provide, as requested, independent scientific advice to HSE, and to ministers through DHSC, Defra, and their counterparts under devolution in Scotland, Wales, and Northern Ireland, on all aspects of hazards and risks to workers and others from exposure to pathogens. Also, the Committee provides these organisations and the Food Standards Agency ("FSA"), as requested, with independent scientific risk assessment advice on transmissible spongiform encephalopathies ("TSEs"). ACDP was established in 1981 and the current chair is Professor Thomas Evans (2016 to present). Previous chairs have been Professor Chris Whitty (2015 to 2016), Professor George Griffin (2004 to 2013, and again from 2014 to 2015), Professor Roland Salmon (who was interim chair in 2014), Professor Donald Jeffries from 1999 to 2003, and Dr M J Crumpton in 1998. The Group advises officials from across the UK. Its secretariat is provided by UKHSA.

1.35. The **National Creutzfeldt-Jakob Disease Research and Surveillance Unit** ("NCJDRSU") was established in 1990. It has two main roles: CJD surveillance in the UK and research into prion disease and related problems.

1.36. The **Serious Hazards of Transfusion** ("SHOT") scheme is an independent, professionally-led, hemovigilance scheme, which, since 1996, has been collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and components in the UK. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. SHOT is funded by the four UK Blood Services (NHS Blood and Transplant, Scottish National Blood Transfusion Service, Northern Ireland Blood Transfusion, and the Welsh Blood Service). SHOT consists of the SHOT office team, the Working Expert Group ("WEG") and the Steering Group ("SG"). SHOT recommendations are put into an annual report, which is then circulated to all relevant organisations including the four UK Blood Services, Departments of Health in England, Wales, Scotland and Northern Ireland, professional bodies and SaBTO. This provides a mechanism for the committee to decide whether current guidance requires review or additional guidance to be developed.

1.37. The **Medical Research Council** ("MRC") is a national funding agency dedicated to improving human health by supporting research across the entire spectrum of medical sciences, in universities and hospitals, in MRC units, centres and institutes in the UK, and in MRC units in Africa. One of the MRC units is the **Medical Research Council Prion Unit** ("MRC Prion Unit"). The MRC Prion unit was established in 1998 and is located at the UCL Institute of Neurology where it is closely integrated with the University Department of Neurodegenerative disease. The MRC Prion Unit at UCL is core funded by the UK MRC **[WITN7590016; WITN3093004]**.

1.38. In August 2000, the Department set up a **National CJD Incidents Panel** ("CJDIP"). This was the expert committee that advised NHS Trusts and other organisations that provide and deliver NHS care. The Panel advised on the most appropriate action to take to handle incidents involving potential transmission of CJD between patients through clinical interventions (including via surgical instruments, tissues, organs, and blood). The panel was dissolved on 31 March 2013.

1.39. The **Spongiform Encephalopathy Advisory Committee** ("SEAC") was jointly sponsored by Defra, DH, and the FSA. The committee was established in 2001 and ran until 2011. SEAC provided advice to Government on spongiform encephalopathies, including CJD and vCJD **[WITN7590017]**.

1.40. The **Rapid Review Panel** ("RRP") was established in 2004 and its role is to evaluate products for potential use in the NHS on the basis of scientific evidence to support claims of improved efficiency or efficacy of IPC interventions to reduce healthcare associated infections ("HCAIs").

1.41. The Department sponsored the **Engineering and Science Advisory Committee into the Decontamination of surgical instruments including Prion Removal** ("ESAC-PR"), which was established in 2006. The committee was responsible for taking forward the practical application of the guidance on decontamination based on latest research. The work of this group focuses on ensuring that decontamination is underpinned by appropriate knowledge and takes into account relevant new research and developments. ESAC-PR continues to encourage research and the translation of new technologies into the hospital setting to ensure the continued high standard of decontamination of surgical instruments.

1.42. Prior to the establishment of SaBTO (see below), the **Advisory Committee on the Microbiological Safety of Blood and Tissues and Organs for Transplantation** ("MSBTO") advised the Department and health sector on blood safety, including on CJD and vCJD transmission risk. From document searches, I understand that, in 2007, following a review of MSBTO, it was agreed that there was a need to establish a new committee, the **Advisory Committee on the Safety of Blood, Tissues and Organs** ("SaBTO"), with the aim of making the committee more visibly independent. This included the appointment of an independent chair and new membership, improved procedures and processes of managing an advisory committee, and improved secretariat support. The scope was widened, and the main role of the new group was risk management; formulating advice on options drawn from risk assessments commissioned from a wide range of sources. It was recommended that the secretariat for the independent committee should

remain within the Department, and that there should be one dedicated CJD expert on SaBTO. SaBTO continues to provide guidance on measures for maintaining the safe supply of blood in the UK. This includes reviewing measures for testing and deferrals of donors **[WITN7590014]**.

1.43. The **ACDP TSE Risk Assessment Subgroup** was established in 2011 following the abolition of SEAC in 2011. The group provided government departments in the UK with independent, expert advice on TSEs **[WITN7590018]**.

1.44. The **ACDP TSE Risk Management Subgroup** (formerly the TSE Working group), provided scientific advice and produced detailed guidance on the management of risks from TSEs to help minimise the risk of transmission of CJD and vCJD in healthcare and other work settings **[WITN7590015]**.

1.45. The **ACDP transmissible spongiform encephalopathies** ("ACDP TSE") **Working Group** was set up in 2013 and operated until 2019. In order to minimise the risk of transmission of CJD in a healthcare setting, the Joint Working Group ("JWG"), set up by the SEAC and ACDP following a merger of the ACDP TSE Risk Assessment and the TSE Risk Management subgroups, provided ACDP with practical, scientifically-based advice on the assessment and management of risks from TSE. The committee's remit covered public health, food safety, and animal health issues. The ACDP Working Group on TSEs drew up guidelines between 2013 and 2019 on the action required to prevent the possible spread from patients who are diagnosed, suspected, or considered to be at risk of developing CJD **[PHEN0000136]**.

1.46. I will now describe in detail how the Department, working with the different organisations detailed above, played a role in the Inquiry's key areas of interest, which I have set out below.

1.47. The Inquiry has asked about decontaminating surgical instruments from 2007 to present **[WITN7590019]**. As set out above, CJD and vCJD are types of prion disease. Prion proteins are resistant to standard disinfection and sterilisation methods used for many other pathogens. This is because prions do not share the same properties of viruses and bacteria, making them very difficult to inactivate and destroy. If found on surgical instruments, they cannot be

removed by 'normal' sterilisation techniques. As a result, there is a risk that those who come into contact with infected surgical instruments may develop CJD. BSG Decontamination guidance published in 2020 notes that aldehyde disinfectants (which aim to achieve sterilisation by damaging proteins), may anchor PrPs within endoscope channels and also render them more difficult to remove by other means. In addition, the guidance notes that conventional sterilisation methods cannot reliably destroy the infecting agent in CJD or vCJD [**WITN7590007]**.

1.48. The Inquiry has asked about notifying and de-notifying 'highly transfused patients' from 2007 to present. These were individuals who were assessed as being at greater risk of developing CJD or vCJD due to the number of blood transfusions they had received. The larger the number of individuals that have donated blood to a recipient, the greater the chance that one of these donors was infected with CJD or vCJD at the time of donation.

1.49. The Inquiry has asked about direct detection assays during 2007 to present. This is in reference to the development of a screening test developed by the MRC Prion Unit. There is no current screening blood test available for CJD or vCJD. Currently the only way to confirm the diagnosis of CJD or vCJD is to examine the brain tissue by carrying out a brain biopsy or a post-mortem examination of the brain. The ACDP provides guidance on diagnosis and classification **[WITN7590020]**.

Section 2: The Decontamination of Surgical Instruments – Actions and Decisions

2.1. The Inquiry has asked what actions the Government and other organisations took to mitigate the risk of transmission of vCJD through the use of contaminated surgical instruments and to protect patients.

2.2. I note the Inquiry has specified the timeframe of 2007 to present for this question. However, as I have been referred by the Inquiry to documents pre-dating 2007, I understand that it is not merely the later timeframe which is of interest and have therefore presented earlier evidence to provide the Inquiry with a more detailed picture of events.

2.3. I would also like to note that, while the Inquiry specifically asks about actions taken to minimise the risk of vCJD transmission, many of the actions I will describe would have been in place to minimise the risk of both vCJD and CJD.

Context: The transmission of CJD and vCJD and surgical instruments

2.4. The transmission of vCJD via surgical instruments is not directly linked to the safety of the blood supply, although it could theoretically arise following insufficient decontamination of surgical instruments previously used on patients considered at higher risk of incubating vCJD as a result, for example, of being a highly transfused patient. Infection prevention and control measures, such as the decontamination of surgical instruments, reduce the likelihood of vCJD transmission and thus reduce the risk to donors and recipients. However, the risk of vCJD transmission through contaminated surgical instruments arises because the PrPs, which are the cause of CJD and vCJD, are very difficult to destroy **[DHSC0020839_067]**. If found on surgical instruments, they cannot be removed by 'normal' sterilisation techniques. As a result, there is a risk that those who come into contact with contaminated surgical instruments may go on to develop CJD or vCJD. The term Iatrogenic CJD (ICJD) is the term sometimes used where the infection is spread from someone with CJD or vCJD through medical or surgical treatment, and it is this form of infection discussed in this statement.

2.5. Many of the IPC measures that are discussed below were taken every time that procedures (such as tonsillectomy) were offered; they were not necessarily restricted to those cases when a patient had been identified as being at higher risk of vCJD, such as in cases with 'highly transfused' patients.

2.6. Thus, whilst IPC measures were taken to ensure that surgical instruments were not a source of infection, these precautions are not directly linked to the transmission of vCJD by blood transfusions or related means. The situation is more analogous to the IPC measures taken to ensure that Hepatitis or HIV were not transmissible in a hospital or other healthcare environment, whether by infected patients or infected healthcare workers. Even that is not a direct parallel, as those are bloodborne viruses, whereas the issue of instrument decontamination was concerned with the difficulty of eliminating abnormal PrPs.

2.7. As a result of the absence of a direct link to infected blood or blood products, I understand that the issue of surgical instrument decontamination was not addressed in, for example, the Second Witness Statement of Charles Lister **[WITN4505002]**, which addressed action to reduce vCJD infection risks from blood and blood products; and it does not figure on documents such as **[WITN4505054],** which is a list dated 17 March 1999 of the steps taken with respect to blood / blood products.

2.8. The Inquiry seeks to understand what IPC measures were taken, not because this is a risk of transmission related to infected blood or blood products, but because those patients who were at higher risk of vCJD (possibly as a result of being a highly-transfused patient) have expressed concerns that their access to healthcare treatments was adversely affected by the perception that they might be vectors of infection. Whilst this is a much narrower issue, we have nevertheless tried to answer its broader questions in the interests of transparency. However, it will be apparent from the account below that the issue of IPC measures is both wide and technical. Again, we suggest that if there are specific concerns, they would best be raised with clinical and technical experts in the area.

Role of the Department in creating and implementing NHS guidance

2.9. Before describing the development of IPC measures in more detail, I will set out the role that the Department plays in the implementation of IPC guidance across the NHS.

2.10. NHS standards of care and operation are underpinned by legislation, through Health and Social Care Acts (HSCA) of which there have been various iterations since 1990. The Health and Social Care Act 2008, which was last updated in July 2015, includes clauses on the Code of Practice on IPC and related guidance. The Code applies to NHS bodies and providers of independent healthcare and adult social care in England, including primary dental care, independent sector ambulance providers, and primary medical care providers.

2.11. The Act states that the Code must be taken into account by the Care Quality Commission ("CQC") when it makes decisions about registration against the infection prevention requirements. The regulations also say that providers must have regard to the Code when deciding how they will comply with registration requirements. So, by following the Code, registered providers will be able to show that they meet the requirement set out in the regulations. However, the Code is not mandatory, so registered providers do not by law have to comply with the Code. A registered provider may be able to demonstrate that it meets the regulations in a different way (equivalent or better) from that described in the Code. The Code aims to exemplify what providers need to do in order to comply with the regulations.

2.12. The CQC is responsible for monitoring the compliance with these regulations by healthcare providers. The Code is also supported by an NHS National IPC Manual, which is mandated for use in all NHS healthcare facilities and recommended for use in other care settings.

2.13. Therefore, the Department does not directly oversee the implementation of guidance across the NHS; the NHS is expected to ensure Trusts adhere to guidance that is set out by the Department with the support of inspections and audits conducted by the CQC. The Department's role is in commissioning expert advisory committees to provide advice on the science to inform guidance

for the NHS. The Department then reviews and publishes this guidance, but it is the NHS that then mandates and implements the guidance operationally.

IPC Measures – Pre 2007

2.14. The DHSC team has conducted searches of Departmental records in order to set out the steps taken to ensure the effective decontamination of surgical instruments. My response to the question below is based on the findings within these documents.

2.15. Shortly after vCJD was first identified in 1996, the possibility of human-to-human blood transmission was considered and, from 1997, the Department implemented successive precautionary measures to reduce what was, at that time, a theoretical risk.

2.16. The risk of contracting CJD/vCJD via surgical instruments has a long and fairly complex history, which is summarised in the text below.

2.17. Documents indicate that a number of measures were put in place to encourage national action to improve decontamination after the *"discovery of prion protein in the appendix of a patient who subsequently developed vCJD in 1998"* In particular, ACDP TSE reviewed all previous guidance on CJD, and subsequently issued new guidance to the NHS in April 1998 emphasising the importance of cleaning and sterilising instruments used on patients with suspected CJD or vCJD. It should be noted that at this time, guidance did not include the risk of 'highly transfused' patients **[WITN7590126]**.

2.18. Following publication of the guidance in April 1998, two Health Service Circulars were issued in England in August 1999 and were aimed at managers and health professionals. The first Circular reinforced the 1998 guidance on cleaning and sterilisation of instruments. It also introduced new guidance on single use equipment for lumbar punctures, along with options to introduce single use instruments. The second Circular introduced Controls Assurance for decontamination of medical devices **[WITN7590127]**.

2.19. It is apparent that the CMO sought advice on these issues from SEAC in 1999. Thus, **[WITN7590021]** is a letter dated 3 March 1999 from the CMO, Professor Liam Donaldson, to Professor John Pattison, the Chair of SEAC, asking for

advice on the reduction of *"any theoretical risk of transmission of nvCJD from medical procedures."* In the letter, the CMO outlined the evidence that classical CJD had been transmitted by medical procedures and he asked for further advice on the potential for vCJD to be transmitted in a similar way.

2.20. Deliberations concentrated initially on three surgical procedures on high risk tissues (tonsillectomy, appendectomy, and lymph node biopsy). The Medical Device Agency ("MDA") recommended that single use instruments should be used in tonsillectomy procedures, however this was not supported by an 'ad-hoc Group', convened to discuss the issue, on 9 March 1999 **[WITN7590022]**. The SEAC meeting of 11 March 1999 reported that this issue was being considered by the Joint SEAC/ACDP Working Group who would report back.

2.21. I have been referred by the Inquiry to **[DHSC0004747_060]**: these are minutes of the ADCP/SEAC TSE Working Group, dated 5 July 1999. Item 4 covers *"Surgical Instrument Issues";* there is extensive discussion of possible precautionary measures to stop the spread of CJD/vCJD through surgery and the minutes show the work of this Group in progress.

2.22. In September 2000, the Department developed a risk assessment model to look at the potential risk of person-to-person vCJD transmission (secondary transmission) via surgery, which included assessing the relative risks and benefits of using single-use instruments. The risk assessment model was endorsed by SEAC on 29 September 2000. In response to the risk assessment, SEAC advised *"where discrete surgical procedures can be identified as suitable for single use instruments, for example tonsillectomy, and provided patient safety would not be compromised, the Committee considered that such use should be considered wherever practicable"* **[WITN7590127]**.

2.23. On 28 November 2000, SEAC gave further advice to the Department on methods to reduce vCJD transmission during surgery. SEAC advised that *"rigorous implementation of washing, decontamination and general hygiene procedures are key measures in minimising the risk of infection"*. SEAC's advice informed the Department's strategy to improve decontamination, which would be announced early the next year (4 January 2001).

2.24. Informed by SEAC's advice, the Department issued a Circular to the NHS (2001) **[WITN7590023]** emphasising the importance of effective decontamination in preventing the spread of vCJD and requiring *"NHS organisations to review their management arrangements urgently and to carry out a health and safety audit"*. The circular stated that *"by 31 March 2002 Chief Executives should have taken steps towards having systems in place to enable the tracing of surgical instrument sets to patients on whom they have been used".*

2.25. At the same time, the Department carried out a survey of the NHS to assess the effectiveness of decontamination measures in place. NHS Trusts were asked to identify a senior member of staff to take responsibility for managing all aspects of decontamination and, as part of the national survey, *"report the actions being taken to ensure that appropriate management arrangements are in place to oversee and, where necessary improve, the overall process of decontamination"*. The survey reported at the end of 2001 **[WITN7590023]**.

2.26. On 4 January 2001, the Department made a public announcement on a strategy to *"move quickly to improve decontamination facilities"* to reduce the risk of vCJD transmission, which had been endorsed by SEAC at its meeting on 28 November 2000 **[WITN7590023]**. The strategy had two components; improving decontamination procedures through better training, management and adherence to protocols, and introducing single-use instruments for tonsillectomies (in June 2001). As part of the same announcement, the Department confirmed a £200million programme to modernise NHS decontamination facilities and ensure that surgical equipment was cleaned and sterilised to the highest standards to protect patients from the theoretical risk of vCJD. The modernisation programme outlined that this risk should be at a minimum by 2004. Parliamentary Questions **[WITN7590024]** described why £200million was allocated to decontamination. It was noted that SEAC had advised that a high standard of decontamination of surgical instruments was "*a key factor in reducing the risk of person-to-person spread of vCJD during surgery*". Documents supporting the announcement showed that an experienced Trust Chief Executive, Roger Evans, had taken up post to lead a team of technical experts who would manage the decontamination

improvement programme. Regional leads were appointed to oversee regional plans. In addition, a new training programme for NHS managers and technical specialists on decontamination was established. **[WITN7590144]**

2.27. I understand that in March 2001, following SEAC's recommendation, the Department conducted a risk assessment on the risk of vCJD transmission through surgical instruments. The assessment concluded "*surgical transmission of vCJD cannot be ruled out as a risk to public health*" and that the most important way of reducing this risk was to *"ensure that decontamination of instruments is as effective as possible"* **[DHSC0004267_014]**.

2.28. In September 2001, a draft submission was sent from Charles Lister to Pat Troop (DCMO) and Lord Hunt (Parliamentary Under-Secretary of State, Department of Health) **[DHSC0038590_080]**. It outlined the advice and recommendations from the CJD Incidents Panel regarding *"interim advice to the NHS on the management of incidents involving vCJD implicated blood and blood products"*. The submission recommended issuing the Panel's advice to the NHS as soon as possible, due to pressure from clinicians and patient representatives. The document notes that individuals who had received transfused blood from anyone with vCJD should be contacted and advised not to donate blood, other tissues, or organs. It also discussed the use of single use instruments, the quarantining and decontamination of re-useable instruments used on CNS, retina and optic nerve, and the need to modify cleaning procedures of endoscopes.

2.29. Separate documents indicate that DHSC officials attended working level meetings (in May 2002) with Medical Device Agency (MDA) officials to discuss improving the design of surgical instruments in relation to vCJD transmission **[WITN7590129]**.

2.30. Separately, we understand from identified documents that DH officials shared a submission with the Chief Dental Officer and Minister (Jacqui Smith) at the time (11 June 2003) to put a dental vCJD risk assessment that had been carried out in the public domain, which was supported by SEAC and the ACDP/SEAC TSE Joint Working Group. While acknowledging substantial uncertainty, the assessment concluded that *"current knowledge does not indicate any*

significant risk to the public from dentistry". **[WITN7590025; WITN7590026; WITN7590027; WITN7590026]**

2.31. I have been referred by the Inquiry to **[ABHB0000177]** and in particular Annex F. This is Guidance from ACDP and SEAC on *"Guidance on Transmissible Spongiform Encephalopathy (TSE) agents: safe working and the prevention of infection",* dated June 2003. It stated that it was a new edition of guidance following scientific breakthroughs and understanding in research and was to replace the edition issued in March 1998. The TSE Guidance is "*essentially the same as the earlier, 1998, publication, this new version is significantly expanded, with additional annexes.*" The guidance was published on the DH CJD website and was endorsed by ACDP, SEAC and JWG. The guidance was published in sections to allow individual sections to be updated when further scientific information became available or future policy decisions needed to be reflected. This guidance, along with guidance from the British Society of Gastroenterologists and the Health Technical Memorandum 01-06, which are referenced later in this statement, became the leading guidance on safe working practices and the prevention of infection in relation to vCJD.

2.32. Page 102 of Annex F outlined specific advice on handling flexible endoscopes following procedures *"in all patients with definite, probable or possible CJD/vCJD, and in those identified as at risk of developing CJD/vCJD*". A summary of precautions advised are presented in table F2a. Annex F at p121 is a Consensus Statement: "*Endoscopy and individuals at risk of vCJD for public health purposes; A consensus statement from the British Society of Gastroenterology Decontamination Working Group and the ACDP TSE Working Group Endoscopy and vCJD Subgroup*". The paper notes "*there is currently no evidence that vCJD has ever been transmitted from one patient to another via an endoscopic procedure*". It acknowledged that, whilst manual cleaning followed by automated endoscope reprocessing was not a validated process, it was good practice. Further precautions were recommended including the use of single use biopsy forceps and the disposal of any biopsy port rubber caps that had been penetrated by an accessory during a procedure. As requested by the Inquiry, I will describe specific guidance on endoscopes in more detail in section 4.

2.33. Annex J of ACDP TSE Guidance in document **[ABHB0000177]** identified high infectivity tissues for CJD and vCJD as: brain, spinal cord, and posterior eye. Anterior eye and olfactory epithelium tissue are classified as medium risk tissues for both vCJD and CJD, whilst lymphoid tissue is also classed as medium risk for vCJD.

2.34. In July 2003, another risk assessment was commissioned by the CMO on the risks associated with different surgical procedures and secondary transmission of vCJD **[WITN7590130; WITN7590144]**. In August, a DH official (Dr Hilary Walker) updated the CMO on plans to conduct a *"rapid operational review"* of decontamination measures to be completed by September 2003 in cooperation with NHS Estates, to check progress against decontamination plans. **[WITN7590144]**

2.35. In December 2003, a draft submission was sent from Liam Donaldson (CMO) to the Secretary of State at the time, which outlined that he believed a clear clinical policy needed to be established and announced to *"reduce risk of transmission of vCJD via surgical instruments for high and medium-risk surgical procedures, and particularly tonsillectomy and appendectomy, in the NHS in England".* The submission recommended that either a statement of preference should be issued advising the use of single use instruments for procedures with high and medium-risk tissue or, if that wasn't practical, then existing advice, supplemented by educating the surgical profession on risks, benefits and options for single-use instruments should be reinforced **[WITN7590029]**

2.36. Following this, in March 2004 the former Chief Scientist and Director of Health Protection (Dr David Harper) shared a submission with Ministers outlining an urgent need for guidance from NICE to limit the patient safety implications of tonsillectomies in relation to vCJD transmission, as requested by Sir Liam Donaldson (CMO) in 2003. The submission noted the Minister had met with the CMO on this issue **[WITN7590145]**.

