Witness Name: Dr Katy Sinka
Statement No.: WITN7080001
Exhibits: WITN7080002 – WITN708010
Dated: 29th April 2022

INFECTED BLOOD INQUIRY

# SECOND WRITTEN STATEMENT OF DR KATY SINKA

## Section 1: Contents


Contents 1

Section 1: 1

Section 2: 7

Section 3: 9

Section 4: 12

Section 5: 14

Section 6: 15

## Section 1: Introduction

1. My name is Katherine (Katy) Sinka, BSc MSc PhD. My date of birth is GRO-C GRO-C. My professional address is UK Health Security Agency (UKHSA), 61 Colindale Avenue, London, NW9 5EQ. I have a BSc in Geography from the University of Nottingham (1989), a PhD in Environmental Sciences from the University of East Anglia (1993), and an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine (2002). I am a member of the faculty of public health (since 2017). I was registered with the Health and Care Professions Council between 2005 and 2021 and am currently registered as a public health specialist regulated by the UK Public Health Register (since 2020).

2. The following table outlines my employment history:

**Table A – Employment History**

| | |
|---|---|
| December 2020 to present | Head of STI section, Blood Safety, Hepatitis, Sexually Transmitted Infections and HIV, National Infection Service, Public Health England (including from April 2021 – joint post as interim deputy director for Blood Safety, Hepatitis, Sexually Transmitted infections and HIV Division, UK Health Security Agency (formerly Public Health England) |
| June 2012 to December 2020 | CJD section head and consultant scientist (Epidemiology) in HIV & STI, National Infection Service, Public Health England |
| July 2007 to May 2012 | Epidemiologist lead (NHS grade 8c), Childhood Immunisation, NHS Health Protection Scotland, Glasgow |
| May 2006 to July 2007 | Information Expert – United Nations Office for the Coordination of Humanitarian Affairs (UN-OCHA), Jerusalem |
| January to December 2006 | (Consultancy) Research Specialist, Hanan Maternal Child Health & Nutrition project in the West Bank & Gaza, John Snow International/USAID |
| July 1997 to August 2005 | Senior Scientist (Epidemiology), Health Protection Agency, Centre for Infections, London |
| December 1996 to June 1997 | Temporary employment via an agency with the Office of the Rail Regulator |

| | |
|---|---|
| September 1996 to November 1996 | The London School of Hygiene and Tropical Medicine – short term contract |
| October 1993 to August 1996 | KATHARINE SINKA<br>Employment:<br>July 1997 to Present<br>PHLS, Communicable Disease Surveillance Centre, HIV & AIDS Reporting Section.<br>Currently a senior scientist co-ordinating the national survey of prevalent diagnosed HIV<br>infection (SOPHID) and taking the lead role on HIV associated with sub-Saharan Africa<br>diagnosed in the UK. I work with a small team to undertake the daily running of the<br>SOPHID survey – this involves liaising with clinicians and HIV commissioners; and dealing<br>with queries by phone. Other duties include undertaking analysis for ad hoc queries;<br>contributing both analysis and text to articles in the Communicable Disease Report;<br>presenting surveillance data to varied audiences; acting in an advisory role – most recently<br>for two groups drawing up framework documents for work with African communities<br>(National AIDS Trust, African HIV Policy Network) and for a working group determining the<br>allocation of care funds (Dept Health – AIDS support grant)<br>April 1999 to July 1999<br>The Population Council. Short voluntary overseas post in Nairobi, Kenya working on the<br>Horizons program for operations research into HIV and AIDS<br>December 1996 to June 1997<br>The Office of the Rail Regulator. Working on general office and administrative duties<br>concerning the regulation of passenger rail networks. A very useful training in<br>administrative procedures.<br>September 1996 to November 1996<br>The London School of Hygiene and Tropical Medicine. A research fellow working on a<br>short contract to develop a proposal to study the potential climate change impacts of global<br>warming on vector-borne diseases in Europe.<br>October 1993 to August 1996<br>School of Environmental Sciences, University of East Anglia. A Postdoctoral Research<br>Fellow |

| | |
|---|---|
| | School of Environmental Sciences, University of East Anglia, Postdoctoral Research Fellow |