2.37. The draft minutes from the SEAC meeting on 28 September 2004 presented the findings of *"a revised risk assessment on the transmission of vCJD via surgical instruments"*. Dr Peter Bennett, from the Department of Health Analytical Team, noted that the risk assessment suggested *"the risks of*

transmission of vCJD from surgical instruments could be significant" and reinforced the need for continued effective cleaning and decontamination of surgical instruments to reduce these risks. The members discussed their concerns around the effectiveness of cleaning and decontamination processes, as well as the risk of secondary infection from surgical instruments. They agreed that research should focus on cleaning and decontamination **[DHSC0038672_045]**.

2.38. Following a search on the DHSC database, I found that the former Chief Executive of NICE (Mr Andrew Dillon) wrote to Sir Liam Donaldson on 16 September 2004 confirming NICE would begin work on guidance for the NHS on how best to manage the risks of CJD and vCJD during surgical practice. The letter outlined that NICE expected the guidance to be published in 2006, and that the scope of the guidance would include the use of reusable and disposable instruments in surgical procedures, balancing risks of CJD and vCJD transmission via reusable instruments against the risks to patient safety and arrangements for sterilisation and cleaning of surgical instruments, including endoscopes **[WITN7590131]**.

2.39. On 5 November 2004, Gerard Hetherington (former Head of Health Protection Division, DH) shared a draft note from Sir Liam Donaldson outlining a request to NICE to extend its work on surgical practice guidance to cover the use of disposable instruments and parts of instruments for other procedures involving tissues that were classified as high or medium risk for vCJD and also CJD. **[WITN7590030, WITN7590132; WITN7590149]**

2.40. In December 2004, Sir Liam Donaldson updated advice from a previous submission on 23 January 2004 on risk reduction measures to reduce the risk of transmission of vCJD through surgical instruments. The submission, to the minister at the time, dated December 2004 noted that an updated risk assessment by DH analysts had been presented to SEAC on 28 September 2004. The chairman of SEAC (Professor C Higgins) concluded that *"the risk of secondary transmission via instruments was at least as great as previously thought; Improving and attaining high standards of decontamination remains of critical importance; Research into decontamination of instruments, including*

procedural aspects (such as steps to avoid protein getting dried onto instruments) continues to be a high priority" **[WITN7590031]**.

2.41. I can see from a published report that, in 2005, the '*Decontamination of Surgical Instruments in the NHS in England Update report'* noted the Department had invested heavily in a number of decontamination research projects. This followed the original report published in December 2001 **[WITN7590032, WITN7590033; WITN7590034]**.

2.42. I have been referred by the Inquiry to **[WITN7091003]**. This is a document from the CJD Incidents Panel entitled "*Management of possible exposure to CJD through medical procedures; Framework Document*". It is dated August 2005 but was amended in January 2011. It noted that *"…The CJD Incidents Panel (the Panel) is the expert committee set up by the Department of Health (in 2000) to advise all those bodies responsible for the provision and delivery of health care on the most appropriate action to take to handle incidents involving potential transmission of Creutzfeldt-Jakob Disease (CJD) between patients through clinical interventions, including via surgical instruments, tissues, organs and blood.*" It set out the framework for the management of risk that a human transmissible spongiform encephalopathies (TSE) may be "*transmitted through contaminated instruments and/or devices, or donated blood or other tissues or organs*". It noted that the framework document was put out to consultation with the general public and stakeholders in 2001 – 2002 and then approved by the UK CMOs. It noted that *"The document additionally draws particularly on two reports, the first being: 'Risk assessment for Transmission of variant CJD via Surgical Instruments: A modelling approach and numerical scenarios"* and the second concerning the "Assessment of the *risk of exposure to variant CJD infectivity in blood and blood products*".

2.43. Appendix 1 to the submission published on 09 November 2005 is titled *"Endoscopy and individuals at risk of vCJD for public health purposes"*. It concerned the incidence of new cases of vCJD appearing to be in decline and noted the lack of evidence for transmission of vCJD via endoscopic procedure. Nevertheless, it outlined the importance of following manual cleaning guidance

and emphasised that biopsies should not be taken unless completely necessary. **[NNUH0000009_006]**

2.44. Documents show that in March 2006, the DH Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion Removal (ESAC-PR) established the Industry Sub-Committee of ESAC-PR, which aimed to promote efficient and appropriate discussion with industry related to decontamination of surgical instruments with the emphasis on prion removal, and also assist with the review of near market anti-prion products Our search of documents indicates that in September 2006, ESAC-PR requested SEAC's advice on scientific principles to consider in "*developing strategies to evaluate and validate new technologies for the decontamination of surgical instruments, particularly the most appropriate prions and experimental systems to use*". The advice strongly recommended the independent and quantitative evaluation of the effectiveness and reliability of new decontamination technologies prior to their implementation **[WITN7590035]**.

2.45. The Department of Health published its Autumn 2006 Report from ESAC-PR on "*The decontamination of surgical instruments with special attention to the removal of proteins and inactivation of any contaminating human prions*". It noted that the main aims of ESAC-PR were to improve decontamination technology and to prevent surgical infection and healthcare associated infections. The paper summarised the ESAC-PRs recommendations, which covered surgical instrument design and surveillance, general and operational factors and research and product evaluation. It highlighted that instrument designers would work to reduce features that could trap proteins, but also noted minor design changes in surgical instruments could have huge impacts, so recommended a national "*fault / failure post-procurement audit*". It outlined the introduction of instrument streams to separate instruments with high risk tissue exposure and instrument traceability. The improvement of cleaning and decontamination procedures, the development of strategies surrounding single use instruments and the possibility that proteins may not have been able to effectively adsorb to wet surfaces were discussed. Finally, it recommended research focusing on various aspects of decontamination.

2.46. A submission to CMO on 2 October 2006 from DHSC policy officials (Dr Darren Hughes) outlined ongoing efforts to provide guidance to the NHS on decontamination. The submission referenced upcoming NICE guidance on decontamination and a planned NHS Estates and Facilities survey for 2007 to audit decontamination practices. The submission also referred to the Code of Practice for the Prevention and Control of Health Care Associated Infections as ongoing guidance for the NHS (as part of Health Act 2006), which included specific guidance on decontamination and single use instruments **[DHSC5055167]**.

2.47. Subsequently, a significant milestone for guidance followed in the same year (2006), where NICE published its Guidance on reducing the risk of vCJD transmission from surgical instruments. This guidance set out, for clinicians, the "*interventional procedures on tissues considered at high risk of transmitting CJD*", which were "*procedures on high-risk tissues are intradural surgery on the brain (including the pituitary gland) and spinal cord, neuroendoscopy, and surgery on the retina or optic nerve*" **[SCGV0002357]**.

2.48. A useful review of the position as at September 2007 is set out in the document for the CMO, "Review of Decontamination and" **[WITN7590036]**.

2.49. On 28 March 2007, the Health Protection team in the Department sent a further submission to Ministers on endodontic instruments (instruments used on root canal procedures) and vCJD following important research findings showing potential vCJD infectivity in dental and oral tissues. The team recommended to Ministers that DH reinforce decontamination advice to dental practitioners and issue guidance advising that, in view of the difficulty in reliably decontaminating endodontic reamers (tools used to clean and shape the root canal) and files, these dental instruments should not be reprocessed and should all be treated as single use. This was following a SEAC position statement on 8 May 2006, which stated *"it is unclear whether or not vCJD infectivity can be transmitted via endontic files and reamers. However, given the plausibility of such a scenario and the large number of procedures undertaken annually, it would be prudent to consider restricting these instruments to single use as a precautionary measure. Since sufficiently rigorous decontamination of these instruments is*

difficult, single use of these instruments would eliminate this risk, should it exist' **[WITN7590037]**.

2.50. In April 2007, the ESAC-PR held a stakeholder event to share preliminary findings from a National Decontamination Survey (NDS). The event was also an opportunity for DH to explain its approach to both the NICE guidance, as well as to hear from the NHS and supporting industry. The survey results indicated that *"implementation has not progressed satisfactorily within the NHS, and some centres lack clear arrangements for the way forward"*. Furthermore, amongst views expressed at the event was a strong preference for *"universal precautions,"* that is applying the same procedures to all decontamination of surgical instruments. This was combined with interest in *"new prion removal and deactivation technologies"* and decontamination techniques to achieve risk reduction as an alternative to the tracking and set containment approach in the NICE guidance **[WITN7590134; WITN7590135]**.

2.51. Papers for an MSBTO meeting in June 2007 included a 2006 Report from ESAC-PR on "*The decontamination of surgical instruments with special attention to the removal of proteins and inactivation of any contaminating human prions*". The report made a number of recommendations, including:

- The introduction of a separate special stream within the use and reprocessing cycle for surgical instruments that come into contact with high-risk tissues as defined by ACDP-TSE and include Central Nervous System ("CNS") / brain (sub-dural) as well as posterior ophthalmic tissues. A stakeholder consultation exercise was recommended in the report with regards to this change of practice.
- Working with the Rapid Review Panel on commissioning research to carry out initial evaluations on commercial and near market products intended to remove prions from surgical instruments.
- Research to understand more about the vCJD decontamination process **[WITN7590035]**.

2.52. The report also noted that a *"number of ongoing initiatives have been established to provide support to the NHS"* with decontamination. This included the "*modernisation of all DH Estates and Facilities guidance relating to*

decontamination" which included *"surgical instrument tracking and management systems".* The report outlined that this work was in collaboration with a steering group led by the DCMO at the time (Martin Marshall) that were developing similar work in this area.

2.53. On 3 March 2008, the CMO (Sir Liam Donaldson) sent a 'Dear Colleague' letter instructing Trusts to review and implement NICE's 2006 guidance as soon as possible, based on ESAC-PR's evidence that this guidance had not been implemented properly. CMO reiterated that the new prion removal, activation technologies and decontamination techniques referenced above had yet to be fully validated, and that Trusts must continue to implement the NICE recommendations on decontamination **[WITN7590038]**.

2.54. I understand from Departmental records that in January 2009, as part of the NHS application for registration with the Care Quality Commission, the Department sought ministerial approval for a consultation exercise for a Health Technical Memorandum (HTM) on decontamination document. Part of the guidance related to the "*decontamination of surgical instruments in acute care*". The supporting documents to the submission that was addressed to Ministers outlined that the HTM was to address the findings of the 2007 National Decontamination Survey, which revealed that implementation of the 2006 NICE guidance had been "*poor, or at least patchy*", which was understood to be partly due to a "*lack of specific advice on how to implement the guidance.*" As the Department at the time had a role in ensuring NHS adherence to standards, the HTM aimed to *"consolidate and update existing technical guidance"* and *"provide further guidance as to how Trusts can achieve existing NICE recommendations"* **[WITN7590039]**.

2.55. The DHSC team has identified guidelines produced by the ACDP TSE working group in March 2009 for pathologists and pathology laboratories for the handling of tissues from patients at risk of vCJD. These guidelines included the procedures for handling tissues of high or medium levels of infectivity from patients with, or at risk from, vCJD. In relation to decontamination, the guidance set out that disposable instruments and sharps used on tissues should be chemically decontaminated with 2M social hydroxide and left for one hour. The

guidance also included information on the types of chemical decontaminates that could be used **[WITN7590040]**.

2.56. On 27 April 2009, Annex B outlined "*Measures in place to reduce the risk of vCJD being transmitted via blood components*". It explained generally what measures the Government had taken from the outset and set out a timeline from 1997 to November 2005 **[WITN7590041]**.

2.57. In 2009, a letter was sent from David Pryer (Chairman, CJD Incidents Panel) to Professor Dame Sally Davies on "*Highly transfused patients and secondary transmission of vCJD*". The paper outlined new guidance on endoscope decontamination. It referred to the draft CFPP 0106, which stated that if endoscopes were decontaminated to a set standard, they could be returned to normal clinical use even if they were used on patients at risk of vCJD. Accepting this draft would allow endoscopy to become a low risk procedure. The document also summarised a number of recommendations. The highly transfused joint working group (a working group of the TSE Risk Management Subgroup) believed that patients with over 300 donor exposures should be informed that they were at risk of vCJD, rather than the current practice of notifying patients with 80 blood donor exposures. Depending on whether this recommendation was accepted, the paper discussed that some patients may need to be de-notified of their vCJD risk. They also advised that prior to all surgery, assessment for general CJD risks should continue as per Annex J of the TSE Infection Control Guidance **[PHEN0000608]**.

2.58. NHS Estates published *"Sterilization. Part 4: Operational management (New edition) with Part 6: Testing and validation protocols. Health Technical Memorandum 2010"*, which provided very detailed advice and guidance. Single-use medical devices are discussed in sections 2.22 – 2.25 and it is noted that *"the construction of many such devices, often with long and narrow lumens, makes them difficult to clean with any degree of confidence"*. Appendix 2 (on page 114) covered the *"Sterilization of items contaminated with TSE agents"*. It noted that all agents of TSE had *"an unusual resistance to conventional decontamination methods"* and referred to two sterilization methods recommended by the ACDP **[WITN7590042]**.

2.59. I have been referred by the Inquiry to a Department of Health document: "*Choice Framework for local Policy and Procedures 01-06 "Decontamination and flexible endoscopes*" (Version 1.0 England, dated 6 June 2012) and represents guidance on the specific topic of endoscopes. This document provided best practice guidance on the management of flexible endoscopes and provided support for commissioners and providers in implementing appropriate and effective decontamination measures to reduce the risks of person-to-person transmission of human prion diseases. This guidance was superseded in March 2016 by "*Health Technical Memorandum 01-06: Decontamination of flexible endoscopes*" (HTM-01-06) – this document is referenced later in the statement **[DHSC5068270]**.

2.60. The ACDP TSE subgroup published guidance on 27 November 2012 on the decontamination of surgical instruments to protect patients from the risk of vCJD transmission. This guidance also referenced the guidance published by NICE in 2006 **[WITN7590044]**.

2.61. Overall, during the time that ACDP TSE subgroup was in operation (2013 to 2019), the group reviewed guidance and scientific evidence to advise the health sector on protocols and guidance to protect patients from CJD and vCJD. Following updates to the guidance, the HPA wrote to hospital leads for surgery, haematology and infection control and clinicians' groups, patient organisations and professional bodies to highlight the amendments to the infection control guidance **[WITN7590045]**.

Summary

2.62. Clearly, guidance on the decontamination of surgical instruments to reduce the risk of vCJD transmission evolved over time and with the understanding of new scientific advice and research findings. This is typical of most clinical guidance, which is updated according to scientific developments. Inevitably, this can potentially lead to confusion over what is the 'latest' guidance, or frustration over the need to change practices. However, the Department's primary objective when producing guidance related to infection prevention and control is to reduce the risk of transmission of infectious diseases within healthcare

settings. To meet this objective, all guidance is regularly reviewed and updated to ensure it remains accurate and compliant with current scientific evidence.

Research Commissioned

2.63. Through the NIHR, the Department has commissioned extensive research projects looking at decontamination of CJD / PrPs. These are set out in the tables below. This table sets out for each project: the project title, lead applicant organisation, project award value and contracted project dates. The information within table is provided by Programme Manager at NIHR who leads on managing CJD project portfolio.

Access to Care and/or Stigma

2.64. We understand that this of interest to the Inquiry, although not the subject of the questions we have been asked. We have set out above how the IPC measures developed and implemented from at least 1998 were ones of general application and were generally not ones that were applied only to treatments when patients had been identified as being at high risk.

Section 3: Pre-Soak Decontamination

Evidence of Professor Collinge

3.1. The Inquiry has stated that it has heard evidence from Professor Collinge about the development of a pre-soak, which he described as a straightforward and inexpensive way to decontaminate surgical instruments in order to reduce the risk of transmission of vCJD.

3.2. The Inquiry has referred me to the transcript of Professor Collinge's oral evidence **[INQY1000206]** and to **[TSTC0000045]**, which is a record of the evidence to the House of Commons' Science and Technology Committee on 5 March 2014, in which Professor Collinge spoke (see p19) of the unquantifiable risk of prions binding to metal surfaces (i.e. surgical instruments). Professor Collinge noted that NICE guidelines had been introduced in 2006 and that a major investment of £500 million had been made by DH. Professor Collinge also spoke about the pre-soak product that he had developed with DuPont and the barriers to implementation (see p23).

3.3. We note that this is again a topic related to the issue of surgical decontamination, which we have discussed at greater length in Section 2 above, including as to the introduction of the NICE guidelines.

Identified limitations of the DuPont product

3.4. I have been asked to explain why this process (pre-soak) was not adopted by the NHS. In particular, I have been asked to set out, first, whether there were any problems with the product, which we understand to be the Rely+On pre-soak developed by DuPont. The DHSC team has carried out an extensive search of its files and a further search of the departmental records has been carried out in order to answer these questions. Based on these searches and the evidence the DHSC team has collated, I have summarised the involvement of the Department in the review of the pre-soak developed by DuPont.

3.5. In summary, DH – or, more precisely, the Rapid Review Panel (RRP) which advised the Department in 2007 - did not agree with the characterisation of the product as effective or straightforward. The reasons are outlined more fully below.

3.6. The Department funded research on the decontamination of surgical instruments in 2007, including the effect of pre-soaks. The research paper *'Effect of drying time, ambient temperature and pre-soaks on prion-infected tissue contamination levels on surgical stainless steel: concerns over prolonged transportation of instruments from theatre to central sterile service departments*' (Lipscomb, Pinchin, Collin, Keevil 2007) concluded that the *"application of a pre-wash is highly beneficial" and that "pre-washing should be performed as soon as possible after instrument contamination*" **[WITN7590046]**.

3.7. In 2007, the Department funded research at the MRC Prion Unit, directed by Professor John Collinge, on the development of novel enzymatic methods to destroy prions on metal surfaces. The laboratory research work was developed in collaboration between D-Gen and DuPont, and the product that resulted from this research work was referred to as 'Rely+On' and is that referred to by Professor Collinge in his evidence **[INQY1000206 and WITN7590047]**.

3.8. Professor John Collinge wrote to the CMO on 29 May 2007, highlighting the Rely+On pre-soak product to the Department. Liz Woodeson, the Director of Public Health Protection in the Department at the time, responded on 11 June 2007 **[WITN7590046 AND WITN7590048]**. Liz Woodeson advised that *"Prion inactivation agents are an exciting field of development, and the Department is closely following these developments with interest"*. Liz Woodeson further advised that the Rely+On product would be reviewed by the RRP on 19 June 2007 and that the use of prion inactivation agents, including Rely+On, would also be considered by the Department's ESAC-PR committee. Liz Woodeson also noted that one of the key issues to be considered was how decontamination using these products could be *"incorporated into the decontamination cycle"* and be supported by some form of quality control system to ensure that the products were effective in practice in a clinical setting.

Rapid Review Panel (RRP)

3.9. The RRP is a panel of experts, such as microbiologists, health protection practitioner leads and decontamination experts, that evaluates products for potential use in the NHS based on scientific evidence **[WITN7590049]**.

3.10. The RRP was convened by the HPA at the request of DH. Its role, as defined by HPA and DH, is *"to provide a prompt assessment of new and novel equipment, materials and other products or protocols that may be of value to the NHS in improving hospital infection control and reducing hospital acquired infections".*

3.11. The RRP is an independent arms-length committee set up following a request from CMO as a specific means of rapidly reviewing new technologies and new ways of providing for hospital infection control.

3.12. The concerns underpinning the establishment of the RRP are outlined in the Department of Health reports: "*Winning Ways: Working together to reduce Healthcare Associated Infection in England*" from the Chief Medical Officer, published in December 2003, and "*Towards cleaner hospitals and lower rates of infection: A summary of action*", from July 2004 **[WITN7590136; WITN7590137]**.

3.13. These reports preceded the first meeting of the RRP in August 2004. **[TSTC0000052]**

3.14. Lord Warner of Brockley (Minister of State for Reform) championed the formation of the Rapid Review Panel in response to DH and Ministers receiving product proposals from numerous commercial organisations who were seeking pathways into the NHS. The panel evaluates a wide range of products, not only those related to vCJD transmission. The RRP provides an independent assessment of new and novel equipment, materials, and other products or protocols that may be of value to the NHS in improving hospital infection prevention and control and reducing hospital acquired infections. Products are voluntarily submitted to the RRP and are evaluated on the basis of supplied scientific evidence to explore the efficiency or efficacy over existing products, and innovation and product quality use. The panel does not consider commercial issues including cost effectiveness of a product **[WITN7590050]**.

3.15. The purpose of the RRP's recommendations is to demonstrate publicly to the NHS supply chain the robustness of scientific evidence supporting the product claims. The RRP meets quarterly to review submitted product applications and recommendations are published on the website. The secretariat for the panel

currently sits with UKHSA, and previously PHE, and prior to that HPA. Further information on the committee can be found here: **[WITN7590051]** and the Panel's Terms of Reference can be found here: **[WITN7590052]**.

3.16. The RRP can make the following evaluations (category rating) of products:

- E1 (category 1 rating): Basic research and development, validation and recent 'in use' evaluations and trials have shown that the product is likely to have benefit(s) in improving infection prevention and control (IPC) interventions to reduce healthcare associated infections (HCAI) within the NHS; the RRP recommends considering the use of this product in the NHS to improve IPC interventions to reduce HCAIs.
- E2 (category 2 rating): Basic research and development has been completed and the product may have potential value; the RRP recommends in use evaluations and trials to demonstrate improved efficiency or efficacy in improving infection prevention and control to reduce healthcare associated infections are considered within an active NHS clinical setting.
- E3 (category 3 rating): Basic research and development has begun and the product may have value; the product requires head-to-head trials against existing available products to demonstrate improved efficiency or efficacy in improving infection prevention and control interventions to reduce healthcare associated infection.
- E4 (category 4 rating): Potentially useful product but insufficient evidence presented; further research and development with the product as intended to be used in the NHS is required to demonstrate improvements in infection prevention and control interventions to reduce healthcare associated infections before it is ready for in use evaluation within the NHS.
- E5 (category 5 rating): Evidence presented does not demonstrate that the product is more efficient or efficacious at improving infection prevention and control interventions to reduce healthcare associated infections than other available products currently in use.

- E6 (category 6 rating): Evidence presented does not demonstrate that the product has a contribution to make to improvements in infection prevention and control interventions to reduce healthcare associated infections.
- NE: (No Evaluation); this product is outside the remit for review or the evidence has been submitted in a way which does not allow for an evaluation by the Rapid Review Panel.

RRP review of Rely+On product

3.17. The RRP reviewed the Rely+On product on 19 June 2007. The product received a category 3 rating (the E3 evaluation, as set out above), and the panel concluded that the "*product may be a useful addition to available decontamination methods; however, evidence concerning extended claims to other infections was not presented. The panel have raised specific concerns with the application of the product in practice*" **[WITN7590053]**.

3.18. Only products with a category 1 rating from the RRP are recommended for use in the NHS. The category 3 rating was granted for a number of reasons. The first was that the manufacturer's claim that Rely+On could kill a wide range of infections as well as vCJD was not supported by the scientific evidence. Furthermore, the panel found that the pre-soak, as with many other pre-soaks on the market at the time, was not proven to be effective as part of a fully-validated decontamination cycle, and additional studies were needed to identify and manage potential safety issues for the individuals handling these agents.

3.19. The feedback on the Rely+On product was sent to DuPont on 17 January 2008. The panel advised:

- Due to the uncertainties over vCJD prevalence in the population in 2008, the panel was concerned that *'the widespread use of the pre-soak may not be justifiable when considerations of logistics versus prevalence are borne in mind'.*
- The panel advised that once a more accurate picture of prevalence in the population was available, the product could be re-considered **[WITN7590054; WITN7590055]**.

3.20. DuPont were advised to engage with the ESAC-PR regarding compatibility with existing procedures and how the product would fit into those procedures.

3.21. Furthermore, the panel asked DuPont to clarify how and where the product was intended for practical use.

3.22. The panel advised DuPont that further instruction was needed on instrument soaking and on whether a lid was required. The panel highlighted that it had been advised that local soaking of instruments in open troughs in the operating theatres was not good practice. Furthermore, the panel advised that provisions were required to ensure lumens (the inner spaces of tubes that transport liquids) of instruments were penetrated.

3.23. Finally, the panel advised evidence would be required to show that the product penetrated box joints – parts of the equipment that are traditionally hard to clean.

Attitude to pre-soak products

3.24. The Inquiry has asked whether the fact that the DuPont product was a pre-soak product ruled it out, and if so, why that was.

3.25. The product was not adopted by the NHS as it did not achieve a category 1 rating from the RRP. All manufacturers of products are required to have a category 1 rating to be suitable for the NHS. Other manufacturers developing similar pre-soaks also did not achieve a category 1 rating from the RRP and were not recommended for use in the NHS **[SCGV0002357]**.

3.26. The problems of the technology were further discussed in the Engineering and Science Advisory Committee (ESAC), which discussed the latest thinking on the decontamination of surgical instruments including wet versus dry prion removal **[WITN7590056]**.

3.27. The committee agreed at the meeting that there needed to be greater discussion between the disinfectant product manufacturers, washer disinfector manufacturers and end users. Decontamination leads and sterile service managers concluded that manual pre-soaks were not a viable option in operating departments or in sterile services department.

3.28. The committee agreed that it was not possible to reliably validate the soaking of instruments in open containers and the question of penetration of chemical into serration and box joints could not be guaranteed. Therefore, it was vital that chemicals intended for this purpose were incorporated into existing practices with regard to decontamination cycles.

3.29. From these documents, I understand that pre-soak products themselves were not ruled out; however, the CJDIP and ESAC advised further work was needed to ensure decontamination of the product and the implementation process was accounted for. DuPont did not resubmit its product.

3.30. Later documents show that on 8 August 2011 the secretariat for the ACDP TSE sub-group shared the research paper '*Adsorption of prion and tissue proteins to surgical stainless-steel surfaces and the efficacy of decontamination following dry and wet storage conditions*' (Secker, Herve and Keevil 2011). Research concluded that "*moist conditions may negate the need for the pre-soak cleaning step altogether*" **[WITN7590057]**.

3.31. On 24 July 2014, the House of Commons' Science and Technology Select Committee published '*After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease'* **[TSTC0000052]**. The report discussed the Government's approach to minimising vCJD transmission and concluded that more was needed to ensure that the UK blood supply was free of dangerous pathogens. The report included the DuPont's Rely+On as a 'case study' and described the RRP as a gatekeeper.

3.32. In October 2014, the Government published its response to the Select Committee's report. This included discussing the Rely+On product, setting out that the '*Government gave significant support to DuPont through the RRPO process, to help ensure that their product was suitable for use within the NHS. This included specialist support from Dr Berly Oppenheim (consultant microbiologist, City Hospital Birmingham), who convened an expert group to work with and advise DuPont. Decisions on whether to market products are a matter for individual commercial companies, and not for the Government.*' Overall, the Government committed to continuing to work with scientific expert

advisory committees, UK Blood Services and PHE to assess and manage the risk of vCJD **[WITN7590058]**.

3.33. From reviewing the documents on the evaluation of the Rely+On pre-product, it appears that the product required further development to ensure adequate decontamination and implementation for use in the NHS. The product was not re-submitted for review and other companies did not achieve a category 1 rating. At that time, pre-soaks were not considered viable products for use in the NHS and, as it was not resubmitted and further development work was not continued by DuPont, it is my understanding that it was not implemented, and other decontamination methods were used.

3.34. The explanation below explains the current decontamination methods used, including guidance on sterilisation and washer disinfectors.

Further documents requested

3.35. I have been further referred by the Inquiry to **[DHSC6711790]**, which is an email chain dated 23 April 2008 relating to the "Collinge Decontamination Product", in which follow-up questions were being asked by Professor Collinge. The Inquiry has noted that this makes reference (see p7) to a letter from the CMO to Professor Thomas (Professor of Clinical Neuroscience, St Mary's), which is embedded as an attachment. I have been asked to provide this document to the Inquiry. Inquiry document **[DHSC5167558]** also summarised the email chain relating to the *"Collinge Decontamination Product"* and included additional discussion. According to these email exchanges, there were several reasons why the NHS did not adopt Dr Collinge's 'pre-soak' idea. Firstly, the Rapid Review Panel (RRP) was "*concerned that the widespread use of the pre-soak might not be justifiable when considerations of logistics versus prevalence are borne in mind. This would need to be re-considered once a more accurate picture of prevalence is available*". There also appeared to be issues with the wording of the DuPont submission to the RRP regarding a claim that the product *"kills all known germs".* The emails outlined other products that were being discussed as well, alongside DuPont. Furthermore, the use of DuPont may have required further protective clothing, which suggested that it may have been dangerous and/or costly to implement.

3.36. The initial document embedded (see p12) was entitled "*DuPont – Rely + On Prion Inactivator.pdf*". It can be found at **[WITN7590059]**, which is dated 19 June 2007 and is a joint document from DH and the HPA. It stated '*This product is a three component system that is designed to inactivate prion protein and has biocidal properties. This product may be a useful addition to available decontamination methods however; evidence concerning extended claims to other infections was not presented. The panel have raised specific concerns with the application of the product in practice.'* The letter "*CMO letter to Prof. Thomas*", which was dated 15 February 2008, can be found at **[WITN7590060]**. In this letter, the CMO referred to the category 3 rating given to DuPont's Rely+On product and set out that '*one of the principle reasons for this was DuPont's claim that Rely+On was active against blood borne viruses and common hospital infections in addition to vCJD, without providing evidence to support these extended claims. The panel also felt that although data was presented concerning activity against a prion strain that is most resistant to chemical attack, the Spongiform Encephalopathy Advisory Committee (SEAC) has recommended the use of a prion strain closely allied to human vCJD strains.*' In addition, the CMO also explained that '*manufacturers will also need to demonstrate that Rely+On is capable of being incorporated into standard automatic washer disinfector cycles in order for it to be acceptable to Sterile Services Departments.*' CMO explained that due to efficacy of pre-soaking not being certain (e.g. such as pre-soaking lumens of instruments) and the health and safety issue of using toxic agents, the '*decontamination community has rejected the use of any form of manual pre-soaking.*'

Further Work on Decontamination

3.37. The Inquiry has asked whether the NHS has found an effective way to decontaminate instruments of vCJD. If so, I am asked to provide details; if not, it asks what if any steps are being taken towards this.

3.38. As I have explained above, findings from extensive searches of Department records detail the actions taken to encourage effective decontamination within the NHS since vCJD was first identified in 1996. To summarise here, the current guidance on the decontamination of surgical instruments advises that all

surgical instruments that come into contact with high-risk tissues during an interventional procedure must be kept moist and separated from other instruments until they are cleaned, and then disinfected and sterilised.

3.39. There are four current pieces of relevant legislation and guidance on decontamination:

- The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance was last published and updated on the 24 July 2015. It replaced the version that was published in 2010. It applies to NHS bodies and providers of independent healthcare and adult social care in England, including primary dental care. The Code now reflects the changes required to meet The Health and Social Care Act 2008 (regulated activities) regulations 2014 and the role of infection prevention (including cleanliness) in optimising antimicrobial use and reducing antimicrobial resistance. The latest 'refresh' is due to be published in December 2022 and includes updates and references to the Health and Social Care Act 2022.
- NICE guidance (2020) on reducing the risk of transmission of vCJD from surgical instrument used for international procedures on high-risk tissues. The guidance is available here: Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues (nice.org.uk) . **[WITN7590061]**.
- The Departments Health Technical Memorandum 01:01: decontamination of surgical instruments. This guidance was published by the NHS in 2016 and is available here: NHS England » Health technical memoranda. **[WITN7590062]** Guidance on decontamination was published by NHS in March 2013 in the health technical memorandum (NHS England » (HTM 01-01) Decontamination of surgical instruments) **[WITN7590063]**. The guidance provides an evidence base and standards for use by providers of care and those decontaminating surgical instruments within the NHS. It explains the management of decontamination and the various ways to sterilize reusable medical devices used in acute care. This includes

guidance on washer-disinfectors (Health Technical Memorandum 01-01. Part D: Washer-disinfectors (england.nhs.uk)). **[WITN7590064]**.

- The ACDP TSE subgroup guidance on decontamination, including details of chemical and gaseous disinfectants and physical processes commonly used for decontamination, and their effectiveness at reducing infectivity. The guidance was last revised in 2015 and is available here: Table X – Selected guidelines and standards related to decontamination and waste disposal (publishing.service.gov.uk) **[WITN7590065]**.

3.40. The decontamination methods set out in the guidance above are thought to be effective. They have been reviewed by the relevant expert advisory committees as viable decontamination methods for managing the risk of vCJD transmission.

Section 4: Endoscopes

Policies and Guidance - Endoscopes

4.1. The Inquiry has asked what quarantine procedures were in place to protect patients from the risks of vCJD transmission via surgical instruments, particularly endoscopes. As I have explained in detail above, a wealth of guidance was developed on the decontamination of surgical instruments since vCJD was first identified in 1996.

4.2. For context, an endoscope is a long, thin, flexible tube with a light and camera at one end. Endoscopes are used for the examination and sometimes treatment of patients. Whilst there are currently no known cases of vCJD being transmitted by surgical instruments or endoscopes, the Health Technical Memorandum 01-06 (2013), Decontamination of Flexible Endoscope states it may be possible as:

- *"sCJD (Sporadic Creutzfeldt-Jakob disease) has been transmitted by neurosurgical instruments used on the brain;* **[WITN7590066]**
- *Abnormal prion protein binds avidly to steel surfaces and can be very difficult to remove from steel surfaces and can be very difficult to remove from surgical instruments; and*
- *Prion infectivity has been found in a range of tissues (brain, spleen, tonsils etc) of patients who have developed symptomatic vCJD."*

4.3. In addition to this, document **[NNUH0000009_006]** A consensus statement from the British Society of Gastroenterology Decontamination Working Group and the ACDP TSE Working Group Endoscopy and vCJD Subgroup (Published in November 2005, and revised and updated on 02 June 2008) states:

"*Flexible Endoscopes are expensive and fragile pieces of medical equipment that are often used for the examination, and sometimes treatment, of one thousand or more patients, during their working life. They cannot be completely decontaminated via current methods, although best practice is expected to reduce the risk of patient-to-patient transmission to below 1% after several cycles of decontamination."*

4.4. The Inquiry has also referred us to **[HCDO0000821]**, which appears to be a 2007 article or note from the Journal "Gut". This reported a survey from 43 Haemophilia Centres by the UK Haemophilia Centre Doctors' Organisation and of Endoscopy Units. It indicated that there were varying guidance or policies or practice around the use and quarantine of endoscopes. In response to these observations, I have been asked to outline the leading guidance or policy on the quarantine procedure surrounding endoscopes for patients at risk and/or diagnosed with vCJD **[NNUH0000009_006]**.

4.5. In response to the Inquiry's questions, I will describe the leading guidance on the use and quarantine of endoscopes in relation to vCJD transmission, which was subject to regular review (according to the development of science) and was communicated with health professionals through different routes over time. I will then explain how this guidance developed chronologically, before responding the Inquiry's questions on specific areas of this guidance.

Leading guidance on Endoscopy

4.6. Currently, based on the review of documents, there are three key pieces of guidance that should be referred to for the quarantining of endoscopes. These are:

- Annex F of the ACDP TSE guidance, last updated in 2015
- The Health Technical Memorandum (HTM) 01-06 (2016)
- Guidance from the British Society of Gastroenterology (BSG), last updated June 2020.

4.7. It should be noted here that the ACDP TSE guidance applies to the whole of the UK, while other pieces of guidance (such as the Health Technical Memorandums) are for England only. Devolved administrations have their own Health Technical Memorandums, which ensure that the technical content is consistent with Department of Health HTM 01-6 series and the requirements of the ACDP TSE subgroup's guidance. Because of this, and because the ACDP TSE was the first piece of guidance on the quarantining of endoscopes in relation to reducing the risk of vCJD transmission, which fed into later pieces of

guidance (which I will go on to explain in more detail), I consider this to be the leading piece of guidance in response to the Inquiry's request **[WITN7590068]**.

4.8. Following a review of current guidance, my understanding is that the quarantining of endoscopes following use on patients that are at medium or high risk of vCJD involves taking the instruments out of use and storing them positioned vertically in a drying cabinet, and whilst in the drying cabinet, ensuring they are clearly marked or secured as not being in use, so as to avoid them becoming mixed up with endoscopes in storage for normal use. Dependent upon the status of the patient, the endoscope may either be only used once, destroyed after use, quarantined for re-use exclusively on the same index patient, or decontaminated and returned to use. For procedures on low infectivity or nondetectable tissues, there are no special precautions taken and following a procedure, decontamination processes outlined in HTM 01-06 and BSG Guidance for Decontamination of Equipment for Gastrointestinal Endoscopy should be followed **[ABHB0000177]**.

Summary of ACDP TSE guidance on endoscopes

4.9. Annex F (last updated in 2015) of the ACDP TSE guidance includes advice on quarantining endoscopes **[WITN7590067]**. This guidance is clear that "*The specific recommendations in this guidance are complementary to national guidance on all aspects of endoscope decontamination such as Choice Framework for local Policy and Procedures 01-06 (CFPP 01-06) and the British Society of Gastroenterology (BSG) Guidance on Decontamination of Equipment for Gastrointestinal Endoscopy*". The ACDP TSE guidance states that it should be considered alongside published NHS guidance on the decontamination of endoscopes **[WITN7590069]**.

4.10. The ACDP TSE guidance provides specific advice for the management of instruments used in all types of endoscopic procedures and states the procedures that should be followed. These are summarised in the table below.

4.11. The guidance is dependent on tissue infectivity and the vCJD status of the patient - whether they are symptomatic or asymptomatic (a symptomatic patient will have a definite/probable diagnosis or possible vCJD, possible sCJD or an unclear diagnosis, whereas an asymptomatic patient could be an at risk patient,

e.g. someone who received blood from a donor who later developed vCJD). For example, a patient with high infectivity tissue (such as brain or spinal cord tissue) and a definite or probable diagnosis will lead to the endoscope either being used once, destroyed after use, or quarantined for use exclusively on that patient again, whereas a patient with low infectivity tissue undergoing an endoscopic procedure will lead to no special precautions on the endoscope being taken, and it can be reused after decontamination.

Table – vCJD and CJD type uncertain, taken from ACDP TSE guidance (Annex F)

Tissue Infectivity	**Status of patient**			
	Symptomatic		**Asymptomatic**	
	Definite / Probable	**Possible vCJD, or possible sCJD or diagnosis unclear (1)**	**At risk (blood *** recipient from a donor who later developed vCJD)**	**At risk (2) Other iatrogenic**
High • Brain • Spinal cord	Single use **OR** Destroy after use **OR** Quarantine (3) for re-use exclusively on the same index patient	Single use **OR** Quarantine pending diagnosis	Single Use **OR** Destroy after use **OR** Quarantine (3) for re-use exclusively on same patient	Single use **OR** Destroy after use **OR** Quarantine (3) for re-use exclusively on same patient
Medium • Olfactory epithelium	Single use **OR** Remove from use **OR** Quarantine (3) for re-use exclusively on the same index patient	Single use **OR** Quarantine pending diagnosis	Single use **OR** Destroy after use **OR** Quarantine (3) for re-use exclusively	No special precautions unless contaminated with olfactory epithelium* If contaminated : single use **OR**

			on the same index patient	Quarantine (3) for re-use exclusively on the same index patient
Medium • Lymphoid tissue **	Single use **OR** Remove from use **OR** Quarantine (3) for re-use exclusively on the same index patient	Single use **OR** Quarantine pending diagnosis	Single use **OR** Destroy after use **OR** Quarantine (3) for re-use exclusively on the same index patient	No special precautions (4)
Low / none detectable: • All other issues	No special precautions (4)	No special precautions (4)	No special precautions (4)	No special precautions (4)

4.12. In addition to Annex F outlined above, Annex E of the ACDP TSE WG guidance refers to the quarantining of surgical instruments. The full guidance can be found **[WITN7590067]** but, to summarise, my understanding of the guidance is as follows:

- Re-usable instruments that have come into contact with high (brain or spinal cord) or medium (olfactory epithelium or lymphoid tissue) infectivity tissues should be washed and then reprocessed (a process to clean and disinfect and sterilise surgical instruments) through the Sterile Services Department before quarantining. After reprocessing, the instruments should be placed in an impervious rigid plastic container with a close-fitting lid. The lid should be sealed, and the box stored indefinitely in a suitable designated place until the outcome of any further investigations is known, or the instruments are required for another surgery on the same patient.
- For patients with a possible CJD/vCJD diagnosis, if the patient is confirmed as suffering from CJD or vCJD, the box (of reusable instruments) should be incinerated or retained for use in research, without any further examination.

If an alternative diagnosis is confirmed, the instruments may be removed from quarantine and returned to use.

- Rarely, it may be necessary to consider the re-use of a quarantined set of surgical instruments on the same patient. ACDP have cited one such scenario, where a patient at risk of vCJD required another transplant. In this circumstance, the instrument set should be reprocessed, and the set tracked through the decontamination cycle **[WITN7590070]**.
- Quarantined instrument sets must not be reprocessed for use on other patients unless the diagnosis of CJD or vCJD has been positively excluded through carrying out a brain biopsy, or more commonly, after death in a post-mortem examination of the brain.
- Records must be kept of all decisions, and the Sterile Service Department must be informed about the decision before instruments are sent for routine reprocessing. Endoscopes used for certain procedures in the CNS and nasal cavity in individuals with possible CJD or in whom the diagnosis is unclear should be removed from use or quarantined pending diagnosis or exclusion of CJD.

4.13. I will now explain how this guidance on the quarantining of endoscopes developed over time.

Chronological development of guidance on quarantining endoscopes

4.14. The ACDP TSE guidance on quarantining endoscopes (Annex F) was first published on GOV.UK in September 2004 but revised and updated subsequently. As explained above, guidance evolves over time informed by the latest scientific advice and research findings.

4.15. From the DHSC blood safety team's search of departmental records, I can see a note prepared for the CMO (Sir Liam Donaldson) in May 2007 from Dr David Harper (Director of Health Protection & Chief Scientist) entitled "*vCJD: Endoscopes and Decontamination*" outlining some of this history. The note related to an incident at Essex Rivers Healthcare NHS Trust where the risk status of a haemophiliac patient was not recognised at the time and the endoscope was then decontaminated and re-used on 12 other patients in

contravention of existing guidance. Section 3 of the note stated that since November 2005, Annex F Guidance had been amended to say that: **[WITN7590071]**

"Endoscopes used for certain procedures in individuals with possible CJD, or in whom the diagnosis is unclear, should be removed from use or quarantined pending diagnosis or exclusion of CJD. Endoscopes other than those used in the CNS and nasal cavity, which have been used for invasive procedures in individuals designated as at risk of vCJD should be removed from use or quarantined to be re-used exclusively on the same individual patient if required."

4.16. In relation to dissemination of this guidance, the note stated that all NHS Trusts were informed of Annex F in issue no.296 of the Chief Executive Bulletin, 18-25 November 2005. It was also flagged up to the British Thoracic Society, the British Society of Gastroenterology, the British Orthopaedic Association, and the British Association of Urological Surgeons.

4.17. The same note stated that this guidance was updated on 30 March 2007, where the TSE Working Group slightly amended Annex F, making some elements less precautionary in relation to patients of vCJD. "*Providing decontamination of the endoscope is to approved standards, the use of the instrument for inspection in the absence of an invasive technique is deemed to be a low-risk procedure. This applies to all endoscopy apart from that of the CNS and nasal cavity, which remains high risk. Where invasive procedures are carried out, the endoscope should be quarantined pending assessment of its likely contact with potentially infected tissue.*"

4.18. In 2007, the CMO wrote to the chairs of the ACDP TSE Working Group and ESAC-PR Endoscopy Subgroup to confirm that the Department was providing £250,000 to support implementation of guidance relating to issues of endoscopy **[WITN7590071]**. The letter did not specify what guidance it referred to. The letter went on to note that it was important that the advice of the TSE WG was consistent with best evidence regarding vCJD transmission risks and that the British Society of Gastroenterology and endoscope manufacturers supported the approach being taken. The CMO advised that they (Donald

Jeffries and Geoffrey Ridgeway) discuss and agree with Dr David Pryer, the chair of the CJD Incidents Panel (CJDIP), the most appropriate allocation of funding at their next meeting, with special regard to the needs of the Haemophilia Centres. The letter concluded by stating that the DH's Health Protection Division should be contacted once the allocations of the funding had been determined.

4.19. A document titled "*Decontamination of equipment for GI Endoscopy and vCJD issues – some good news at last*!" **[ABMU0000043]** was sent from Miles Allison, BSG Representative – CJD Incidents Panel. The paper outlined that BSG guidelines from 2003 had been updated and that the 2008 version would be circulated soon, which included the use of purpose built drying and storage chambers for the first time. It stated that DH wanted to unify advice, as there were multiple sets of guidelines available for the decontamination of endoscopes. The document also explained that endoscopy patients should be asked if they had been told they were "*potentially at risk of CJD for public health purposes*" and if so, Annex F should be followed, and the consensus document taken. It said that DH granted central funding to refurbish some quarantined endoscopes, enabling more to be returned to use. The submission also recommended that potentially invasive endoscopy should be performed by specific endoscopists in each Trust, so they would be able to keep up to date on the latest guidance relating to vCJD.

4.20. On 8 March 2011, a document was produced by the Department - "*Choice Framework for Local policy and procedures ("CFPP") – Reprocessing of flexible endoscopes: management and decontamination*"**[WITN7590072]**. This document provided guidance for those undertaking commissioning and quality inspection related to the management and decontamination of flexible endoscopes both at local level and in centralised facilities. The CFPP document provided guidance on endoscope decontamination to endoscopy services in England.

4.21. The recommendations in the ACDP TSE guidance complemented the national guidance on all aspects of endoscope decontamination, including in the CFPP.

4.22. This document formed part of the "*Choice Framework for local Policies and Procedures (CFPP) 01 Decontamination*" series; there are seven parts in total. The guidance used references Essential Quality requirements (EQR) to ensure high quality services from providers and benefits for patient outcomes and experiences. A summary of the guidance is provided below:

> *"The policy and guidance provided in this CFPP is driven by the aim of ensuring progressive improvement in decontamination performance both in centralised facilities and at local level giving a continuous reduction in infection risk from both "conventional" and prion infectious disease.*
>
> *The guidance provides options to flexible-endoscope decontamination practices within which choices may be made and a progressive improvement programme established. By the end of the first year of the implementation of this guidance, all units where flexible endoscopes are used or decontaminated should be working towards or above."*

4.23. The CFPP was a pilot initiative by the Department. The purpose of the framework was to provide a structure that enabled local decision making regarding the management, use, and decontamination of flexible endoscopes. This framework of policy and protocol was intended to be used by care commissioners and quality inspectorates and also provide an evidence base and standards for use by providers of care and those decontaminating flexible endoscopes within the NHS or commercially **[WITN7590072]**.