3. Between July 2012 and March 2013 (when the Panel was abolished) I was the scientific secretary to the CJD Incidents Panel. The secretariat to the Panel was provided by the Health Protection Agency. After this I continued to support CJD related public health work within Public Health England's National Infection Service including: support for the Transmissible Spongiform Encephalopathies (TSE) expert groups; working with stakeholders on production of guidelines and supporting materials; enhanced surveillance (public health follow-up) of individuals at increased risk of CJD as a result of healthcare exposures; and CJD notification exercises and research. Following the closure of the Advisory Committee on Dangerous Pathogens (ACDP) TSE subgroup in February 2019, I continue to oversee the enhanced surveillance and provide advice on the public health guidance, but this now comprises a small part of my current role.

**Evidence to the House of Commons Science and Technology Committee**

4. I gave evidence to the House of Commons Science and Technology Committee inquiry into Blood, Tissue and Organ screening on the 30 April 2014. This was in response to questions about how the risks of prion transmission via surgery are minimised both generally and specifically – including infection control guidance, and instrument traceability. Measures include guidance published by NICE (National Institute for Health and Care Excellence) which applies to surgery within the population in general and the ACDP guidance which is specific to those with or at risk of CJD.

5. Since giving this evidence the NICE guidance has been reviewed and revised – and no longer requires that separate neurosurgical instrument sets are established and maintained for individuals born after 1996. 1996 is the date

considered as a reasonable estimate for the population who would have been unexposed to a risk of variant CJD through diet.

6. The revised NICE guidance also places further emphasis on keeping instruments moist post-use and pre-decontamination, which has been shown to be an effective measure to ensure that proteins (of any kind) deposited on instrument surfaces are more readily removable.

7. The Committee asked about the process of notifying individuals who have been identified as being at risk of classical or variant CJD, as a result of their healthcare; of providing them with support; and the process of establishing whether individuals at risk who may develop dementia later in life can be identified as having developed CJD rather than another condition, in particular in regard to the limited conduct of post mortems. The processes for notifying individuals at risk of CJD remains similar to those established by the CJD Incidents Panel, although new notifications are now rare, and only occur in the context of CJD surgical incidents. It remains the case that there have been no identified surgical transmissions of variant CJD and no recent transmissions of any other type of CJD or prion disease through surgery since the four cases of transmission linked to neurosurgical instruments which have been documented from the 1950s and1960s and the two cases of transmission linked to use of stereotactic EEG needles in the mid-1970s.

**Other Inquiries**

8. Aside from the evidence provided to this Committee I have not provided evidence to any other inquiry or investigation, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

**Dissemination of Information regarding vCJD**

9. The early understanding of the potential transmission of vCJD via blood or blood products and the risk assessments in relation to this potential were undertaken several years before I took up my role as the CJD Incidents Panel scientific secretary in 2012 and before I worked in the area of CJD public health. I was not involved in the major activities to inform or educate the medical profession or patients of the risks of vCJD transmission via blood and blood products and through receipt of UK produced plasma products which occurred around 2003-04.

10. Following this risk assessment exercise, by the end of December 2004, an estimated 4,000 patients with bleeding disorders and a further 12 patients with other conditions that had been treated using plasma products had been considered 'at-risk' of vCJD for public health purposes and had been informed of this.

11. The background, rationale and process followed for this notification exercise is described in the report [PHEN0000721]. The consideration and discussion that led to the notification exercise can be found in the papers and records from the CJD Incidents Panel Technical Subgroup to discuss blood product issues 21 April 2004 [PHEN0000504] and the papers and records from the CJD Incidents Panel Meeting of May 2004 (12th meeting) [PHEN0000502]. These were provided to the Inquiry in 2019.