4.24. In February 2013, guidance from the British Society of Gastroenterology, (Document **[CVHB0000088]** referred to by the Inquiry), was published, entitled *"Changed guidance on the need to quarantine endoscopes following invasive gastrointestinal endoscopy in patients at risk of vCJD."* It stated that the guidance had been revised in light of the Choice Framework for local Policy and Procedures (CFPP 01-06), which was published at a similar time by the Department of Health.

4.25. The BSG updated guidance on the need to quarantine endoscopes following invasive gastrointestinal endoscopy in patients at risk of vCJD transmission. **[CVHB0000088]**. The BSG update noted that ACDP produced TSE infection control guidance that applied to the whole of the UK and that, in their guidance,

Annex F referred to flexible endoscopes and Annex J addressed pre-assessment of patients for possible infection control risks.

4.26. The main changes in the BSG document were that, following endoscopy in most patients at risk of vCJD, including people with haemophilia and other plasma product recipients – (the different types of at risk classification can be found in ACDP TSE Guidance – Part 4 – table a), it was advised that an endoscope could be returned to use provided that it went through a conventional thorough decontamination process. National guidance on decontamination, drying and storage must be adhered to. The summary of quarantine recommendations in the guidance regarding the management of endoscopes and quarantine was as follows:

Type and status of vCJD diagnosis	**Management of the endoscope**
1. vCJD diagnosis confirmed	Destroy or decontaminate and store in quarantine for use on the same patient
2. Symptoms of CJD but awaiting diagnosis	Decontaminate and store in quarantine. If vCJD confirmed, manage as 1. Above
3. Asymptomatic patients at increased risk through receipt of labile blood components (whole blood, red cells, white cells or platelets) from a donor who later developed vCJD.	Destroy or decontaminate and store in quarantine for use on the same patient
4. At increased risk – e.g plasma product recipients. (Different types of at risk classification is covered in ACDP TSE Guidance Part 4 – table 4a)	Decontaminate and reuse

4.27. If patients were not at risk of CJD or vCJD for public health purposes, surgery or endoscopy would proceed using normal infection prevention and control procedures, unless the procedure was likely to lead to contact with high risk tissue **[CVHB0000088]**.

4.28. On 20 March 2013, the Department published the *"Choice Framework for local Policy and Procedures 01-06 – Reprocessing of flexible endoscopes: management and decontamination"* (CFPP 01-06) **[DHSC5068270]**.

4.29. In 2014, it was agreed that all references to the dedicated endoscopic equipment held by the NCJDRSU (National Creutzfeldt Jakob Research and Surveillance Unit) in Edinburgh for use on probable vCJD cases should be

removed from '*Annex F – Endoscopy*' of the ACDP TSE Guidance, as the TSE Steering Group felt that this dedicated equipment was no longer fit for clinical use and, as such, should no longer be made available. Dr Ronald Salmon (Chair of the ACDP TSE SG) recommended that disposal of the equipment should take place unless an alternative non-clinical use could be found for it, such as in a decontamination research project **[WITN7590073; WITN7590067]**.

4.30. In March 2016, the Department published guidance on the NHS website, *"Health Technical Memorandum (HTM 01-06: Decontamination of flexible endoscopes – Part A Policy and Management"*. This document superseded the Choice Framework for local Policy and Procedures (CFPP) series, which are referenced above. The HTM guidance continues to refer to ACDP TSE SG Annex F Guidance in relation to quarantine of endoscopes **[WITN7590066]**.

4.31. The HTM guidance provides best practice guidance on the management and decontamination of flexible endoscopes and also advice on the management and handling of an endoscope following use on a patient at increased risk of vCJD. In the preface, it was noted that the guidance remains a work in progress and that it would be updated as additional evidence became available and that each iteration of the guidance was designed to incrementally help reduce the risk of cross-infection.

4.32. The HTM-01-06 has been updated (March 2016) to take account of the ACDP TSE subgroup's changes to the general principles of decontamination, in particular paragraphs C5 and C20 from the Annex F guidance. The updated HTM focuses *"on improving the washing and cleaning process, reducing time from patient use to the decontamination process, and monitoring the cleaning efficacy of endoscope washer-disinfectors."* ACDP Annex F Guidance was updated in February 2015; the previous version was in 2009. **[WITN7590066; WITN7590067]**

4.33. The major changes to the Part A HTM guidance from the 2013 CFPP 01-06 document include:

- *"CFPP 01-06 has reverted to the Health Technical Memorandum title format and now becomes Health Technical Memorandum 01-06.*
- *Chapter 5 on prion diseases has been updated.*

- *New Appendix on General principles of decontamination and pathway of a flexible endoscope" has been included to reinforce the importance of the bedside clean and the reduction in time from use of the endoscope on a patient to its route through the decontamination process.*
- *A new Appendix has been included on the decontamination recommendations for Endoscopic retrograde cholangiopancreatograpy (ERCP) procedures and on-table bile duct exploration (new material and not a requirement of the ACDP-TSE Subgroup's recommendations).*"

4.34. HTM 01-06 discussed above, was part of a series of 6 documents. The first in the series is entitled '*Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care'*. In this guidance, it notes the importance of traceability of all surgical equipment: "*A traceability system for equipment especially when used on patients with, or at increased of, human risk of prion disease is very important.*" In particular, it notes: "*Subsequent storage (including quarantine if indicated) or use of instruments must be recorded and where appropriate specialist advice obtained from the local Health Protection Team;*"

4.35. In June 2020, the BSG produced the most up-to-date guidance on Decontamination of Equipment for Gastrointestinal Endoscopy, which supersedes earlier versions of BSG guidance. The guidance is a report prepared by a Working Party of the British Society of Gastroenterology Endoscopy Committee **[WITN7590066]**.

Identifying patients' vCJD risk prior to Surgery or Endoscopy

4.36. The Inquiry asked for a summary of the guidance in place for identifying patients at risk of vCJD transmission prior to surgery or endoscopy. I will summarise this guidance now.

4.37. Annex J of ACDP TSE Guidance (First published on 31 July 2006 and revised and published in August 2017), provides a method of assessing CJD and vCJD risk prior to surgery or endoscopy.

4.38. The guidance recommends that all patients who are about to undergo any surgery or endoscopy should be asked if they have ever been notified as being

at increased risk of CJD or vCJD. If the patient responds 'no', the surgery or endoscopy should proceed using normal infection prevention and control procedures.

4.39. If patients respond 'yes' to being at risk of increased risk of CJD or vCJD, or the risk status is unknown at the time of the procedure, table J6 in the Annex J guidelines outlines the special infection prevention and control precautions that should take place. Separately, Appendix B within this guidance is an information sheet for patients undergoing surgery on neuro-endoscopy on high risk tissues. It notes that if patients answer 'yes' to having an increased risk of CJD, medical staff will examine their medical records in more detail to determine whether or not they have an increased risk of CJD and, if they do have an increased risk of CJD, special precautions will be taken with surgical instruments used in their operation.

4.40. In addition to this, the guidance recommends that patients undergoing surgery or neuro-endoscopy that may involve contact with tissues of potentially high level TSE infectivity should, through a set of detailed questions, be assessed for their possible, unrecognised, CJD/vCJD risk.

4.41. Table 4a in *ACDP TSE Part 4 guidance Entitled "Infection Prevention and control of CJD and Variant CJD in healthcare and community settings"* categorises patients by risk. The table defines patients identified as "at increased risk" of vCJD through receipt of blood from a donor who later developed vCJD and includes the following patient group: **[WITN7080009]** "*Individuals who have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later went on to develop vCJD.*"

Multiple Uses of Endoscopes

4.42. The Inquiry has asked if the same endoscope was used on multiple patients at risk of vCJD. We would note that the issue more precisely relates to whether the same endoscope might be re-used on other patients, after use on a patient found to be at risk of CJD or vCJD. I will describe the development of the Department's policy on this, based on the review of the Department's records **[WITN7590066]**.

4.43. In line with the Health and Social Care Act 2008, the Department commissioned an audit tool concerned with decontamination facilities associated with re-processing of flexible endoscopes. The new Care Quality Commission was responsible for ensuring that the Act was complied with; the DH considered that it would be appropriate to support that by ensuring that an audit tool was available. Thus, the Infection Prevention Society (formerly the infection control nurses association) was commissioned in 2009 to prepare an audit based on the guidance relating to decontamination of endoscopes **[WITN7590074]**.

4.44. We have previously explained that (at para 7.17 above) on 8 March 2011, a document was produced – "*Choice Framework for Local policy and procedures (CFPP) – Reprocessing of flexible endoscopes: management and decontamination*". This document provided guidance for those undertaking commissioning and quality inspection related to management and decontamination of flexible endoscopes, both at a local level and in centralised facilities. The document was produced by the Endoscopy Decontamination Steering Group, appropriate learned and professional bodies, and expert consultants. Expert consultants include Stuart Line and Geoff Ridgway **[WITN7590072]**.

4.45. Section 9.3 of this guidance stated that, if a patient is considered to be at risk of vCJD, that a procedure must comply with local guidance and national guidance contained in TSE Guidance Annex F. This might mean quarantining an endoscope or retaining it for dedicated re-use on the same patient.

4.46. Section 9.4 went on to say that it is therefore important to determine the likelihood of a patient with, or at risk of, vCJD in whom the performance of an invasive endoscopy will necessitate quarantining of the endoscope pending further investigation. A possible option was to send the endoscope back to the manufacturers for a dedicated refurbishment process, for which central funding was available in some circumstances. Details of the criteria are given in TSE Guidance annex F.

4.47. Section 4.34 of Annex F states that traceability system for equipment used on a patient at risk of vCJD is very important, and that its subsequent storage or use must be recorded and the advice of the CJD Incidents panel (which was

set up in 2000 to examine all cases of CJD, to monitor their management and to determine the risk potential of transmission of CJD through clinical interventions and the public health risk of CJD) should be obtained.

4.48. In February 2013, guidance from the British Society of Gastroenterology was published **[CVHB0000088]** regarding changed guidance on the need to quarantine endoscopes following invasive gastrointestinal endoscopy in patients at risk of vCJD. Changed guidance stated that following endoscopy in most patients at risk of vCJD (including people with haemophilia and other plasma product recipients), an endoscope can return to use provided that it goes through a conventional thorough decontamination process consisting of manual pre-cleaning and a subsequent validated automated machine disinfectant and rinse cycle. The summary of the quarantine recommendations in the BSG guidance has already been set out above.

Length of Quarantine Period

4.49. The Inquiry has asked about the length and purpose of any quarantine period. In general, the answer to these questions is set out in the policy documents summarised in this statement and exhibited to it. However, the following may also be helpful.

4.50. There was a meeting of the TSE Working Group on 3rd May 2006. Paper 5 states that "*instruments that have been used on a possible CJD or vCJD patient must not be re-used but may be quarantined by securely storing in a rigid, sealed container after use until the diagnosis is confirmed*" **[WITN7590138; WITN7590075]**.

4.51. In Annex F of the TSE Guidance, it is recommended that endoscopes are quarantined after use in patients at risk of vCJD until the absence of vCJD or CJD can be confirmed by eventual post-mortem. Annex H (After Death) of ACDP TSE Guidance states that post-mortem examinations are required in order to confirm a clinical diagnosis and the cause of death in patients with suspected CJD, vCJD or any other form of human prion disease **[WITN7590067; WITN7590075]**.

4.52. The quarantined endoscope may be re-used exclusively on the same patient if required.

4.53. The guidance also states that instruments that have been used on a possible CJD or vCJD patient must not be reused but may be quarantined by securely storing in a rigid, sealed container until the diagnosis is confirmed. If the case is confirmed as CJD or vCJD, or if after testing, the diagnosis is inconclusive, the instruments should be disposed of by incineration (or stored safely for use in research). Only if a definitive alternative diagnosis is confirmed may the instruments be decontaminated following the usual routine procedures and returned for use.

4.54. The purpose of the quarantine is to prevent cross-infection until the risk has been clarified or eliminated.

Possible Reluctance to Quarantine

4.55. I have been referred by the Inquiry to document **[NCRU0000154_012],** which is a letter dated 19 November 2007, from Dr Peter Fairclough, Consultant Gastroenterologist, sent to Dr Yimmy Chow, Medical Secretary of the CJD Incidents Panel. In the letter, Dr Fairclough said that advice given by the Panel was illogical, inconsistent, and out of proportion to any demonstrated risk, and encourages bad practice.

4.56. In the letter, Dr Fairclough stated that the basis for this view is that advice can be at times inconsistent and illogical. He argued that the harm done to patients by withdrawing the instrument from circulation far exceeded the purely theoretical risk of transmission of vCJD, as there are budget constraints.

4.57. Dr Fairclough noted that there had never been a case of CJD attributed to surgery, much less to a *"contaminated"* endoscope, and that the risk of endoscopy of any kind were infinitely greater than those of acquiring vCJD from a contaminated endoscope and the risks are currently theoretical rather than practical. The letter concluded that the standard the Panel was setting was completely unrealistic and too precautionary. He asked that the panel reconsider its advice and advised that endoscopes could be used after thorough cleaning by conventional methods for a specified number of times.

4.58. As I outlined in section 2, based on the responses from the 2007 ESAC-PR stakeholder event, we know there was some hesitancy within the NHS around the decontamination guidance from NICE. While we did not find any evidence

within the Department's records relating to reluctance to quarantine of endoscopes specifically, it is possible to infer that this reluctance from health practitioners recorded at the 2007 event related to endoscopes. Documents also show that there were guidelines in place to standardise practice, funding for decontamination and measures taken to audit compliance. Details of implementation are more likely to be held at Trust level.

Measures Other than Quarantining

4.59. We have been asked to outline if any decontamination measures that were potential alternatives to quarantining were considered.

4.60. Using single-use instruments was considered as one alternative to quarantine. It was introduced when considered appropriate (see for example – CMO to Milburn and please refer to earlier section on January 2001 announcement). However, it is clear that this could not be a long-term solution or implemented in relation to all forms of surgical instruments. **[NCRU0000154_012]**

4.61. As I have explained above, the Department's approach was pursuing effective decontamination as the main potential alternative to quarantining. If this were to be possible, quarantining would not be necessary. This issue has been considered throughout the period discussed in this Statement (and lies at the heart of much of the commissioned research outlined in Annex F) **[WITN7590067 AND NCRU0000154_012]**.

4.62. By way of example only:

- Document **[NCRU0000154_012],** states that prion decontamination methods may become available in the next few years.
- A note for the CMO in September 2007, stated that in 2004, the DH Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion removal (ESCA-PR) was in the final stages of establishing a sub-committee to advise DH specifically on policy development and guidance to service providers in respect of rigid and flexible endoscope decontamination **[WITN7590077]**. The new sub-committee would review the existing guidance in terms of conventional cleaning and disinfection as well as seek to examine the potential of new technologies to

improve decontamination effectiveness against prions. It would also look at the issue of training and education in the use of decontamination equipment. A letter sent from Sir Liam Donaldson to Donald Jeffries and Geoffrey Ridgway on 16 October 2007 confirmed that ESAC had set up an Endoscopy Subgroup led by Dr Geoffrey Ridgway.

- At a meeting of the Advisory Committee on Decontamination Science and Technology meeting in 2010, a working group was set up to consider all aspects of endoscope decontamination and then produce a report for the Department of Health. The cover sheet document stated that whilst there were no known transmissions from invasive GI endoscopy, any major change in the guidance may have been difficult to defend if cases of vCJD linked to endoscopy started to appear **[WITN7590078]**.

Information to Patients

4.63. We have been asked a series of questions about the information given to patients who were suspected or confirmed as having vCJD, with regards to the use of endoscopes.

4.64. We have been asked to outline:

- if patients were informed of any risks that were associated with the quarantined endoscopes; and
- whether patients were informed that they were at risk of vCJD prior to the endoscope being used on them.

4.65. We address these questions below. However, we observe first that the questions appear to be addressing the issue of risk from the wrong end of the telescope. The risk relating to patients "*who were suspected or confirmed as having vCJD*" did not arise from the use of an endoscope in the course of their treatment. Their status would have derived from their health prior to the procedure and they would not have been at added risk in the course of treatment. Rather, the risk was that they might inadvertently contaminate the instrument being used in the procedure, and that this might then infect others. That was why the endoscopes used were subsequently subject to quarantining or other protective measures. There were no "*risks associated with the*

quarantined endoscopes" as these were, by definition, not being used. Only in situations when the endoscopes were, wrongly, not identified as requiring quarantining and reused inappropriately (as in the case of the incident in 2004, which is discussed in section 5 below) did a risk arise – but it was for all subsequent patients, rather than specifically for those who were suspected or confirmed as suffering from CJD or vCJD prior to surgery.

4.66. Turning back to the question of whether patients were informed of any risks, Annex J of ACDP TSE Guidance details an assessment to be carried out before surgery and/or endoscopy to identify patients with, or at, increased risk of CJD or vCJD (the guidance was first published on 31 July 2006 and was revised and updated on August 2016). Within this document, Appendix B is an information sheet for pre-surgical patients undergoing surgery or neuro-endoscopy on high-risk tissues, telling them about the questions they would be asked. The questions are outlined, and their purpose explained. The aim was to identify increased CJD risk: "*If you do have an increased risk of CJD, special precautions will be taken with the surgical instruments used in your operation. Your GP will be informed and will ask you to come and discuss what this means in more detail. Please remember that the overall risk of CJD spreading by these routes is generally very low. These questions are an extra measure to prevent CJD spreading through surgery. This should not affect the medical care you receive now or in the future*." **[WITN7080005]**.

4.67. In relation to that last point, I note that the instruction to medical professionals also includes the advice that "*Procedures should not be delayed whilst information is being collected, and clinicians should be careful not to prejudice overall patient care*." (p3).

4.68. The second part of the question was whether patients were informed that they were at risk of vCJD prior to the endoscope being used on them. Again, the procedures to be followed are set out in the Guidance outlined above and included an information sheet for patients.

4.69. Looking at the information sheet now, it is not wholly clear whether pre-surgery answers that suggested – for the first time – that patients were 'at risk' for CJD would lead to discussion before the treatment itself, or whether the issue would

be referred back to the patient's GP for further discussion in a less time-pressured environment. It is possible that practice varied depending on the patient's own reactions to the questions. However, as I have explained, the endoscopy was not the source of the risk, so – as far as I am aware - further information on the issue of CJD/vCJD risks was not required as part of the consent process for the procedure itself.

4.70. That is not to say that these conversations might not be difficult. In the letter from Dr Pryer to Dame Sally Davies referred to below, Dr Pryer noted that CJDIP "*had received reports of the difficulties of giving patients information on vCJD risks at a time of stress e.g. prior to neurosurgery*." His letter related specifically to the issue of highly transfused patients, but it might be thought that the comments would have a wider application **[PHEN0000608].**

4.71. It should be noted here that while the Department can provide guidance on the interaction with patients on these issues, it cannot be too descriptive on what health practitioners should or should not say to patients – this is ultimately down to the health practitioner. Furthermore, the exact offers made to patients and the route followed would vary locally, depending on available services.

Section 5: Look Back Exercises

Look Back, 2004

5.1. The Inquiry notes that it is aware that a lookback study was undertaken regarding transmission of vCJD via plasma and plasma products received by patients. It is said that, in the study, it was discovered that a single endoscope had been used 72 times prior to it being put into quarantine.

5.2. In relation to this account, I have been referred by the Inquiry to **[DHNI0000034_047]**, which sets out the history. It is a letter dated 8 December 2004, from, I understand, a hospital in Northern Ireland, to the Medical Secretary of the CJDIP of the HPA. I note that the function of the CJDIP was to advise on the management of incidents where surgical instruments have been used when the possibility of vCJD infection was either not known or not recognised (see the Review of Decontamination and CJD addressed to the CMO in September 2007) **[WITN7080005]**.

5.3. The author notes that a haemophiliac patient had had a biopsy performed on 20 July 2004. The patient had subsequently been identified as being at-risk of vCJD, through a lookback review of patients who had received plasma concentrates. The instrument was then quarantined (on 19 October 2004), but "*had been used 72 times between the date of the procedure and it being quarantined."* However, the letter stated that: "*We follow best practice when it comes to decontamination of flexible endoscopes*". Advice on the treatment of the endoscope was requested.

5.4. I have been asked about the response to this incident. I note, first, that as far as I can see, there are really two "lookbacks" referenced. The first is the lookback of patients who had received plasma concentrates, which identified the 'at risk' patient. The second is the exercise that followed, which examined whether, as a consequence of that new information, the endoscope used during a procedure on that patient might subsequently have put other patients at risk.

5.5. More broadly: I have reviewed the documents and believe there were two incidents in Northern Ireland at a similar time. One incident, as referred to by the Inquiry above, relates to an individual that had a biopsy performed on 20

July 2004 and who was subsequently identified as being at risk of vCJD. As set out above, a flexible endoscope used on this patient was used 72 times prior to quarantine. The other incident occurred in May 2004 and refers to a lookback exercise of 400 patients who had been treated with an endoscope that had not been adequately decontaminated. Whilst these are separate incidents, I have been unable to distinguish which subsequent actions resulted from which incident. Therefore, I have set out a history of action regarding endoscope decontamination practice generally in 2004.

5.6. I have been referred to a submission from David Harper to the CMO dated 1 May 2007, on the subject of endoscopes and decontamination. This stated at paragraph 7:

> *"In May 2004, following an incident in Northern Ireland concerning a failure to adequately decontaminate a flexible gastrointestinal endoscope, an Endoscope Task Force was set up, and a look back exercise was initiated in England. This led to the publication of: Endoscope Decontamination: Ten Top Tips. The report of the Task force and the Top Ten tips were issued in the Chief Executives Bulletin in October 2005. A copy of the Top Ten Tips is attached at* Annex xx". **[WITN7590071]**.

5.7. Thus:

- The investigations began in May 2004, in Northern Ireland;
- After concerns were raised, an Endoscope Task Force was set up and a look back exercise was initiated in England;
- Ten Top Tips on Endoscope Decontamination were developed and published **[WITN7590079]**.

5.8. There are further details relating to the Northern Ireland situation in an email sent from Sally Wellsted to DH colleagues sent on 15 June 2004. She noted that the Belfast Telegraph ran a story about a lookback exercise of 400 patients who had been treated with inadequately cleaned endoscopes at Lagan Valley Hospital in Northern Ireland. Key points in the email included:

- After identifying the problem at Lagan Valley, an audit of the decontamination protocols for all endoscopes was carried out in Northern Ireland. Of 1,000 endoscopes, potential faults were identified with the decontamination protocols for 25 endoscopes. These 25 instruments were withdrawn from use until a risk assessment is carried out.
- Although unaware of similar incidents in England, as a precautionary measure, the MHRA was issuing a medical device alert "next week", which would advise Trust Chief Executives to assess their endoscope decontamination process (this was issued on 23/06/04, see the Endoscope Incident Task Force Report above);
- An expert group was being convened by the Health Protection Agency. This would provide a risk assessment within the next week (of the article being published) and assist in deciding whether any further action was needed. **[WITN7590080; WITN7590081 WITN7590088; WITN7590082]**.

5.9. A letter was sent on 6 August 2004 from to CMO (Dr Armstrong) in the Scottish Executive to go to all CEOs in UK healthcare establishments **[WITN7590086]**. The letter stated that the MHRA had issued a Medical Device alert on 23 June 2004 as a result of reported endoscope decontamination failure incidents in Northern Ireland. The alert required Trusts to undertake assessments of endoscope decontamination processes, ensuring that manufacturers advice and instructions for the use of the endoscopes and re-processors were being followed and that, before purchasing a new endoscope, there should be a check on whether it could be processed using the decontamination process available. The letter asked that Chief Executives (of Primary and Acute care) to bring this to the attention of their Directors of Infection Prevention and Control and ensure that there was an active review of reprocessing of all endoscopes in their trust and that urgent steps were taken to remedy any inadequacies that are identified. If failures of adequate decontamination were identified, the endoscopes should not be used until the problems had been remedied and the incidents reported to the local CCDC.

5.10. The Endoscope Incident Task Force was established to review endoscope decontamination incidents in England from 2003 to 2004 **[WITN7590082;**

WITN7590083; WITN7590085]. The taskforce produced a report dated 30 September 2004. It is apparent that the reports relate to general infective risks (i.e. not CJD/vCJD specifically, but a wide range of risks including bacteria such as Staphylococci and Streptococci). The report stated that in total, twelve incidents had been reported to the Task Force as of 30 September 2004 regarding endoscope decontamination; full details are set out in the report. The report noted whether or not lookback investigations (i.e. patient contact exercises) had been conducted and, if not, the reasons for this. It also noted that, in relation to the original incidents in Northern Ireland, *"Approximately 1300 patients have been contacted for counselling and offered blood testing"* (p1).

5.11. Wider context is given by the Submission to the CMO in 1 May 2007, to which I have already referred **[WITN7590071]**.

5.12. I explained at para 5.4 above that the letter from the Northern Ireland Hospital to which the Inquiry refers mentions a lookback review of patients who had received plasma concentrates. There are no specifics about the exercise in the letter provided by the Inquiry and we would not hold details relating to the actions of the Northern Ireland hospital. However, the Statement provided to the Inquiry on 20 May 2022 by Lord John Reid references a risk assessment carried out in December 2003 for patients that might have received plasma. Lord Reid also refers to further notification exercise carried out in August 2004 that was informed by a risk assessment completed by HPA in June 2004.

5.13. It may be that the identification of the fact that the patient was at risk of vCJD is linked to these activities, but they are beyond the scope of this Statement.

Procedural Changes, 2004

5.14. I have been asked whether any changes were made to the decontamination and quarantine procedures as a result of the lookback investigation findings.

5.15. I refer back to the comments that I made above. It seems that the lookback, whilst important in identifying patients at risk of vCJD, was not the immediate trigger of the various reviews that took place in 2004. The answer below relates more broadly to the IPC work that followed.

5.16. The main body of this Statement has already referred to Annex F of "*Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*" (from the Advisory Committee on Dangerous Pathogens (ACDP) TSE Working Group). As the May 2007 submission to CMO noted, there was specific guidance on vCJD and endoscopes in Annex F, which from November 2005, has stated that:

> *"Endoscopes used for certain procedures in individuals with possible CJD, or in whom the diagnosis is unclear, should be removed from use or quarantined pending diagnosis or exclusion of CJD. Endoscopes other than those used in the CNS and nasal cavity, which have been used for invasive procedures in individuals designated as at risk of vCJD should be removed from use or quarantined to be re-used exclusively on the same individual patient if required."*

5.17. A document entitled *"Review of Decontamination and CJD"* for the CMO written in September 2007 stated that the Endoscope Task Force was set up in 2004 to look into the decontamination of flexible endoscopes incidents between 2003 and 2004. The group was established following an incident in Northern Ireland in which a flexible gastrointestinal endoscope was not adequately decontaminated. The Task Force concluded that the current guidelines were sufficient, but that there was a need to ensure that endoscope users were aware of the guidelines. This led to the MHRA publishing Endoscope Decontamination: Top Ten Tips, which was then circulated along with the report of the Task Force in the Chief Executives Bulletin in October 2005. **[WITN7590077; WITN7590079; WITN7590087]**.

Information to Patients

5.18. We have been asked what, if anything, was communicated to at-risk patients as a result of the look-back findings.

5.19. There are a number of potential issues raised by this question:

5.19.1. The Northern Ireland endoscopic audits or investigations that begun in early 2004;

5.19.2. The English 'lookback' of 2004/5;

5.19.3. The (possible) reference to the wider issue of a lookback study regarding transmission of vCJD via plasma and plasma products received by patients, which was referenced by the IBI in its question but is not the same exercise as the audits of endoscopic use.

5.20. Taking each in turn:

5.20.1. In relation to Northern Ireland, I have already referred at [5.10] to the reference in the Endoscope Task Force's report, to how "*Approximately 1300 patients have been contacted for counselling and offered blood testing"* (p1) **[WITN7590082]**. There is further information in a news release that was published on 15 June 2004 by the Social Services and Public Safety (Northern Ireland). Further details might be obtained from Northern Ireland Executive. **[WITN7590088]**.

5.20.2. In relation to England, I refer again to the information in the Report of the Endoscope Task Force **[WITN7590082]**.

5.20.3. In relation to Lookback regarding transmission of vCJD via plasma and plasma products, I do not understand that to be the subject matter of this request.

Section 6: Notification and denotification for highly transfused patients of their vCJD risk

Notification of vCJD risk to Highly Transfused Patients

6.1. I have been asked to set out the role of the Department of Health in ensuring 'highly transfused' patients were informed of their status of being at increased risk of vCJD, so that they could take appropriate public health measures (such as refraining from giving blood, etc.).

6.2. The DHSC blood safety team has reviewed documents stored by DHSC, and documents provided by the IBI. From such documents, it is apparent that the *'responsibility for investigating, assessing, and managing CJD incidents (and where appropriate notifying patients), rests with local trusts, health boards and health protection teams*.' **[WITN7590089]**.

6.3. The HPA, then PHE from 2013 onwards, published relevant guidance and reports on notification:

- The Department held liaison meetings with the HPA to discuss notification. In September 2005, the HPA agreed to develop proposals for GPs and clinicians on the follow up of contactable 'at risk' patients **[WITN7590091; WITN7590092]**.
- In 2015, PHE published guidance setting out 'public health action following a report of a new case of CJD or a person at increased risk of CJD' (Untitled (publishing.service.gov.uk)) **[WITN7590093]**.
- Further information was also published by PHE in June 2018 providing information for people who have increased risk of CJD (Information for people who have an increased risk of Creutzfeldt-Jakob disease (CJD) (publishing.service.gov.uk)). This includes guidance on refraining from donating blood **[WITN0672092]**.
- UKHSA, formerly PHE, publishes bi-annual reports (reference) **[WITN7590094]**. The reports include data collected by UKHSA on individuals identified as at increased risk of vCJD and which individuals have been informed of this. The reports can be found online here:

Creutzfeldt-Jakob disease (CJD) surveillance: biannual updates – GOV.UK (www.gov.uk) **[WITN7590095].**

6.4. Following a search of the Departments records, I have been referred to a background briefing pack **[WITN7590096; WITN7590097]** for the chair of the Clinical Governance Advisory Group (CGAG), which was provided for the CGAG meeting on 16 June 2006. The CGAG considered follow-up care and support for individuals identified as 'at risk' from developing vCJD. The pack includes a letter to GPs from Dr Kate Soldan (Epidemiologist HPA) asking them to provide information of clinical status of 'at risk' patients, consider referring patients for specialist evaluation and highlight whether any clinical care could generate samples for archive.

6.5. The DHSC blood safety team has also identified information leaflets sent to patients in June 2007 considered to be at risk of vCJD because they had received 80 or more blood transfusions. The leaflets were published by the HPA and Health Protection Scotland and set out public health measures for individuals, including:

- Restriction from donating blood, organs, and tissues
- Advice to "*inform whoever is treating you before surgical, endoscopy and dental procedures so they can make special arrangements for cleaning or disposing instruments*";
- Informing relatives in case individuals need to inform health care professionals and are unable to do so **[WITN7590098; WITN7590100 and WITN7590101]**.

6.6. The leaflet also advised patients that the medical professionals that provided care would discuss their risk of developing vCJD and highlight ways to avoid infection transmission.

6.7. During the search of records, correspondence was also found from Dr Sara Trompeter (consultant haematologist at UCLH) to the HPA in June 2011 **[DHSC5043608]**. The email advised that further help was needed preparing two documents for multiple transfused patients: a patient information leaflet and guidance to clinicians regarding procedures. In the letter to patients, it stated

that 'multiple transfused' patients were those who have received blood products from more than 80 donors, and the reason a patient would receive this letter was that they were potentially a multiple transfused patient **[WITN7590099; WITN7590102]**. As set out above, DH was not the lead for this work and if there is further detailed information required then UKHSA will be better placed to answer.

Identification of the Strategy

6.8. I have been asked to set out the strategy of identifying 'highly transfused patients' in order to provide them with public health information about their vCJD risk.

6.9. The records show that the development of a strategy to identify highly transfused patients can be traced back to c2005.

6.10. On 25 June 2004, a follow up note "*vCJD and plasma products: update on patient notification*" to David Harper's submission dated 15 January 2004 was sent to PS (PH) (at the time, Ms Melanie Johnson). It notes that the actions in the submission were as a result of a statement made by the SofS to the House of Commons on 17 December 2003 about "*the first case of probable transmission via blood transfusion*" **[WITN7590084]**. The paper summarised the ways DH calculated risks for various types of plasma product, and the preliminary risk assessments carried out by HPA on behalf of the CJDIP. The findings of the risk assessments included: notifying every patient with a blood clotting disorder of their increased risk of vCJD based on the advice of many experts, however an alternative approach would be to advise haemophiliacs on an individual risk assessment basis. Precautionary quarantining of surgical instruments and the deferral from making blood, tissue and bone donations should be adopted, endoscopes used on 'at risk' patients did not need to be quarantined if a biopsy was not performed and other patients who may be at risk should be traced. This led to the proposal that DH would develop various strategies with HPA to inform both clinicians and patients with haemophilia and PID (via the clinicians), ensure that implicated products were traced back to patients, and inform EMEA and European Commission of products distributed abroad.

6.11. In July 2005, a paper was presented to the CJDIP on secondary vCJD infection of patients who had received a high number of blood transfusions. The paper summarised the Epidemiology and Survival of Transfusion Recipients (EASTR) study by the national blood service. The EASTR study analysed 68,569 transfusion recipients between October 2001 to September 2002, which concluded that the risk of a recipient being infected with vCJD via blood transfusion went up almost in proportion to the number of donor exposures. **[JPAC0000051_026]**

6.12. A subsequent CJDIP meeting was held on 20 December 2005. A paper (reference) was circulated ahead of the meeting on *'the risk of secondary vCJD infection of patients receiving a high number of blood transfusions'*. The paper set out the risk of secondary vCJD infection, concluding that the risk of vCJD infection in people who received high numbers of transfusions was high and therefore public health precautions should be taken. **[JPAC0000051_026]**

6.13. As summarised in the submission from policy officials to CMO, Dr David Pryer, Chairman, (CJDIP), wrote to the CMO on 12 September 2006 recommending that patients in receipt of 80 or more blood transfusions should be considered at risk of vCJD for public health purposes. In reply, the CMO (Sir Liam Donaldson) requested that a Working Group of CJDIP and the ACDP TSE WG, together with HPA, should develop proposals for the identification and management of highly transfused patients **[WITN7590103]**.

6.14. Whilst a number of documents have been identified showing the progress of this sub-group and the process of identification of its proposals, the chronology can be picked up again on 24 January 2008, when the Working Group's proposed recommendations were discussed by CJDIP **[WITN7509104]**. The group concluded that a combination of strategies should be followed:

- It determined that pre-surgery assessment for procedures on high-risk tissues would be the primary strategy for identification and notification of highly transfused patients (i.e., those with 80 or more donor exposures);
- In the absence of a national database of transfusion recipients, it was not feasible to prospectively identify and notify all surviving highly transfused patients independently of pre-surgery assessment. Therefore,

establishing procedures for standardising and linking blood transfusion databases as part of NHS Connecting for Health initiative would enable this to be done in real time for patients in the future;

- It would be necessary to have a public communication strategy and to liaise with Connecting for Health to support the prospective identification of the highly transfused in future.

6.15. On 17 March 2008, the Chair of the joint Sub-Group of the ACDP TSE Working Group and the CJDIP, Dr Pryer, sent a report CMO. A submission dated 16 April 2008 to the CMO **[WITN7590103]** refers to this report and its recommendations. The CMO accepted the six recommendations in principle, whilst noting that further work remained to be done on implementation (and that the situation on patient identification in Scotland might differ at times from that in the other three nations). Annex A of the submission includes a letter from CMO to Dr Pryer, dated April 2008. The letter sets out the detail of how the recommendations would be taken forward or implemented. The submission stated that *"As this is work in progress, there are no plans to publish the report currently. It will be used as a basis for discussion with stakeholders and other experts and updated as necessary. Once agreed by the ACDP, the recommendation relating to pre surgical assessment will be issued as revised ACDP TSE Working Group guidance."*

6.16. This last point was a reference to Recommendation 1, the primary recommendation to "*Identify and notify highly transfused patients during pre-surgery assessment for surgery in contact with high-risk tissue*". On this, the CMO replied in a letter outlining the following:

"…This recommendation is accepted. The recommendation accords with the guidance published in November 2006 by NICE "Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures". I understand that amendments to the ACDP TSE Working Group infection control guidance to implement this recommendation have been prepared in readiness for approval by the Working Group and main ACDP, and I support this action." **[SCGV0002357]**

6.17. I have been referred by the Inquiry to **[PHEN0000531]**, which are the minutes of the next meeting of the CJD Incidents Panel, 14 May 2008. Item 10 records: *"At the previous meeting [see above] the Panel considered the recommendations of a joint subgroup of the Panel and the ACDP TSE Working Group and it was agreed that, following the meeting, the Chairman would write to the Chief Medical Officer recommending pre-assessment before high risk surgery as the primary strategy for identifying and notifying patients with >_80 donor exposures that they were 'at risk of vCJD for public health purposes".*

6.18. The minutes note that the recommendation had been accepted by the Chief Medical Officer and the HPA proposed establishing an implementation working group to implement this recommendation and further consider the prospective notification of the very highly transfused (individuals with >_200/400/800 donor exposures) and individuals with nine specific diagnoses, thalassaemia and sickle cell disease (emphasis added). The meeting raised a series of concerns about this conclusion, and practical issues. "*It was agreed that a special meeting of the Panel and invited experts would be held to give detailed consideration to the notification strategy, taking into account the practical implications as well as underlying prevalence estimates.*"

6.19. The minutes illustrate that there remained practical issues of implementation to be addressed; see further below.

Implementation of the Strategy

6.20. I have been asked how this strategy was implemented and by whom. I have been asked to include information about both prongs of the strategy, i.e. in relation to patients who attended for high risk surgery, and for those who did not.

6.21. I have been referred by the Inquiry to a number of documents:

6.22. The CJD Incidents Panel and ACDP TSE Working Group, Highly Transfused Implementation Subgroup Meeting draft minutes, 5 February 2009 explains the *"aims of the meeting were to discuss the detailed process of identifying and notifying highly transfused patients at increased risk of vCJD and to consider*

the draft documentation prepared by the HPA." It was noted that CMO had accepted the Panel's recommendation for a two-pronged strategy:

- Identifying highly transfused patients with >_80 donor exposures through pre-assessment for surgery and neuro-endoscopy on high risk tissues, i.e. central nervous system and posterior eye, to start in April 2009.
- Prospective notification of very highly transfused patients with >_800 donor exposures, in July 2009. **[NCRU0000152_060]**.

6.23. The Ninth Annual Report of the CJD Incidents Panel (1 January to 31 December 2009) chapter 3.2.1 addresses highly transfused patients. It repeats the information about the CMO's acceptance of the advice on a 2-pronged strategy and added "*In July 2009 the advice to undertake vCJD pre-surgical assessment to identify and notify highly transfused patients was disseminated to UK hospitals. One highly transfused patient was identified in Scotland. An evaluation was undertaken towards the end of the year to inform the identification and notification of very highly transfused patients*". **[PHEN0000142]**.

6.24. In 2008 the ACDP TSE subgroup recommended:

Pre-surgical identification of all individuals who had received blood from 80 or more donors and who require surgery on high infectivity tissues	CMO accepted this recommendation and requested confirmation of implementation by April 2009 **[WITN7590151; NCRU0000169_039]**
Identification of all individuals who have received blood from a 'very large' number of donors, starting from a threshold of 800+ in the first instance	CMO accepted individual notification. CMO requested before progressing to notify further cohorts of recipients with lower exposure levels that the group report first on the impact of the exercise by October 2009 **[WITN7590151].**

6.25. The ACDP TSE RM SG recommended to CMO in 2008 that all individuals identified through these two approaches should be informed that they had an increased risk of having been infected with vCJD, and that they should follow public health precautions to reduce the risk of transmission to others. This includes not donating blood, organs, or tissues. The recommendation also stated that advice should be given to their doctors that any surgical instrument

used in procedures that involved medium or high infectivity tissues should be removed from general clinical use.

6.26. These recommendations were approved by CMO (Sir Liam Donaldson) in Oct 2008 **[WITN7590146]**.

6.27. We would refer to document **[NCRU0000152_060]** for detail on the implementation of the first prong of the strategy are the draft Minutes of the CJD Incidents Panel and ACDP TSE Working Group Highly Transfused Implementation Subgroup Meeting, 5 February 2009. The minutes stated:

> *"It was agreed that the Department of Health would initiate the exercise by sending a letter to trust chief executives, summarising the advice and rationale for the patient notification exercise, copied to the Panel, the ACDP TSE Working Group and the HPA to indicate the provenance of the advice and state that detailed instructions and supporting documentation would be available from the HPA. The letter would also need to emphasise the importance of inter-trust cooperation in relation to requests for help in the completion of blood transfusion histories.*
>
> *The HPA would, in parallel, send a complementary second letter to trust chief executives copied to directors of infection prevention and control."*

6.28. A search has not identified any further documents referenced in the minutes.

6.29. In 2009, HPA issued a Dear Colleague letter to UK haemophilia doctors instructing them to provide patients with bleeding disorders relevant information. As set out above, this indicates that HPA was also responsible for detailed instructions to clinicians to carry out notification exercises. **[PHEN0000531]**

6.30. It is apparent from the subsequent letter from Dr Pryer to the CMO (Dame Sally Davies) dated 26 April 2012 that the second part of the strategy, the identification of all of those who had received blood from a large number of donors (more than 800, initially), was subsequently put on hold. Dr Pryer wrote:

> *"Identification of individuals who had received blood from 80 or more donors who were identified prior to surgery on high infectivity issues, was undertaken in 2009, through additions to the existing pre surgical assessment (Annex J of*

the TSE Infection Control Guidance). At the subsequent request of the Department of Health, the identification of all individuals who had received blood from at least 800 donors, was put on hold, in order to concentrate on the pre-surgical identification exercise, and bearing in mind the continuing scientific uncertainties affecting the vCJD blood risk assessment." **[PHEN0000608]**

6.31. See further the answers at Section 7, which addresses the issue of De-Notification.

Information and Counselling of Patients

6.32. I have been asked what information was given to such patients, and whether they offered any psychological services.

6.33. I have been referred by the Inquiry to **[NCRU0000152_060]**. As noted above, these are the draft Minutes of the CJD Incidents Panel and ACDP TSE Working Group Highly Transfused Implementation Subgroup Meeting, 5 February 2009. They state that "*The HPA would work with the appropriate patient organisations to obtain their input into the identification and notification process and communications strategy*." Item 10 was "Patient information documents (papers 13 and 14 and tabled paper)"

6.34. Paragraph 6.3 and 6.5 sets out what information was given to highly transfused patients about their vCJD risk.

6.35. The DHSC blood safety team identified a paper that was written by the HPA in June 2006 on '*the status of national monitoring and research involving individuals at risk of CJD'.* The paper stated that clinical care services were made available to at risk individuals to optimise their wellbeing in the face of any psychological consequences of their at-risk status. The patients' GPs were considered by the panel the key person for coordinating each individual's care, and the key point of contact for providing these patients with information about options for clinical care **[WITN7590106]**.

6.36. The ACDP TSE's 2013 report **[WITN7590107]** on the proposal to identify and notify patients with 300 or more donor exposures stated the need for clear messaging from the outset to patients on the potential benefits of undertaking

this notification. The report also references patient outreach and support groups available for patients, led by hospitals and clinicians.

6.37. On 13 May 2009, an information leaflet was published setting out guidance for healthcare staff regarding pre-surgical assessment procedures: "*Pre-surgical assessment (CNS and posterior eye surgery only) to identify highly transfused patients at increased risk of variant CJD (vCJD)*". The guidance outlines the role the CCDC and GPs had in informing and supporting patients at increased risk of vCJD. It notes that the CJD Incidents Panel "*does not advise contacting any patients exposed to … instruments that have been used on patients at increased risk of vCJD*". The leaflet describes an analysis exploring the impact "*of receiving a large number of blood transfusions on a patient's risk of vCJD infection*" carried out by the Department of Health. The analysis concluded that individuals who received infected blood may be able to cause secondary infections, despite not presenting any vCJD symptoms themselves. **[NCRU0000152_059]**.

6.38. Patients were also given information on the CJD Support Network, a UK charity set up to provide emotional and practical support for all strains of CJD and those at greater risk of CJD. The network included a helpline for patients that have been notified that they were at risk of vCJD.

6.39. Again, ultimately, while the Department can provide guidance on the interaction with patients on these issues as set out above, the Department cannot be too prescriptive about what health practitioners should or should not say to patients. Furthermore, as we noted at paragraph 4.71 above, Furthermore, the exact offers made to patients and the route followed would vary locally, depending on services available locally. Similarly, it is beyond the corporate knowledge of the Department to have records of these conversations and referrals. The key responsibility for patient support lies with the relevant health practitioner, working within their local network of resources.

Audit

6.40. The Inquiry has asked whether any audits were undertaken to examine how successful this strategy was in identifying those who were at risk of vCJD for public health purposes as a result of being a highly transfused patient.

6.41. The DHSC blood safety team was unable to locate a specific audit regarding the identification of those at risk of vCJD as a result of being a highly transfused patient in the Department's records. However, evaluation and surveys were carried out, according to the letter from Dr Pryer to Dame Sally Davies (CMO) dated 26 April 2012 (referred to above). In that, he stated:

> "*The questions intended to identify patients exposed to 80 or more donors were added to the 'Annex J' guidance …. in July 2009. It was specified that these new questions about transfusion history should apply only to patients about to undergo neurosurgical or posterior eye procedures. Since then, 9 highly-transfused patients have been identified across the UK, 7 in England. However, only 2 of these 7 were identified through proper implementation of Annex J, i.e. prior to high risk surgery, the others having been identified through incorrect application of the new questions prior to low or medium risk surgery.*
>
> *An interim evaluation carried out by the HPA, and two other surveys carried out by transfusion centres and trusts, all showed patchy knowledge and implementation of the guidance. This might explain the very low numbers of patients correctly identified. (Although the actual number of highly transfused patients undergoing high risk surgery is uncertain, estimates of the order of 50 - 60 per year in England were suggested by the DH Health Protection Analytical Team).*" (emphasis added).

6.42. It appears that guidance on this issue evolved over time, and proposals shared with the CMO were informed by learning from the impact of current policies, and similar policies.