12. In 2012, I undertook work to consider whether and how the revised risk assessment for vCJD transmission through blood [RLIT0001005] would affect the risk assessment that had been conducted for UK produced plasma products in 2003-2004.

## Section 2: Notification exercises

13. In 2011, a re-examination of blood borne transmission of vCJD was undertaken. Three specific parameters were modified in light of new evidence:

    (a) A hundred-fold reduced estimate of infectivity per unit of non-leucodepleted blood – a reduction in the risk

    (b) Confirmation, and more precise estimates, of asymptomatic population prevalence of abnormal prion protein (1 in 2,000) – and the precautionary assumption that this figure translates to a prevalence of potentially infective blood donors – an increase in the risk.

    (c) A smaller window of time that blood donations in general could have been infectious (now 1990 to 2001 instead of 1980 to 2001)– a reduction in the risk.

14. These changes to the parameters were considered and accepted by the ACDP TSE Risk Assessment Subgroup (ACDP TSE RA SG).

15. These modifications were also relevant to the risk assessment for those who had received UK sourced plasma products, who had been notified of an increased risk of vCJD in 2003-2004.

16. Using similar risk assessment parameters to those that had been used in the 2003-04 exercise the new evidence outlined above was considered to see whether this would change the advice for plasma product recipients who had been designated as at increased risk of vCJD for public health purposes.

17. The revisions did not change the risk assessment for some products, specifically Factor VIII and Factor IX. For most recipients there was no change in the at increased risk status.

18. The reduced window period of exposure did have an effect. It was recommended that notified patients who only received plasma products outside of the new window period (i.e. during 1980 to 1989 but not during 1990 to 2001) should have their treatment history re-assessed to confirm this, and if it was confirmed they should be de-notified.

19. The UK Haemophilia Centres Doctors Organisation (UKHCDO)'s National Haemophilia Database which holds a record of the plasma product treatment history indicated that this change applied to up to 560 individuals. It included individuals with different types of bleeding disorders, among them people with milder disease who received plasma products infrequently.

20. The UKHCDO contacted the haemophilia centres for these individuals to confirm the treatment history and to trace and contact patients and let them know the update so far as records permitted.

21. I worked with the UKHCDO with help from the Haemophilia Society to draft the content of a letter to be sent to patients explaining the change [DHSC5292488].

22. The UKHCDO reported that the process of informing the patients was difficult to verify, but around 300 individuals were eventually traced and informed of the change [WITN7080007].

23. I cannot comment on any considerations of the ethical issues that were made as my involvement in the process largely concerned communicating the rationale behind the changed risk assessment and I was not involved in

discussions concerning provision of any psychological support to those individuals who were de-notified.

## Section 3: Infection Control Measures

24. In June 2012 new guidance on decontamination of flexible endoscopes was published. The document was entitled "CFPP 01-06 Decontamination of flexible endoscopes" and is exhibited to my witness statement [DHSC5068270].

25. The process that led to this change occurred before I started my role within CJD public health. I was involved in updating the guidance documents that were affected by the change and helping to ensure that they were consistent with each other, in particular the following two documents (also exhibited to this statement):

(1) **The ACDP's Annex F: Endoscopy guidance** – which concerns infection control where endoscopes are to be used for patients with or at risk of CJD, variant CJD or other prion diseases [WITN7080008];

(2) **CFPP 01-06 Choice Framework for local Policy and Procedures 01-06 Decontamination of flexible endoscopes** (since renamed Health Technical Memorandum (HTM) 01-06) – which concerns management and decontamination of flexible endoscopes generally and includes a section about Human prion diseases (including variant CJD and other forms of CJD) in Part A: Part A – Policy and management (Part A being the first of 5 parts) [DHSC5068270].

26. A meeting on the 20th September 2012 recorded a discussion on aligning these two guidance documents [WITN7080010].

27. Following the publication of CFPP 01-06, the guidance changed such that a single cycle of verifiable decontamination to the approved standard was recommended for flexible endoscopes in most circumstances.