Guidance for Specific Conditions

6.43. I have been asked whether DHSC provided any specific guidance about the importance of identifying highly transfused patients, to the departments within Hospitals and to clinicians administering blood transfusions in relation to the following medical conditions:

- Sickle Cell
- Thalassemia

- Leukaemia
- Any other medical condition typically requiring a high number of transfusions

6.44. The ACDP TSE subgroup and CJDIP have shared multiple pieces of guidance on identifying highly transfused patients.

6.45. With reference to the medical conditions requiring a high number of blood transfusions, as part of proposals put forward by the ACDP TSE in 2012 for applying a donor exposure limit of 300, rather than 80, the final report presented to the CMO at the time referenced the need to consult thalassaemia and sickle cell disease patient networks and outreach groups in considering the impact of notification on these groups **[WITN7590107]**. As requested by the CMO, the report included views from clinicians and patient groups including the CJD network, haemophilia society, the TTP network, UK Thalassaemia Society, and the Sickle Cell Society, and emphasised the need for language to be considered in patient information materials and to signpost patients to outreach and support groups.

Section 7: Denotification of highly transfused patients of their vCJD risk for public health purposes

Denotification

7.1. I have been told that the Inquiry understands that, in 2013, there was a denotification exercise in relation to some patients who had been informed that they were at risk of vCJD for public health purposes.

Change of approach.

7.2. I have been asked, first, to explain how this came about.

7.3. In section 6, I have outlined the development of the strategy to identify and notify patients who had received blood transfusions from 80 donors or more and who should therefore have been considered to be at risk of vCJD for public health purposes.

7.4. In June 2011, a paper was produced by the Department's Health Protection Analytical team titled *"Blood-borne transmission of vCJD: Re-examination of scenarios*". The paper highlighted that the CJDIP had used the highly precautionary assumption that 1 in 4,000 donors would have been infective, and that establishing a more credible working assumption was particularly important in assessing risks to *"highly transfused"* patients with no links to known vCJD-infected donors, where calculated risks were entirely dependent on estimates of historical prevalence and transmissibility. The paper included the statement: *"Despite the many remaining uncertainties about future transmission risks, we suggest that current evidence is now sufficient to justify a marked revision of existing calculations"* **[RLIT0001005]**.

7.5. Following this paper, the TSE Risk Management Subgroup reviewed the overall risk assessment and recommended changes to the limit of donor exposures. Dr Pryer, the Chair of the CJDIP, wrote to the CMO on 26 April 2012 **[PHEN0000608]** to provide an update on the ACDP TSE Risk Management Subgroup and the CJDIP position regarding variant CJD risk and highly transfused patients. In the letter, David Pryer stated that the highly transfused

joint working group (a working group for the TSE Risk Management Subgroup) recommended that 80 blood donor exposures was no longer a suitable cut off limit for categorising an individual as "*at risk of variant CJD*". Instead, the limit of 300 donor exposures endorsed by the ACDP TSE Risk Assessment Subgroup should be employed.

7.6. A submission to the CMO in August 2012 recommended accepting the CJDIP's recommendation to raise the cut-off of 80 donor exposures to 300 patients to be considered 'highly transfused'. This was based on the recent revision of evidence-based blood related risks **[WITN7590140]**.

7.7. A letter from the CMO on 9 August 2012 sent to David Pryer confirmed agreement with the recommendation to apply a donor exposure limit of 300, rather than 80, to categorise an individual as at increased risk of vCJD **[WITN7590108]**.

Those patients denotified

7.8. I have been asked to explain which patients were denotified and why.

7.9. The Department does not hold patient identifiable information and does not keep on record which individual patients were denotified. However, following a review of the Department's records, the patients that were denotified were those that had less than 300 donor exposures, as set out above.

7.10. UKHSA publishes bi-annual updates on surveillance carried out on CJD. This includes a summary of all 'at increased risk' groups for vCJD and the current status of increased risk groups. The reports are published online and are available here: Creutzfeldt-Jakob disease (CJD) surveillance: biannual updates - GOV.UK (www.gov.uk) **[WITN7590095]**.

7.11. At the ACDP TSE committee meeting on 13 November 2014, PHE provided a paper updating the committee on public health follow up of individuals at risk of vCJD. From reviewing this document, the paper included information on the denotification of patients. PHE advised that the threshold for notification had changed for at risk patients, and that individuals who had received between 80 and 300 donor exposures were no longer considered at risk, as the threshold had changed to 300 or more donor exposures. PHE advised that any notified

patient that received less than 300 donations would need to be denotified. PHE advised that this process had begun in April 2013 stating that *"of the five notified individuals still alive, two individuals have been denotified, three have already or will, as a consequence of ongoing treatment, exceed the 300 donor exposure threshold"* **[WITN7590089]**.

7.12. The letter from Mr Pryer to the CMO in 2012 explained how only small numbers of patients had been identified as 'highly transfused' patients. The numbers set above appear to be consistent with that information to the CMO.

How the patients were denotified

7.13. As set out in and as referenced above, this exercise appears to have been led by PHE. PHE sent a letter to GPs informing them of an important change that affected their patients. The letter requested that doctors inform patients of the revised risk assessment and that the patients were therefore no longer regarded as being at increased risk of vCJD compared with the general population of the UK **[WITN7091009]**.

7.14. The letter suggested that doctors communicated the following messages to patients:

- *"…S/he is no longer considered at increased risk of vCJD for public health purposes.*
- *Whilst PHE cannot rule out the risk of vCJD infection, evidence now indicates that the exposure your patient has received is not significantly different to the background population level. As a result, no special precautions need to be taken by your patient or by any medical professionals providing care.*
- *Your patient does not have a significantly higher risk of developing vCJD nor does s/he pose a significantly greater risk to others than the rest of the UK population who had a dietary exposure during the BSE epidemic.*
- *If the patient would like to discuss how they feel about their risk of CJD, the CJD Support Network are experienced in discussing CJD risks with patients, they can be contacted on* GRO-C *."*

Offers of support following denotification

7.15. I have explained above that patients who were identified as 'highly transfused' were signposted to different channels of support. As outlined, this support would have varied patient to patient, depending on the services available locally, and the nature of the advice from a particular clinician. However, it should also be noted that the Department would not be in a position to state what support was offered or accessed by a specific patient. On page two of the letter **[WITN7091009]** quoted above (Re: Patient at increased risk of vCJD due to receipt of blood from a large number of UK donors), PHE suggested that clinicians (GPs) provide their patients with information about how to access the CJD Support Network (see the quotation at paragraph above).

Section 8: The MRC Prion Unit's DDA Test

The MRC Prion Unit's Direct Detection Assay (DDA)Test

DH Funding for the Development of a Screening Test for vCJD

8.1. I have been asked to explain what funding DHSC gave to the MRC Prion Unit to develop a screening test (Direct Detection Assay, or DDA) for vCJD.

8.2. Since vCJD was discovered (1996), the Department has prioritised funding for vCJD research. Overall, since 2002, the Department has made available over £43 million for funding specific research projects to address key evidence gaps on vCJD including mitigating the risk of secondary transmission of the disease. Research on vCJD has been taken forward by the NIHR, the MRC Prion Unit and university research facilities.

8.3. The MRC, as part of UK Research and Innovation ("UKRI"), is the Government's main biomedical research funding agency **[WITN7590109]**. The MRC's vision is to accelerate improvements in human health and economic prosperity by supporting world-class biomedical research and innovation across the spectrum from fundamental science to early clinical trials and preventive medicine. Each year the MRC spends around £900m, which is awarded to researchers in universities, medical schools, and research organisations. The MRC has strong partnerships within UKRI, across the UK and around the world, and works closely with the NHS and the UK health departments to deliver its mission, which is to:

8.3.1. encourage and support research to improve human health

8.3.2. produce skilled researchers

8.3.3. advance and disseminate knowledge and technology to improve the quality of life and economic competitiveness of the UK

8.3.4. promote dialogue with the public about medical research.

8.4. The MRC uses a variety of funding models to support UK science. The MRC Prion Unit at UCL is an example of the MRC 'Unit' funding model, which are

strategic, mission-focused initiatives, led and driven by an expert scientific director to promote novel, high risk approaches, cooperative research programmes or the development of shared infrastructure and resources. Alongside performing ground-breaking research, they are also responsible for providing an excellent training environment to develop outstanding researchers with specialist and transferable skills. The strategic need for MRC core support will change over time and to ensure MRC continues to support high quality research in the most relevant strategic areas and emerging needs for UK medical research, MRC Units are usually assessed every five years. MRC Units are expected to attract additional external grant funding leveraging their MRC core support. The MRC Prion Unit is further supported by grants from NIHR, other UKRI councils and a number of charities, with key external investment for the National Prion Monitoring Cohort, supported by the UCLH NIHR Biomedical Research Centre **[WITN7590110]**.

8.5. The Department commissions research through the NIHR, and previously the Department's Policy Research Programme, to better understand the prevalence of abnormal PrPs. The NIHR has commissioned the following studies set out in Table 1. This includes the Appendix II and III studies, which I will go on to explain in more detail below. These tables have been put together with contracting information held by the Central Commissioning Facility ("CCF"), which manages and administers research programmes funded by the NIHR, and previously the Department's Policy Research Programme. The CCF is one of the coordinating centres responsible for the day to day management and operations of the NIHR as part of the overall governance of the NIHR.

Table 1: Research projects related to prevalence studies as commissioned by NIHR. Table 1 sets out for each project: the project title, lead applicant organisation, project award value and contracted project dates.

Project title	Lead applicant organisation	Award value	Project dates
National Tonsil Archive phase III	Health Protection Agency	£7,024,560	01/04/2006 - 31/03/2013
HPA CJD Enhanced Surveillance	Health Protection Agency	£2,224,278	01/04/2011 - 30/09/2012

(appendix/tonsil/ spleen/post mortem)			
Prevalence of Abnormal Prion Protein in Appendix Tissue Collected from "Non-Exposed" Populations (the 'Appendix 3' study)	Health Protection Agency	£3,970,800	01/01/2013 - 31/12/2016
Development of methods to retrospectively analyse fixed appendix tissue from prevalence studies	University College London	£551,099	01/07/2018 - 31/12/2020

8.6. The Inquiry has requested information on the funding for a vCJD screening test. While the Department has not provided specific funding to the MRC Prion Unit for the development of the DDA test, the development of the test was supported through the core MRC funding of the MRC Prion Unit up to 2017. The Department of Health has made available £1.25 million to the MRC Prion Unit at University College London towards two relevant projects looking at developing for vCJD, including one to test for abnormal prions, between 2018 and 2023, as set out in Table 2 below. I will go on to explain the decision making around funding for the specific test developed by Professor Collinge below.

Table 2: NIHR / DHSC research funding to the MRC Prion Unit to develop a screening test for vCJD. [Details of these awards are in the public domain at The Development of an Effective Treatment for Prion Infection of Humans - NIHR Funding and Awards] **[WITN590111].**

Project title	Lead applicant organisation	Award value	Project dates
Development of methods to retrospectively analyse fixed appendix tissue from prevalence studies	University College London	£551,099	01/07/2018 - 31/12/2020
Development of a cell-based bioassay to accurately measure variant Creutzfeldt-Jakob disease prions in human tissues and biofluids	MRC Prion Unit	£696,583	01/07/2018 - 31/03/2023

8.7. In addition, the Department is also providing funding towards the following research projects relevant to ongoing questions on vCJD in Table 3 below. Table 3 sets out for each project: the project title, lead applicant organisation, project award value and contracted project dates. As requested by the Inquiry, I will go on to explain research for subclinical vCJD screening in more detail below.

Table 3: Research projects addressing key health protection questions on vCJD as commissioned by NIHR (and previously the Department's Policy Research Programme).

Title	Lead applicant organisation	Award	Project dates
Assessing and defining pre-clinical vCJD infectivity using transmission and protein aggregation models	University of Edinburgh	£1,553,441	01/11/2017 - 31/03/2024
Comparative evaluation of the performance of proposed diagnostic tests for vCJD in preclinical blood samples	University of Edinburgh	£968,046	01/12/2017 - 31/08/2021
Evaluation of Candidate Tests for Pre-clinical Detection of Prion Disease in Blood	Medicines and Healthcare Products Regulatory Agency	£592,627	01/11/2017 - 31/07/2021
Modelling sub-clinical vCJD infection in the UK population	The Roslin Institute	£1,130,627	01/04/2015 - 31/03/2019

8.8. All research funding was granted through an open and competitive process and was informed by the advice of independent experts.

Development of the Product by the Market

8.9. The Inquiry has noted that in his evidence to (i) the Inquiry on 13 May 2022, and (ii) to the House of Commons Science and Technology Committee on 27 November 2013, Professor Collinge described being in what he called *'the valley of death'* **[TSTC0000051]**. By this he meant the situation in which commercial companies considering whether to invest in bringing the screening

test being developed by the MRC Prion Unit (the DDA) to market needed more data, but the MRC Prion Unit were unable to get the funding for this.

8.10. I have been asked to explain why, given that the Department had funded MRC Prion Unit research work into developing a screening test, it did not provide the necessary funding to enable the DDA to be developed to the stage at which commercial companies could (if they were interested) develop it for market. We have provided details of funding provided by the Department to the MRC Prion research unit for the development of a screening test above.

8.11. A letter from the CMO, Dame Sally Davis, to Professor Collinge dated 8 April 2011 **[WITN3093007]** noted the public health interest and importance of having available for the NHS, both an effective decontaminant for prions to use on surgical instruments and an effective (both sensitive and specific) blood test for screening blood donors and potential patients for vCJD. Dame Sally Davis congratulated Professor Collinge on the recent publication of his blood test, and that he had "*delivered on both these goals for the Department.*" She continued: *"Taking your products forward into the market is clearly an industry role and was never expected of an individual academic or an academic unit."* It noted that he had been working with industry and there had been interest from industry in developing these products **[NHBT0033626]**.

8.12. A letter dated 8 April 2011 was sent following a meeting between Professor Collinge and the-then Public Health Minister (Anne Milton) and the CMO (Dame Sally Davies) to update them on the work carried out by Professor Collinge. The letter went on to state "…*we recognise that commercialising these products is not your job and that the market will have to be left to work*" **[WITN3093007]**.

8.13. As with any new drug or medical device, it is an industry role to take a product to the market.

8.14. DHSC remains committed to ensuring that all test developers, such as MRC Prion Unit, NHSBT, other academic teams, or commercial developers, have access to vCJD samples to carry out research and that any tests developed comply with the relevant legal requirements. DHSC will not commit additional resources to support development of one particular test over another.

vCJD Blood Prevalence Study

8.15. The Inquiry has noted that, in July 2014, the House of Commons Science and Technology Committee published a report "*After the Storm? UK Blood Safety and the risk of variant Creutzfeldt-Jakob Disease*" **[TSTC0000052]**. One of its recommendations was that a large scale vCJD blood prevalence study should be initiated in the UK.

8.16. The Inquiry has asked what steps were taken by DHSC to secure implementation of this recommendation. Our review of available evidence suggests that overall, the Department was not opposed in principle to the idea of a blood prevalence study and could see its potential benefits. However, there were concerns about the DDA test not being good enough and uncertainty about what additional value a further prevalence study could add to the evidence base generated by the Appendix I and II studies. I will describe these events in more detail, based on the available evidence from our review of documents. The table below setting out the chronology of events may be useful.

Event	Date	Description
National Tonsil Archive phase III (known as Appendix I)	01/04/2006 – 31/03/2013	The overall aim of the prion prevalence tissue archive was to estimate the prevalence of infection with the BSE agent in residents of England who were likely to have been exposed to the BSE agent through their diet. This was achieved by measuring the prevalence of detectable abnormal prion protein (PrPsc) in the tonsil tissue of at least 50,000 residents of England born before 1st January 1996.
HPA CJD Enhanced Surveillance (appendix/tonsil/ spleen/post mortem) 'Appendix II'	01.04.2011 – 30.09.2012	The Appendix-II study concludes. The study indicated that 1 in 2000 of the population may be sub-clinically infected with vCJD

Prevalence of Abnormal Prion Protein in Appendix Tissue Collected from "Non-Exposed" Populations (the 'Appendix 3' study)	01.01.2013 – 31.12.2016	HPA led Appendix III study begins in 2013 and continues until 2016. The study looked at the presence of abnormal prion proteins in samples of appendixes in population groups thought to have been unexposed to BSE.
House of Commons Science and Technology Committee 'After the Storm' report	Published July 2014	Report recommended that a large scale vCJD blood prevalence study should be initiated in the UK.
Govt response to 'After the Storm' report	Published October 2014	DHSC stated it would explore the possibility of using a prototype test developed by MRC Prion Unit to conduct a blood prevalence study but noted remaining uncertainties on the test.
Conclusion of Appendix III study	2016	The Appendix III estimated that prevalence of abnormal prion protein in appendixes tissue of roughly 1 in 4,200 people
ACDP TSE 'position statement' on results of Appendix III study	August 2016	The statement noted that the results of the study suggested that only a few of those with this protein abnormality will develop any symptoms of prion disease. However, the statement also noted that differences in interpretation of the Appendix-III study findings had practical implications for risk management.

8.17. In the Government's response to the report 'After the Storm' published October 2014, DHSC stated that it would explore the possibility of using the prototype test developed by the MRC Prion Unit to carry out a blood prevalence study. However, it further noted that:

> "…[*whilst] we appreciate that a blood prevalence study using the MRC Prion Unit's test (or another test) could yield some useful information, there are scientific and technical issues that must be resolved before such a study could be initiate*d."

8.18. For example, it was not clear at the time whether the MRC Prion Unit blood test could detect asymptomatic vCJD-infected individuals. In order to do a prevalence study in the general population it was essential that the test could detect vCJD in asymptomatic individuals, i.e. individuals showing no symptoms of vCJD. In addition, the actual test would also need to be reviewed and possibly further evaluated independently.

8.19. At that time, the results of another prevalence study looking at abnormal prions in appendix tissue (called the Appendix III study) were also awaited. This study was looking at stored appendix tissue from a population thought not to have been exposed to dietary BSE (patients born after 1996 after meat controls were in place). This was being run specifically to increase the understanding of how many individuals in the population had been infected sub-clinically with abnormal PrPs. This study, costing approximately £3.9 million, was commissioned by DHSC through the NIHR, in addition to a previous study (known as the Appendix II study) looking at the prevalence of abnormal PrPs in appendix samples collected from patients born before 1980 (therefore before the presumed presence of BSE).

8.20. The earlier Appendix-II study had indicated that 1 in 2,000 of the population may be sub-clinically infected with vCJD and informed the Department's risk assessments at the time. The results from a separate prevalence study that either confirmed or suggested less than this estimate were unlikely to change our blood risk assessment, or the range of precautionary blood-related risk reduction measures advised by SaBTO at the time. If the study showed prevalence greater than 1:2000, we would have needed to reconsider the risk assessment, and such a revision would need to have been informed also by the results of the Appendix III study and any new evidence on the other key inputs to the risk assessment: infectivity and susceptibility.

8.21. The Government's response to the report 'After the Storm' (a response published in October 2014) set out that it would explore the possibility of using the prototype test developed by the MRC Prion Unit to carry out a blood prevalence study. It added that [DHSC] would take expert advice from the ACDP TSE Sub-Group on a number of issues that needed to be resolved. This included scientific and technical issues, as well as on other issues such as the interpretation of the results from the Appendix III study, the potential value of a blood prevalence study, and how the findings of such a study could be used. This was done to inform our views on whether a blood prevalence study would be a scientifically justified use of the Department's budget, and its importance in comparison to other research priorities **[WITN7590148]**.

8.22. Specifically, on a possible blood prevalence study, the ACDP TSE Subgroup set out its position upon a potential blood prevalence study at a meeting of the ACDP on 3 July 2014 as below:

> *"The Prion Working Group (PWG) of the UK Blood Services had discussed the possibility of a vCJD blood prevalence study and noted that the TSE SG would be asked for input into protocol design and methodology. Agreement had been made, in principle, in favour of a strictly anonymised blood prevalence study. It was acknowledged that the primary and confirmatory assays currently in development had limitations and that the required scaling up and independent quality assurance of any test protocol would also be challenging. Members discussed whether blood specimens from across the UK population may be preferable to those just from blood donors to make the prevalence study representative of the population"* **[WITN7080006]**.

8.23. In its 2014 Annual Report, the ACDP again considered the potential value of an anonymised 'blood prevalence study' and set out its position as follows:

8.24. *"Although there was support for such a study in principle, the Sub Group were of the opinion that the blood test developed by the MRC Prion Unit and D-Gen requires further development before it could be used for such a purpose. They suggested that NHS Blood and Transplant and the National Institute for Biological Standards and Control work together with the test developers to*

evaluate the ability of the test to detect preclinical disease, and to scale up the assay to a replicable higher throughput version" **[RLIT0000725]**.

8.25. Also relevant to a possible blood prevalence study and/or future research on remaining questions on vCJD, were the results of the Appendix III study. This looked at the presence of abnormal PrPs in samples of appendixes in population groups thought to have been unexposed to BSE. These results showed an estimated prevalence of abnormal PrP in appendix tissue of roughly 1 in 4,200 and went to the ACDP TSE Subgroup for consideration, as pledged in the Government's response to 'After the Storm'. Its position statement on occurrence of vCJD and prevalence of infection in the UK (August 2016), stated that:

> *"…the contrast between the prevalence of abnormal prion protein and the number of clinical vCJD cases seen to date suggests that only a few of those with this protein abnormality will develop any symptoms of prion disease."*

8.26. The sub-group stated that differences in interpretation of the Appendix-III study findings therefore had some practical implications for risk management. Remaining questions were likely to be better understood by study of the natural course of vCJD infection and development (or otherwise) of clinical disease, including variations in host / agent interactions. The group also considered that it was essential to maintain a high level of both human and animal TSE surveillance.

8.27. Partly as a result of this advice from the sub-group and ongoing health protection policy questions around vCJD, the Department launched an open competition in 2016 inviting proposals to undertake research to inform understanding of vCJD infection in the following areas:

- prevalence of pre-clinical vCJD infection in the UK population, including interpretation of existing prevalence studies
- variations in estimated prevalence studies and actual cases of vCJD
- the natural course of vCJD infection, including variations in host/ agent interaction

- Risk management and health protection measures, including the ability of pre-clinical infection to transmit.
- development of a specific and sensitive test which is able to detect pre-clinical levels of infection, in blood or non-blood, which can be scaled to process large numbers of samples
- development of decontamination technologies for re-usable medical instruments.

8.28. The research commissioned as a result of this call is set out under question 20, research bid, 2016. As stated above, all research bids are granted through a fair and competitive process.

8.29. The ACDP TSE subgroup also met on 29 September 2016 where the Committee's opinion was being sought by DHSC on the utility of assays under development, including suitability for a population level study. Specifically, the Committee's opinion was being sought with respect to the usefulness of the MRC Prion Unit's DDA for a study of this type and what further development might be needed before it was used more extensively (i.e. make it more automated/scale it up). As set out in the minutes for this Committee meeting, the ACDP TSE subgroup concluded as follows:

> *"It was clear to the Committee that a population based study could take several forms. It might be used in an attempt to clarify the Appendix study results" and that "ideally there should be a comparative study carried out using at least two different assays. This would allow for relative sensitivity and specificity between tests to be examined. The DDA was suggested as the initial screen but this was not supported"* **[PHEN0002461]**.

8.30. The committee questioned whether it was feasible to carry out tests on a high enough number of samples for all the assays as this would require tens of thousands of samples to be tested. This would have to be a large scale study and would take time and resources to complete. It was also concluded that the outstanding questions from the Appendix studies "*needed to be resolved and if carefully designed, such a study could contribute to achieving this*."

8.31. DHSC is not aware of any changes to the scientific situation that would change the view of the Committee or warrant any further consideration.

Research Bid, 2016

8.32. I have been told that the Inquiry understands that the Department of Health Policy Research Programme ("PRP") put out a research call for issues relating to vCJD in 2016. The Prion Unit submitted a stage one application "*Comparative study of UK and US blood samples to determine if asymptomatic vCJD carriers are detected using a prototype test*". They were not successful in being invited to proceed to stage 2 **[WITN3093023]**. I have been asked to explain why this was.

8.33. The research call referenced above invited research proposals to help understand remaining questions on vCJD, which were a priority for health protection policy including to develop a specific and sensitive test that is able to detect pre-clinical levels of vCJD prion infection in blood or non-blood.

8.34. The Policy Research Programme's Commissioning Panel ("the Panel") commissions research across the full policy remit of DHSC. The Panel reviewed the application from the Prion Unit. The MRC Prion Unit submitted an application "*Comparative study of UK and US blood samples to determine if asymptomatic vCJD are detected using a prototype test*". **[WITN7590120]**

8.35. The Panel was unable to recommend that the Prion Unit's application proceed to stage 2.

8.36. As indicated in the research specification, the assessment criteria used by members of the Panel to assess applications for funding from the PRP included:

- Relevance of the proposed research to the research specification;
- Quality of the research design;
- Quality of the work plan and proposed management arrangements;
- Strength of the research team;
- Impact of the proposed work;
- Value for money;

- Involvement of patients and the public (where appropriate)

8.37. In assessing the application, the Panel used its professional judgement to assess the information provided in the application form. The Panel agreed that the proposal addressed an important policy priority but felt that pre-clinical work to fully and independently validate the prototype test (the DDA test) was necessary before committing significant financial resources to undertake this study. In addition, there were also some concerns about the lack of details regarding US human blood samples. The Panel also judged the Public and Patient Involvement ("PPI") to be weak, commenting that the PPI section was mainly focused on describing University College London's communications strategy. Overall, the Panel did not recommend the proposal for further consideration at stage 2 to DHSC.

8.38. More information on the stages of research applications and commissioning process is set out below:

> *'The standard NIHR PRP commissioning cycle has two stages of assessment. Outline Stage 1 applications are short-listed by a Committee which is composed of independent experts (possibly with observers from other government departments and executive agencies) who will advise the NIHR on which applications are most suitable for funding. Applications too remote from the issues set out in the research specification, or applications that have clearly inadequate presentation of methods may be rejected at this stage.*
>
> *Applications that are successfully short-listed by the Committee will usually then proceed to Stage 2 of the application process and will be invited to submit a Stage 2 full application for consideration. In certain calls a committee funding recommendation may be made based on assessment of outline (stage 1) applications, in which case funding outcomes will be communicated to applicants after a single stage of assessment.*
>
> *All full (stage 2) applications submitted to PRP will be peer-reviewed by both stakeholder and independent academic referees. Wherever time*

permits, applicants will be given one week to respond to the peer reviewers' comments.

Full applications, peer reviewers' comments and any responses to those comments will then be considered by the stage 2 assessment Committee. The Committee will be informed by the reviewers' comments and any responses made to these comments by the researchers. However, it is ultimately the responsibility of the Committee to make any funding recommendations to DHSC' **[WITN7590120]**.

8.39. DHSC accepted the Panel's independent recommendation, based (as it was) on agreed criteria. No further research proposals for prevalence studies have been commissioned.

8.40. As a result of the Panel's recommendations the following research projects were commissioned to help answer outstanding questions of significance:

PR-R17-0916-23005	Professor Bill Keevil	University of Southampton	Combined ultrasonically activated water stream and novel disinfectant for vCJD decontamination of re-usable medical instruments.	£817,076.00	01/09/2017	31/12/2022
PR-R17-0916-23001	Dr Alison Green	University of Edinburgh	Assessing and defining pre-clinical vCJD infectivity using	£1,553,441.00	01/11/2017	31/03/2024

			transmission and protein aggregation models			
PR-R17-0916-23007	Dr Jillian Cooper	Medicines and Healthcare products Regulatory Agency	Evaluation of Candidate Tests for Pre-clinical Detection of Prion Disease in Blood.	£592,627.00	01/11/2017	31/07/2021
PR-R17-0916-23006	Dr Fiona Houston	University of Edinburgh	Comparative evaluation of the performance of proposed diagnostic tests for vCJD in preclinical blood samples.	£968,046.00	01/12/2017	31/08/2021
PR-R17-0916-23002	Dr Jonathan Wadsworth	University College London	Transmission studies in humanised transgenic mice to investigate recent MV vCJD case	£737,960.00	01/05/2018	01/12/2021

PR-R17-0916-23003	Professor Simon Mead	University College London	Development of methods to retrospectively analyse fixed appendix tissue from prevalence studies	£551,099.00	01/07/2018	31/12/2020
PR-R17-0916-23004	Professor Parmjit Jat	MRC Prion Unit	Development of a cell-based bioassay to accurately measure variant Creutzfeldt-Jakob disease prions in human tissues and biofluids	£696,583.00	01/07/2018	31/03/2023

Funding of Research for subclinical vCJD screening

8.41. I have been asked whether I am aware whether there have been any successful applications made to the Department for research to be funded into subclinical vCJD screening.

8.42. The Department has previously funded the Appendix studies, including the Appendix-III study looking at the prevalence of the abnormal PrP associated with vCJD in two presumed uninfected UK populations:

- 15,000 samples of stored appendix samples collected before 1980 (before the presumed presence of BSE); and
- 15,000 appendix samples collected from patients born after 1996 after meat controls, presumed effective, were in place

8.43. In addition, the Department has providing funding towards the following research projects relevant to subclinical vCJD screening set out in Table 3 below. Table 3 sets out for each project: the project title, lead applicant organisation, project award value and contracted project dates.

Table 3: Research projects related to sub-clinical vCJD screening as commissioned by NIHR

Title	Lead applicant organisation	Award	Project dates
Assessing and defining pre-clinical vCJD infectivity using transmission and protein aggregation models	University of Edinburgh	£1,553,441	01/11/2017 - 31/03/2024
Development of methods to retrospectively analyse fixed appendix tissue from prevalence studies	University College London	£551,099	01/07/2018 - 31/12/2020
Development of a cell-based bioassay to accurately measure variant Creutzfeldt-Jakob disease prions in human tissues and biofluids	MRC Prion Unit	£696,583	01/07/2018 - 31/03/2023
Comparative evaluation of the performance of proposed diagnostic tests for vCJD in preclinical blood samples	University of Edinburgh	£968,046	01/12/2017 - 31/08/2021
Evaluation of Candidate Tests for Pre-clinical Detection of Prion Disease in Blood	Medicines and Healthcare Products Regulatory Agency	£592,627	01/11/2017 - 31/07/2021
Modelling sub-clinical vCJD infection in the UK population	The Roslin Institute	£1,130,627	01/04/2015 - 31/03/2019

8.44. In addition, the Department also received a proposal in the form of a letter of intent regarding funding for extending the project `*Surveillance for asymptomatic prion infection in primary immunodeficiency patients exposed to UK sourced immunoglobulin*' **[WITN7590122]**.

Other issues

8.45. We have been asked to exhibit all documents relevant to this written statement.

8.46. We have aimed throughout to exhibit the material that has been identified by the team and drawn on to draft this Statement, and also to make plain what we have relied upon. However, it will also be apparent from the Statement that the questions cover a vast area: see for example, the topic of the development of IPC CJD-related measures for surgical instruments in the NHS. We therefore cannot affirm that "all documents relevant to this request" have been exhibited. We suspect that aiming to do that would be positively unhelpful, given the volume of documentation that would be likely to be produced. There have also been practical constraints on the nature and scale of the searches and checks which could be conducted in the time available to draft this statement. But we would seek to work with the Inquiry if, having filed this statement with it, the Inquiry would like to explore aspects of what we have set out in further detail, or requires further documents.

8.47. We have also been asked to include any other information which has not been specifically requested above if it may assist the Inquiry and is relevant to the Terms of Reference. Whilst we are, of course, happy to respond to any further questions, the breadth of this request is such that we have not been able to evaluate what might be of assistance.

Glossary of Acronyms

ACDP	Advisory Committee on Dangerous Pathogens
ACDP TSE RA SG	Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Risk Assessment Subgroup
ACDP TSE RM SG	Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Risk Management Subgroup
ACDP TSE WG	Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Working Group
ACDP TSE	Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy
AIDS	Acquired Immunodeficiency Syndrome
BSE	Bovine Spongiform Encephalopathy
BSG	The British Society of Gastroenterology
CCDC	Communicable Disease Control
CFPP	Choice Framework for local Policy and Procedures
CJD	Creutzfeldt-Jakob Disease
CJDIP	Creutzfeldt-Jakob Disease Incident Panel
CMO	Chief Medical Officer
CNS	Central Nervous System
DCMO	Deputy Chief Medical Officer
DDA	Direct Detection Assay
DH	The Department of Health
DHSC	The Department of Health and Social Care
EASTR	Epidemiology and Survival of Transfusion Recipients
ERCP	Endoscopic Retrograde Cholangiopancreatography
ESAC-Pr	Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion removal
GLD	Government Legal Department
GPs	General Practitioners

HCAI	Healthcare Associated Infections
HPA	Health Protection Agency
HTM	Health Technical Memorandum
IBI	Infected Blood Inquiry
iCJD	Iatrogenic Creutzfeldt-Jakob Disease
IPC	Infection Prevention and Control
MCA	Medicines Control Agency
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
MSBTO	Microbiological Safety of Blood and Tissues and Organs for Transplantation
NCJDRSU	National Creutzfeldt-Jakob Disease Research and Surveillance Unit
NDS	National Decontamination Survey
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
ORC	Operational Response Centre
PHE	Public Health England
PPI	Public and Patient Involvement
PRP	Policy Research Programme
PS(L)	Private Secretary
PWG	The Prion Working Group
R9	Rule 9
RA	Risk Assessment
RRP	Rapid Review Panel
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SEAC	Spongiform Encephalopathy Advisory Committee
SSDs	Sterile Services Departments
Secondary transmission [vCJD]	Infection being passed on from person to person

The Panel	Policy Research Programme's Commissioning Panel
TSE	Transmissible Spongiform Encephalopathy
UCLH	University College London Hospital
UKHSA	UK Health Security Agency
vCJD	Variant Creutzfeldt-Jakob Disease

Statement of Truth

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

Signed:

Dated: 20 December 2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
	Section 1				
5	Undated	Causes Creutzfeldt-Jakob disease	1.10 1.13	Exhibit 1 Creutzfeldt-Jakob disease - Causes - NHS (www.nhs.uk)	WITN7590150
5	2012.11.05	Glossary of relevant medical and scientific terms	1.11	Exhibit 2 Groups and bodies (ed.ac.uk)	WITN7590002
6	1999.05.15	Codon 129 prion protein genotype and sporadic Creutzfeldt-Jakob disease	1.11	Exhibit 3 Codon 129 prion protein genotype and sporadic Creutzfeldt-Jakob disease - The Lancet	WITN7590003
6	2021.09.07	Overview of Creutzfeldt-Jakob diseases	1.11 1.12	Exhibit 4 Creutzfeldt-Jakob disease - NHS (www.nhs.uk)	WITN7590004

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
6, 8	2012.06.01	Iatrogenic Creutzfeldt - Jakob disease, Final Assessment	1.13 1.15 1.16 1.17	Exhibit 5, Iatrogenic Creutzfeldt-Jakob Disease, Final Assessment - PMC (nih.gov)	WITN7080004
7	2021.12.01	Report on the epidemiological investigation of a single BSE case in England	1.13	Exhibit 6 Report on the epidemiological investigation of a single BSE case in Somerset (publishing.service.gov.uk)	WITN7590005
	2010.12.23	Uncertainty in the Tail of the Variant Creutzfeldt - Jakob disease Epidemic in the UK	1.13 1.14	Exhibit 7 Uncertainty in the Tail of the Variant Creutzfeldt-Jakob Disease Epidemic in the UK | PLOS ONE	WITN7034008
8	Undated	vCJD Trust-Advice and Legal assistance for victims of vCJD	1.16	Exhibit 9 vCJD Trust – Advice and Legal assistance for victims of vCJD – vCJD Trust – Advice and Legal	WITN7590006

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
				assistance for victims of vCJD	
8, 18	2014.03.01	BSG guidance for decontamination of equipment for Gastrointestinal Endoscopy The Report of a working party of the British society of Gastroenterology Endoscopy committee	1.17 1.47 4.35	Exhibit 10 BSG-Decontamination-guidance-2020-update.pdf	WITN7590007
9	2021.09.01	vCJD Position Statement.2 2021.pdf	1.18	Exhibit 8	WITN7590123
11	01.01.2010	In 2010, the Government embarked on a health reform programme which included significant changes to public health responsibilities.	1.26	Exhibit 10A https://www.legislation.gov.uk/ukpga/2012/7/contents/enacted	WITN7590124
12	Undated	Article - The NIHR was established in 2006 to "create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public	1.29	Exhibit 11 Who we are - NHS Blood and Transplant (nhsbt.nhs.uk) Exhibit 11B 2010 to 2015 government policy: health and social care integration - GOV.UK (www.gov.uk)	WITN7590008 WITN7590141

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
12	Undated	After your donation – NHS blood donation	1.29	Exhibit 12 After you donate - NHS Blood Donation	WITN7590009
12	2004.12.01	The changing scene of the regulation of medicines in the UK. Paper from The Use of Medicines: Regulation & Clinical Pharmacology in the 21st Century Symposium – December 2003	1.30	Exhibit 13 The changing scene of the regulation of medicines in the UK. Paper from The Use of Medicines: Regulation & Clinical Pharmacology in the 21st Century Symposium – December 2003 - PMC (nih.gov)	WITN7590010
12	2003.04.08	Minutes of the Microbiological safety of blood and tissues for transplantation vCJD subgroup	1.30	DHSC0004526_142	DHSC0004526_142
12	2022.08.09	First written statement of June Munro Raine	1.30	WITN7135001	WITN7135001
13	Undated	What we do – NIHR – National Institute for Health and Care Research	1.31	Exhibit 14 What we do | NIHR	WITN7590125
13	Undated	Best Research for best Health: The next chapter our operational priorities	1.31	Exhibit 14B Best Research for Best Health: The Next	WITN7590011

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
				Chapter (nihr.ac.uk)	
13	Undated	Who we are – by National Institute for Health and Care Research	1.32	Exhibit 14C Who we are | NIHR	WITN7590012
13	2009.09.01	House of Lords - Science and Technology Committee - Written Evidence (parliament.uk)	1.33	Exhibit 15 https://publications.parliament.uk/pa/ld200910/ldselect/ldsctech/104/104we64.htm	WITN7590013
15	2022.04.01	Prion protein monoclonal antibody (PRN100) therapy for Creutzfeldt-Jakob disease: evolution of a first in human treatment programme	1.37	Exhibit 18 Prion protein monoclonal antibody (PRN100) therapy for Creutzfeldt–Jakob disease: evaluation of a first-in-human treatment programme - The Lancet Neurology	WITN3093004
15	1988.01.01	University College London Institute of Neurology MRC Prion Unit	1.37	Exhibit 17 University College London Institute of Neurology MRC Prion Unit |	WITN7590016

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
				Public Marketplace (scientist.com)	
15	2019.09.12	National Institute for Health and Care excellence – IP1553 Reducing the risk of transmission of CJD from surgical instruments used for interventional procedures on high-risk tissues	1.39	Exhibit 19 Interventional Procedures Guidance (nice.org.uk)	WITN7590017
16	2007.06.01	Advisory committee on the Microbiological safety of blood, tissues and for transplantation (MSBTO) Review of MSBTO and Implementation of a new committee	1.42	Exhibit 16	WITN7590014
17	Undated	Animal Disease safety and regulation re Transmissible Spongiform Encephalopathies, BSE Risk Status, Control measures in place, etc	1.43	Exhibit 20 https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/approval-of-meat-plants/animal-disease	WITN7590018
17	2003.08.01	Third annual report 2002-2003	1.44	Exhibit 16A	WITN7590015
17	2002.08.01 – 2003.08.01	CJDIP Third Annual Report to the Advisory Committee on Dangerous Pathogens Working Group on Transmissible spongiform encephalopathies	1.45		PHEN0000136
17	2003.12.15	Background and introduction of Transmissible spongiform encephalopathies (TSEs)	1.47	Exhibit 21 ~4175378.doc (publishing.service.gov.uk)	WITN7590019

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
18	2008.10.22	Annex B – Diagnostic Criteria Guidance from the Advisory Committee on Dangerous Pathogens' TSE Working Group	1.49	Exhibit 22 Annex B (publishing.service.gov.uk)	WITN7590020
	Section 2				
19	2000.11.10	Minute of the meeting of the CJD incident Panel	2.4	DHSC0020839_067	DHSC0020839_067
20	2022.05.19	Second Statement from Charles Lister	2.7	WITN4505002	WITN4505002
20	1999.03.17	Email from Gwen Skinner to Sue Shepherd re: Progress with blood	2.7	WITN4505054	WITN4505054
22	1988.04.01	New guidance to the NHS in April 1998 emphasising the importance of cleaning and sterilising instruments used on patients with suspected CJD or vCJD	2.17	Exhibit 23A Exhibit 23B	WITN7590126
22	2005.09.01	Second Circular introduced Controls Assurance for decontamination of medical devices	2.18	Exhibit 23B Page [] of Exhibit	WITN7590127
22	1999.03.03	Letter from Professor Liam Donaldson to Sir John Pattison re: vCJD and surgical instruments	2.19	Exhibit 23	WITN7590021
23	1999.03.09	Note on Ad hoc group meeting to consider vCJD and surgical instruments	2.20	Exhibit 24	WITN7590022
23	1999.07.05	Minutes of the Advisory Committee on Dangerous Pathogens (ACDP)/Spongiform Encephalopathy Advisory Committee (SEAC) - TSE Joint Working	2.21	DHSC0004747_060	DHSC0004747_060

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
		Group 12th meeting, 5 July 1999 at the Department of Health			
23	2000.09.29	Response to SEAC risk assessment 29 Sept 2000. quoted “where discrete surgical procedures can be identified as suitable for single use instruments, for example tonsillectomy, and provided patient safety would not be compromised, the Committee considered that such use should be considered wherever practicable”	2.22	Exhibit 23B Page [] of Exhibit	WITN7590127
24	2001.01.04	Decontamination and single use instruments – Jan 2001 Announcement – Associated Q&A	2.24 2.25 2.26	Exhibit 25	WITN7590023
24	2003.12.16	Letter from Liam Donaldson to PS/Secretary of State re: Variant CJD and Surgical instruments	2.26	Exhibit 28	WITN7590024
25	2003.08.18	Note from Dr Hilary Walker to CMO re VCJD and surgical instruments	2.26 2.34	Exhibit 27	WITN7590144
25	2001.01.25	Assessment concluded “surgical transmission of vCJD cannot be ruled out as a risk to public health”	2.27	DHSC0004267_014	DHSC0004267_014
25	2001.09.01	Letter from Charles Lister to Oat Troop and Lord Hunt re: CJD incidents panel: Handling of advice on vCJD implicated blood products	2.28	Exhibit 29	DHSC0038590_080
25	2002.05.02	Meetings with the Medical Device Agency (MDA) officials and DHSC officials to discuss improving the design of surgical instruments in relation to vCJD transmission	2.29	Exhibit 29B	WITN7590129

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
26	2003.06.11	Email from Martin Hall to Raman Bedi re: Dental vCJD risk assessment	2.30	Exhibit 30A Exhibit 30B Exhibit 30C	WITN7590025 WITN7590026 WITN7590027
26	2003.06.11	Note from Martin Hall to CDO and Jacky Buchan re: Publication of DH Dental CJD risk assessment	2.30	Exhibit 31	**WITN7590026**
26, 27, 50	1998.03.01	Guidance on Transmissible Spongiform Encephalopathy (TSE) agents: safe working and the prevention of infection.	2.31 2.33 4.8	ABHB0000177	ABHB0000177
27	2003.08.14	July 2003 CMO risk assessment on the risks associated with different surgical procedures and secondary transmission of vCJD	2.34	Exhibit 31B Exhibit 27	WITN7590130 WITN7590144
27	2003.12.16	Draft submission was sent from Liam Donaldson re: Variant CJD and Surgical instruments	2.35	Exhibit 32	WITN7590029
27	2004.03.01	Submission with Ministers outlining an urgent need for guidance from NICE to limit the patient safety implications of tonsillectomies in relation to vCJD transmission	2.36	Exhibit 33	WITN7590145
28	2004.09.28	Spongiform Encephalopathy Advisory Committee Draft minutes of the reserved business of the 84th meeting	2.37	Exhibit 34	DHSC0038672_045
28	2004.09.16	Letter from Mr Andrew Dillon (NICE) to Sir Liam Donaldson re: guidance for the NHS on how best to manage the risks of CJD and vCJD during surgical practice	2.38	Exhibit 35	WITN7590131

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
28	Undated	Draft for possible CMO letter to ENT surgeons, CEs and Medical directors of NHS Trusts Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob Disease (CJD) via surgical instruments	2.39	Exhibit 36	WITN7590030
28	2004.11.05	Draft note shared by Gerard Hetherington from Sir Liam Donaldson re: Request to NICE to extend its work on surgical practice guidance	2.39	Exhibit 36B Exhibit 36C	WITN7590132 (Exhibit 36B) WITN7590149 (Exhibit 36C)
29	2004.12.01	Letter from Sir Liam Donaldson to PS (L) re: Surgical instruments and vCJD	2.40	Exhibit 37	WITN7590031
29	2005.01.01	Decontamination of surgical instruments in the NHS in England update report: A step change	2.41	Exhibit 38	WITN7590032
29	Undated	The Decontamination of Surgical Instruments in the NHS in England Update report “A Step change”	2.41	Exhibit 39	WITN7590033
29	2002.01.29	Decontamination of Surgical Instruments	2.41	Exhibit 40	WITN7590034
29	2011.01.01	CJD Incidents Panel's framework document titled "Management of possible exposure to CJD through medical procedures"	2.42	WITN7091003	WITN7091003
30	2005.11.09	Appendix 1 to the submission published on 09 November 2005 is titled “Endoscopy and individuals at risk of v CJD for public health purposes”	2.43	Exhibit 41	NNUH0000009_006
30, 32	undated	Papers from MSBTO meeting in June 2007 included a 2006 Report	2.44 2.51	Exhibit 42	WITN7590035

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
31	2006.10.02	Submission to CMO from Dr Darren Hughes outlined ongoing efforts to provide guidance to the NHS on decontamination	2.46	Exhibit 44	DHSC5055167
31, 42, 78	2006.11.22	NICE guidelines Interventional procedure guidance 196 - Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures.	2.47 3.25 6.16	Exhibit 44B	SCGV0002357
31	2007.02.21	Review of Decontamination and CJD - Recommendations of the Kirkup Report	2.48 5.2	Exhibit 45	WITN7590036
32	2007.03.28	Letter from Barry Cockcroft to MS (HS), MS (PH) re: Endodontic Instruments and variant Creutzfeldt-Jakob disease (vCJD)	2.49	Exhibit 46	WITN7590037
32	2007.08.31	ESAC-Pr held a stakeholder event to share preliminary findings from a National Decontamination Survey	2.50	Exhibit 47	WITN7590134
32	2007.08.31	Summer Review for CMO September 2007 v0.2	2.50	Exhibit 48	WITN7590135
33	2008.03.03	Decontamination of surgical instruments NICE guidance - Patient safety and reduction of risk of transmission of CJD via interventional procedures	2.53	Exhibit 49	WITN7590038
33	2010.05.19	Email from Keith Morton to Peter Bennett re: IA for HTM 0101b	2.54	Exhibit 50	WITN7590039
34	2009.03.01	Guidelines produced by the ACDP TSE working group in March 2009 for pathologists and pathology laboratories for the handling of tissues from patients at risk of vCJD	2.55	Exhibit 51	WITN7590040
34	Undated	Annex B – Measures in place to reduce the risk of vCJD being transmitted via blood components	2.56	Exhibit 52	WITN7590041