28. Special precautions, including the removal of an endoscope from general use, should continue for:

(1) Symptomatic patients with confirmed, probable or possible vCJD, and possible sporadic cases, where vCJD has yet to be ruled out. (NB. There have been very few individuals who fall into this group since the incidence of variant CJD has reduced to very small numbers (0 cases in recent years) [WITN7080003].

(2) The sub-group of asymptomatic patients at increased risk who are considered to be most at risk ("presumed infected") – there are less than 20 individuals alive who fall into this group. These are the recipients of blood from a donor who later died from vCJD. Please refer to the first row in Table 1, Section 6 below. Also see Exhibit WITN7080003 which is the NCJDRSU monthly report. These figures are published monthly but present CJD statistics as annual figures. The figures in the latest years are subject to change as the most recent year is partial and previous years may increase as delayed reports are received.

(3) For other asymptomatic "at increased risk" for vCJD patient groups, including those who have received UK manufactured plasma products (1990 and 2001), a single cycle to the approved standard would suffice.

29. Currently the pre-surgical assessment guidance "Annex J" [WITN7080005] requires that all patients 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 answers "yes" then they will be asked to explain further the reason they were notified. Special infection prevention and control precautions should be taken for all surgery or endoscopy involving contact with medium or high infectivity tissues. Tissues assumed or proven to have high level infectivity for CJD or vCJD are:

(1) Brain

(2) Spinal cord

(3) Implanted dura mater grafts prior to 1992

(4) Cranial nerves

(5) Cranial nerve ganglia

(6) Posterior eye

(7) Pituitary gland

30. Tissues assumed or proven to have medium levels of infectivity for CJD or vCJD are:

(1) Olfactory epithelium

(2) Spinal ganglia

31. In addition to this, for vCJD only:

(1) Tonsil

(2) Appendix

(3) Spleen

(4) Thymus Adrenal gland

(5) Lymph nodes

(6) Gut associated lymphoid tissues

32. The pre-surgical guidance signposts to the guidance at Annex F and CFPP 0106 for procedures that involve endoscopy. Also see Part 4 TSE guidance: infection control [WITN7080009].

33. Patients that have been "de-notified" would no longer be considered at increased risk of CJD or vCJD for the purposes of the pre-surgical assessment.

34. The 2021 vCJD update that re-introduces the use of UK plasma has not (to my knowledge) been considered as to whether it has a consequential effect on the risk assessment for historical recipients of UK sourced plasma products.

## Section 4: Surveillance

### Recording cause of death (including from vCJD)

35. The UKHSA (and its predecessors) undertake long term follow-up of 550 individuals who have been exposed to an increased risk of CJD or vCJD through their healthcare, 346 were alive at the end of 2020. These individuals are summarised in the first 6 rows of Table 1 in section 6 beneath. The figures include 106 individuals exposed to an increased risk through receipt of blood or blood products, 29 of whom were alive at the end of 2020 (rows 1,3, 4 and 6 in table 1, section 6 beneath).

36. The number of individuals being followed up by UKHSA has increased slightly since 2014 as a result of a small number of CJD surgical incidents, none relating to variant CJD.

37. For a small number of individuals, who had received a blood transfusion from a donor who later died from vCJD, a semi-regular process of clinical follow-up via their general practitioners occurred to identify the development of any neurological symptoms that could be related to CJD. This was often done in

conjunction with correspondence providing an update on significant developments such as the identification of further cases of vCJD transmitted via blood transfusion. This follow up was last done in 2016.

38. For most patients that are followed up by UKHSA –the main process of ascertaining cause of death is by cross-reference to official mortality records to provide the fact and cause of death. This may not detect instances where individuals have died from or with variant CJD without symptoms or with symptoms that are classified and recorded as another condition. However, any clinical cases of variant CJD or other forms of prion disease would most likely be detected by the continued surveillance undertaken by the National CJD Research and Surveillance Unit (NCJDRSU) in Edinburgh or referral to the National Prion Clinic in London. NCJDRSU publishes monthly updates of their surveillance figures [WITN7080003].