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
34	Undated	Letter Mr David Pryer to Professor Dame Sally Davies re: Highly transfused patients and secondary transmission of vCJD	2.57, 4.70, 6.30, 7.5	Exhibit 53	PHEN0000608
34	1977.01.01	Sterilization Part 4: Operational management (New edition) with Part 6: Testing and validation protocols Health Technical Memorandum 2010	2.58	Exhibit 54	WITN7590042
35	Undated	Choice Framework for local Policy and Procedures 01-06 - Decontamination of flexible endoscopes: Policy and management. Version: 1.0: England	2.59	DHSC5068270	DHSC5068270
35	2020.01.22	Article re - Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues	2.60	Exhibit 55 https://www.nice.org.uk/guidance/ipg666/resources/reducing-the-risk-of-transmission-of-creutzfeldtjakob-disease-cjd-from-surgical-instruments-used-for-interventional-procedures-on-highrisk-tissues-pdf-1899874227866821	WITN7590044
35	2009.07.16	Media message - Pre-surgical assessment for vCJD risk in neurosurgery and eye surgery units	2.61	Exhibit 56	WITN7590045
	Section 3:				
37	2022.05.13	Transcript of IBI oral hearing held on 13 May 2022. Witness Professor John Collinge	3.2 3.7	INQY1000206	INQY1000206

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
37	2014.03.05	House of Commons Science and Technology Committee Oral evidence regarding investment in prion related technologies	3.2	TSTC0000045	TSTC0000045
38	2008.01.01	Draft of Department of Health Funded Research on Decontamination of Surgical Instruments: Progress Review 2008	3.6 3.8	Exhibit 57	WITN7590046
38	2007.04.25	Medical press release -New Prion Decontamination System for Surgical Instruments Presented at Sterilising Meeting	3.7	Exhibit 58	WITN7590047
38	2007.06.11	Letter from Liz Woodeson to Professor John Collinge re: Rely+On Prion Inactivator	3.8	Exhibit 59	WITN7590048
38	2016.04.01	Rapid review panel guidance and requirements for applicants	3.9	Exhibit 60 RapidReviewPanelGuidanceandRequirementsforApplicants2016.pdf (publishing.service.gov.uk)	WITN7590049
39	2003.12.01	Department of Health reports: "*Winning Ways: Working together to reduce Healthcare Associated Infection in England*" from the Chief Medical Officer, published in December 2003, and	3.12	Exhibit 61	WITN7590136
39	2004.07.01	"*Towards cleaner hospitals and lower rates of infection: A summary of action*", from July 2004	3.12	Exhibit 61B	WITN7590137
39, 43	2004.07.24	STC report: The Rapid Review Panel (RRP)	3.13 3.31 8.15	Exhibit 62 / TSTC0000052	TSTC0000052

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
		UK blood safety and the risk of variant Creutzfeldt-Jakob Disease - Science and Technology Committee			
39	2007.06.01	An overview of the UK Department of Health's Rapid Review Panel	3.14	Exhibit 63 https://www.sciencedirect.com/science/article/abs/pii/S0195670107600103	WITN7590050
40	Undated	Link - The Rapid Review Panel (RRP) assesses innovative infection prevention and control products, equipment and materials for potential use in the NHS.	3.15	Exhibit 64 Rapid Review Panel - GOV.UK (www.gov.uk)	WITN7590051
40	2014.09.01	Letterhead with fold lines (publishing.service.gov.uk)	3.15	Exhibit 65 (Letterhead with fold lines (publishing.service.gov.uk))..	WITN7590052
41	2007.01.17	Letter from Ben Cole ID&BP tp PS (L) re: Correspondence from professor John Collinge: Rely+On	3.17	Exhibit 66	WITN7590053
41	2008.01.17	Email from Ben Cole to Christopher Gush re: Du Pont	3.19	Exhibit 67	WITN7590054
41	Undated	Annex c - DuPont - Rely+On (TM) Prion Inactivator	3.19	Exhibit 68	WITN7590055

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
42	2006.11.22	NICE guidelines Interventional procedure guidance 196 - Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures.	3.25	Exhibit 68B	SCGV0002357
42	2008.08.01	Engineering & Science Advisory Committee into the Decontamination of Surgical Instruments Including Prion Removal (ESAC-Pr) New Technologies Working Group Report on Prion Inactivating Agents Published August 2008	3.26	Exhibit 69	WITN7590056
43	2011.03.29	Adsorption of prion and tissue proteins to surgical stainless steel surfaces and the efficacy of decontamination following dry and wet storage conditions	3.30	Exhibit 70	WITN7590057
44	2014.10.01	Government response to the House of Commons Science and Technology Committee Report of session 2014-15: After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease	3.32	Exhibit 71	WITN7590058
44	2008.04.23	Email chain between Christopher Gush, Mark Noterman and others discussing the RRP submission by DuPont	3.35	DHSC6711790	DHSC6711790
44	2008.04.23	Email chain between Elizabeth Woodeson, Elaine Gadd, Mark Noterman, Ailsa Wight, Christopher Gush, David Izatt, re: Collinge decontamination product, Rowena Jecock cc'd	3.35	DHSC5167558	DHSC5167558
45	2007.06.19	DuPont - Rely+On (TM) Prion Inactivator	3.36	Exhibit 72	WITN7590059
45	2008.02.15	Letter from Sir Liam Donaldson to Professor S J Thomas re: Decontamination of surgical instruments: Rely+On	3.36	Exhibit 73	WITN7590060

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
46	2020.01.22	Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues	3.39	Exhibit 74 Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues (nice.org.uk)	WITN7590061
46	Undated	Health technical memoranda	3.39	Exhibit 75 NHS England » Health technical memoranda	WITN7590062
46	2021.08.31	Health Technical Memorandum (HTM) 01-01 explains the management of decontamination and the various ways to sterilize reusable medical devices used in acute care	3.39	Exhibit 76 NHS England » (HTM 01-01) Decontamination of surgical instruments	WITN7590063
47	2016.07.01	Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care	3.39	Exhibit 77 Health Technical Memorandum 01-01. Part D: Washer-disinfectors	WITN7590064

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
				(england.nhs.uk)).	
47	2009.11.01	Annex C General principles of Decontamination and Waste Disposal	3.39 4.32	Exhibit 78 Table X – Selected guidelines and standards related to decontamination and waste disposal (publishing.service.gov.uk)	WITN7590065
	Section 4				
48, 58, 59, 60	2016.03.01	Health Technical Memorandum 01-06: Decontamination of flexible endoscopes	4.2 4.30 4.31 4.32 4.35 4.42	Exhibit 79 Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. Part A: Policy and management (england.nhs.uk)	WITN7590066
48, 49	2008.06.02	Endoscopy and individuals at risk of vCJD for public health purposes" - A consensus statement from the British Society of Gastroenterology Decontamination Working Group and the ACDP TSE Working Group Endoscopy and vCJD Subgroup	4.3 4.4	NNUH0000009_006	NNUH0000009_006

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
49	2007.01.01	Report, Endoscopy in people at risk of vCJD: from scope quarantined to access denied by MC Allison, G. Dolan	4.4	HCDO0000821	HCDO0000821
50	2017.01.01	Decontamination of flexible endoscopes – Part A: Policy and management	4.7	Exhibit 81 WHTM 01-06 Part A 2017.pdf (wales.nhs.uk)	WITN7590068
50, 52, 58, 63, 64	2015.10.01	Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex F	4.9 4.12 4.32 4.51 4.61	Exhibit 80 Annex F: Endoscopy (publishing.service.gov.uk)	WITN7590067
50	2021.08.31	Management and decontamination of flexible endoscopes	4.9	Exhibit 82 https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06/	WITN7590069
53	2011.01.01	Annex E - Quarantining of surgical instruments	4.12	Exhibit 83 Annex E (publishing.service.gov.uk)	WITN7590070
54	2007.05.01	Letter from David Harper HPIH&SD to CMO re: vCJD Endoscopes and Decontamination	4.15 4.18	Exhibit 84	WITN7590071

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
55	2008.03.31	A document titled "Decontamination of equipment for GI Endoscopy and vCJD issues – some good news at last!"	4.19	Exhibit 85	ABMU0000043
55, 56	2011.03.08	Decontamination Choice Framework for local Policy and Procedures 01-06: Reprocessing of flexible endoscopes: management and decontamination	4.20 4.23	Exhibit 86	WITN7590072
56, 57	2013.02.01	Changed guidance on the need to quarantine endoscopes following invasive gastrointestinal endoscopy in patients at risk of vCJD, includes a table containing a summary of quarantine recommendations	4.24 4.25 4.27 4.48	CVHB0000088	CVHB0000088
57	2013.03.20	Choice Framework for local Policy and Procedures 01-06 – Reprocessing of flexible endoscopes: management and decontamination (CFPP 01-06).	4.28	Exhibit 87B	DHSC5068270
58	2014.03.14	Letter from Dr Ronald Salmon to Professor Richard Knight re: Disposal of dedicated endoscopic equipment held by the National Creutzfeldt-Jakob Disease Surveillance Unit (NCJDRSU), Edinburgh for use on probable vCJD cases	4.29	Exhibit 88	WITN7590073
60	2015.02.01	Part 4 - Infection prevention and control of VJD and variant CJD in healthcare and community settings	4.41	Exhibit 89 PART 4 (publishing.service.gov.uk)	WITN7080009
61	2009.06.29	Letter from Geoffrey Ridgway to Dr Edwin Swarbrick re: Peer review of Endoscopy unit Decontamination practice	4.43	Exhibit 90	WITN7590074

INDEX SERVED 20.12.2022

Page#	Date	Description	§ in Statement	Electronic reference	Witness Number
61	[2011.03.08]	Decontamination Choice Framework for local Policy and Procedures 01-06: Reprocessing of flexible endoscopes: management and decontamination	4.44	Exhibit 91	WITN7590072
62	2006.03.01	ACDP TSE Working Group At-risk patients and negative post-mortem results	4.50	Exhibit 92	WITN7590138
62, 63	2010.05.01	Annex H final version	4.50 4.51	Exhibit 93	WITN7590075
63, 64	2007.11.19	Letter from Peter Fairclough to Dr Yimmy Chow re panel advice	4.55 4.60 4.61 4.62 4.51	NCRU000154_012Exhibit 93	NCRU0000154_012
65, 72	2007.02.21	Review of Decontamination and CJD	4.62 5.17	Exhibit 95	WITN7590077
65	2011.02.07	Advisory Committee on Decontamination Science and Technology	4.62 5.17	Exhibit 96	WITN7590078
66, 68	2017.08.01	Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex J	4.66 5.2	Exhibit 87 ANNEX J - PRE-SURGERY ASSESSMENT TO IDENTIFY PATIENTS WITH, OR AT RISK OF, CJD	WITN7080005

INDEX SERVED 20.12.2022

				(publishing.service.gov.uk)	

	Undated	Letter from Dr Pryer to Dame Sally Davies re: Highly transfusedpatients and secondary transmission of vCJD	4.70	Exhibit 96B	PHEN0000608
	Section 5				
68	2004.12.08	Letter to Dr Nicky Connor, Communicable Disease Surveillance Centre, re: and quarantine of flexible endoscope. Patient that has an endoscopy and has now been identified as being 'at risk' of vCJD	5.2 5.11	DHNI0000034_047	DHNI0000034_047
69	2007.05.01 2004.12.08	Letter from David Harper to CMO re vCJD: Endoscopes and Decontamination	5.6 5.11	Exhibit 97	WITN7590071
69	2013.08.01	Guidance for healthcare professionals on effectively decontaminating endoscopes	5.7 5.17	Exhibit 98 Top 10 tips on endoscope decontamination - GOV.UK (www.gov.uk)	WITN7590079
70	2004.06.15	Email from Sally Wellsteed to Alison Langley re: Endoscope incident in NI	5.8 5.17	Exhibit 99A Exhibit 99B Exhibit 98 Top 10 tips on endoscope decontamination	WITN7590080 (Exhibit 99A) WITN7590081 (Exhibit 99B)

INDEX SERVED 20.12.2022

				- GOV.UK (www.gov.uk)	
70, 73	2004.06.15	New release – Department stresses low risk over hospital endoscopes	5.8 5.20	Exhibit 100	WITN7590088 (Exhibit 100)
70, 73	2004.09.30	Endoscope Incidents Task Force - A collation of the incidents reported as of 30th September 2004	5.8 5.10 5.20.1 5.20.2	Exhibit 101	WITN7590082
70	2004.08.06	CMO letter re Flexible and rigid Endoscopes: Risks from inadequate decontamination	5.9	Exhibit 103B CMO Letter 16.doc (scot.nhs.uk)	WITN7590086
70	2007.11.19	Endoscope decontamination incidents in England 2003-2004	5.10	Exhibit 102 Endoscope decontamination incidents in England 2003-2004 - PubMed (nih.gov)	WITN7590083
71	2007.12.01	Endoscope decontamination incidents in England 2003–2004	5.10	Exhibit 103 Endoscope decontamination incidents in England	WITN7590085

INDEX SERVED 20.12.2022

				2003–2004 - ScienceDirect	
72	Undated 2004.08.30	Review of Decontamination and CJDQ&A on blood transfusion-associated transmission of vCJD decontamination and leucodepletion published in August 2004	5.17	Exhibit 104 DHSC0006494_078	WITN7590087
72	2004.06.15	New Release on department stresses low risk over hospital endoscopes	5.20.1	Exhibit 105	WITN7590088
	Section 6				
74, 88	2014.11.13	PHE update to the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Meeting 13th November 2014	6.2 7.11	Exhibit 106	WITN7590089
74	2005.09.05	Draft summary note of DH/HPA liaison meeting	6.3	Exhibit 107	WITN7590091
74	2006.11.17	Email from Neil Ebenezer to David Pryer re: Highly transfused patients and HPA/DH liaison committee	6.3	Exhibit 108	WITN7590092
74	2015.10.01	Public health action following a report of a new case of CJD or a person at increased risk of CJD	6.3	Exhibit 109 Untitled (publishing.service.gov.uk)	WITN7590093
74	2018.07.01	Information for people who have an increased risk of Creutzfeldt-Jakob disease (CJD)	6.3	Exhibit 110	WITN0672092

INDEX SERVED 20.12.2022

				Information for people who have an increased risk of Creutzfeldt-Jakob disease (CJD) (publishing.service.gov.uk))	
74	2013.07.01	Monitoring of people at increased risk of Creutzfeldt - Jakob disease Biannual Report	6.3	Exhibit 111	WITN7590094
75	2022.06.21	Research and analysis Creutzfeldt-Jakob disease (CJD) surveillance: biannual updates	6.3	Exhibit 112	WITN7590095
75	2006.06.16	The Meeting of Clinical governance advisory Group (CGAG) Chairman PackResearch and analysis	6.4	Exhibit 113A Exhibit 113B	WITN7590096 (Exhibit 113A) WITN7590097 (Exhibit 113B)
75	2007.06.01	Leaflet re: Variant Creutzfeldt-Jakob disease (vCJD) and repeated blood treatment	6.5	Exhibit 114	WITN7590098
75	Undated	Information for medical staff Variant Creutzfeldt-Jakob disease (vCJD) and treatment with blood or blood	6.5	Exhibit 116	WITN7590100

INDEX SERVED 20.12.2022

		products from 80 or more donors Information for medical staff			
75	Undated	Information for patients vCJD and repeated blood treatment	6.5	Exhibit 117	WITN7590101
75	2011.07.27	Email from Ailsa Wight to Peter Bennett re: vCJD and multiply transfused patients	6.7	Exhibit 118	DHSC5043608
76	2007.06.01	Information for medical staff re: Variant Creutzfeldt-Jakob disease (vCJD) and treatment with blood from 80 or more donors	6.7	Exhibit 115 Exhibit 114	WITN7590099
75	Undated	Letter from Dr Sara Trompeter re: Bovine spongiform encephalopathy (BSE)	6.7	Exhibit 119	WITN7590102
76	2006.06.25	Submission from Ailsa Wight to CMO and SoS re: vCJD and plasma products: update on patient notification	6.10	Exhibit 119B	WITN7590084
77	2005.07.25	The risk of secondary vCJD infection of patients receiving a high number of blood transfusions	6.11 6.12	Exhibit 121	JPAC0000051_026
77, 78	2008.04.16	Submission from Mark Noterman to CMO re: Highly Transfused patients and vCJD	6.13 6.15	Exhibit 122	WITN7590103
77	2008.01.24	CJD Incidents Panel Public Summary of the 23rd meeting	6.14	Exhibit 123	WITN7590104

INDEX SERVED 20.12.2022

79, 80, 81	2008.05.14	Minutes of the 24th meeting of the CJD Incidents Panel	6.17, 6.23, 6.29	PHEN0000531 Exhibit 123	PHEN0000531
79, 81	2009.02.05	CJD Incidents Panel and ACDP TSE Working Group highly transfused implementation subgroup meeting	6.22 6.27 6.33	NCRU0000152_ 060	NCRU0000152_060
80	2009.12.01	CJD Incidents Panel ('CJDIP') Ninth Annual Report 1st January to 31st December 2009 to Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathies Working Group	6.23	PHEN0000142	PHEN0000142
80	2008.10.29 2008.04.23	Email from Mr Noterman, DoH, to Professor David Harper DoH re CJD Incidents Panel –highly transfused – letter to CMO Letter from Sir Liam Donadlson to Mr David Pryer, CJD Incidents Panel, re highly transufed patients and secondary transmission of vCJD	6.24 6.24	WITN7590151 Exhibit 123D	WITN7590151 (123D -) NCRU0000169_039
81	2008.11.01	Recommendations were approved by CMO (Sir Liam Donaldson) in October 2008	6.26	Exhibit 123C Exhibit 123D	(123C) WITN7590146
82, 84, 86	2012.04.26	Letter from Dr Pryer to the CMO (Dame Sally Davies) dated 26 April 2012	6.30 6.41 7.5	Exhibit 125	PHEN0000608
82	Undated	First meeting of CGAGLetter from Dr Pryer to the CMO (Dame Sally Davies) dated 26 April 2012	6.35	Exhibit 126	WITN7590106
82, 85	2013.07.01	A report on the potential impact on services and patients of a proposal to identify and notify patients with 300 or more donor exposures that they are at increased risk of variant CJD for public health purposes	6.36 6.45	Exhibit 127	WITN7590107

INDEX SERVED 20.12.2022

83	2013.07.01	Guidance on the interaction with patients A report on the potential impact on services and patients of a proposal to identify and notify patients with 300 or more donor exposures that they are at increased risk of variant CJD for public health purposes	6.39	Exhibit 127B	NCRU0000152_059
	Section 7				
86	2011.06.24	Draft – Blood – Borne transmission of vCJD: Re-examination of scenarios	7.4	Exhibit 128	RLIT0001005
87	2012.08.09	Minute from Mark Noterman to CMO Re: CMOPO00699418 (PO80 2012)	7.6	Exhibit 128B	WITN7590140
87	2012.08.09	Letter from Professor Dame Sally Davies re: Highly transfused patients and secondary transmission of vCJD)	7.7	Exhibit 129	WITN7590108
87	2022.06.21	Research and analysis Creutzfeldt-Jakob disease (CJD) surveillance: biannual updates	7.10	Exhibit 130 Creutzfeldt-Jakob disease (CJD) surveillance: biannual updates - GOV.UK (www.gov.uk) Exhibit 129	WITN7590095
88	2014.11.13	ACDP TSE Public Health England Update meeting 13 November 2014	7.11	WITN7590089	WITN7590089

INDEX SERVED 20.12.2022

88, 89	2014	Draft letter from Public Health England to unnamed re Patient at risk of VCJD due to receipt of blood from a large number of UK donors	7.13 7.15	WITN7091009 Exhibit 130B	WITN7091009
	Section 8				
90		MRC - part of UK Research and Innovation ("UKRI"), is the Government's main biomedical research funding agency	8.3	Exhibit 131 Medical Research Council - GOV.UK (www.gov.uk)	WITN7590109
91		MRC use of variety of funding models to support UK science	8.4	Exhibit 132 Types of funding we offer – MRC – UKRI	WITN7590110
92	2013.07.01	Research award - The Development of an Effective Treatment for Prion Infection of Humans	8.6	Exhibit 133 The Development of an Effective Treatment for Prion Infection of Humans - NIHR Funding and Awards	WITN7590111
93	2013.11.27	Transcript of the "Oral Evidence: variant Creutzfeldt-Jakob Disease (vCJD), HC 846" from witnesses Professor James Ironside, Dr Roland Salmon and Professor John Collinge.	8.9	TSTC0000051Exhibit 133	TSTC0000051

INDEX SERVED 20.12.2022

94	2011.04.08	Letter dated 8 April 2011 from the CMO, Dame Sally Davis, to Professor Collinge dated 8 April 2011. She noted the public health interest and importance attached to having available for the NHS, an effective decontaminant for prions to use for surgical instruments and an effective, both sensitive and specific, blood test for screening blood donors and potential patients	8.11 8.12	WITN3093007Exhibit 133B	WITN3093007
94	2011.02.05	Lancet Article re - Detection of prion infection in variant Creutzfeldt-Jakob disease: a blood-based assay Julie Ann Edgeworth, Michael Farmer, Anita Sicilia, Paul Tavares, Jonathan Beck, Tracy Campbell, Jessica Lowe, Simon Mead, Peter Rudge, John Collinge, Graham S Jackson	8.11	NHBT0033626W	NHBT0033626
95	2014.07.16	House of Commons Science and Technology Committee After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease Second Report of Session 2014-15	8.15	TSTC0000052	TSTC0000052
98	2014.10.17	Policy paper - UK blood safety and the risk of variant Creutzfeldt-Jakob disease	8.21	Exhibit 133C UK blood safety and the risk of varient Creutzfeldt-Jakob disease - GOV.UK (www.gov.uk)	WITN7590148
98	2016.08.01	ACDP's updated position statement on occurrence of infection in the UKAppendix II study	8.22	Exhibit 134 ACDP's August 2016 Updated position statement on occurrence of vCJD and prevalence of infection in the UK .pdf | Powered by Box Exhibit 133D	WITN7080006

INDEX SERVED 20.12.2022

99	2020.03.30	Prevalence in Britain of abnormal prion protein in human appendices before and after exposure to the cattle BSE epizootic	8.24	Exhibit 135 https://pubmed.ncbi.nlm.nih.gov/32232565/	RLIT0000725
100	2016.09.29	Advisory committee on dangerous pathogens Transmissible Spongiform Encephalopathy Sub Group The 12th meeting of the ACDP TSE SG held on 29' September 2016	8.29	PHEN0002461	PHEN0002461
101	2016	Submission of a stage one application "Comparative study of UK and US blood samples to determine if asymptomatic vCJD carriers are detected using a prototype test	8.32	WITN3093023 Exhibit 133C	WITN3093023
101, 103	2021.04.08	Policy research programme – Standard Information for Applicants Policy research programmer by National	8.34, 8.38	Exhibit 138 Policy Research Programme - Standard Information for Applicants | NIHR	WITN7590120
106	Undated	Letter to Dr Elaine Gadd, Deputy Director, Policy Research Programme	8.44	Exhibit 139 'PRES-DS13-00151634' Exhibit 138C	WITN7590122

INDEX SERVED 20.12.2022