39. Those who were treated for bleeding disorders and who received UK sourced plasma products between 1990 and 2001 are followed up by the UKHCDO (2,671 individuals were in this group at the end of 2020). This is taken from Table 1, at Section 6 below. These individuals are those who are alive and notified from a total of 3,636 individuals who received UK sourced plasma products between 1990 and 2001. This total figure was originally larger, at around 4,000 individuals, when it included individuals who only received UK sourced plasma products between 1980 and 1989 (see paragraph 18 above).

40. Figures concerning individuals at risk of vCJD or CJD are monitored by the UKHSA and Public Health Scotland; and at risk of vCJD are monitored by the UKHCDO, totalling 6,069 individuals. These are combined and published in the UKHSA Health Protection Report, including Table 1. There were 4,465 individuals from this total number who were alive and notified when the figures were most recently published in April 2021 [WITN0672091].

41. I am not aware of any other organisations that monitor individuals who are at risk of vCJD via secondary transmission through blood and blood products.

## Section 5: Prevalence and Scale of Exposure

42. I am familiar with the studies that were done to try to establish the prevalence of variant CJD in the general population, consequent to the widespread exposure to BSE contaminated beef, from an unknown start date (in or before the early 1980s) continuing throughout the 1980s and to the mid-1990s.

43. These studies have detected the presence of abnormal prion deposits in the appendix tissues of a sample of the population in the range of 1 in 2,000 to 1 in 5,000, see exhibits ACDP position papers 2012 [PHEN0000614] and 2016 [WITN7080006]. There is a marked divergence (amounting to tens of thousands) between these estimates which could represent asymptomatic or pre-symptomatic prevalence and the clinical cases that have been seen.

44. Of the 178 people who have been diagnosed with and died from variant CJD, in the UK, 175 are presumed infected from contaminated beef and three became infected following a blood transfusion (from a donor who later died from vCJD) (See 1) Table below at Section 6, titled "Table 1. Summary of all 'at increased risk' groups on which data are collected (data correct as of 31 December 2020)", and 2) TMER timeline) [WITN7080002]. The evidence indicates that the measures put in place to prevent new infections in cattle, to prevent infective materials from entering the food chain, and to protect the blood supply have been successful in preventing further transmission or at least vastly reducing the scale.

45. It is not certain whether there remain further asymptomatic or pre-symptomatic individuals who may yet develop disease or who could transmit prion infection without having symptoms. The lack of further variant CJD cases related to

either dietary exposure of linked to a blood transfusion or treatment with blood or plasma products and the increasing time span without these is reassuring.

46. A major source of uncertainly stems from previous experience with healthcare exposures to prions, which show that the incubation periods for a transmitted prion infection to become apparent usually span years and often decades, see exhibit "Brown final assessment [WITN7080004] and the NCJDRSU surveillance tables" [WITN7080003].

## Section 6: Statistics

47. The most recent summary of individuals who are at a higher risk of vCJD is included in the "HPR report published in April 2021" exhibited to this statement. The two groups in greyed font are not at risk of variant CJD but have been exposed to an increased risk of sporadic (or classical) CJD through their healthcare: recipients of human derived growth hormone and certain surgical contacts of patients diagnosed with CJD.

**Table 1. Summary of all 'at increased risk' groups on which data are collected (data correct as of 31 December 2020)**

| 'At increased risk' Group | Identified as 'at increased risk' | Number notified | | Cases | Asymptomatic infections[a] |
|---|---|---|---|---|---|
| | | All | Alive | | |
| Recipients of blood from donors who later developed vCJD | 67 | 27 | 13 | 3 | 1 |
| Blood donors to individuals who later developed vCJD | 112 | 108 | 100 | 0 | 0 |
| Other recipients of blood components from these donors | 34 | 32 | 13 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| Plasma product recipients (non-bleeding disorders) who received UK sourced plasma products 1990 to 2001 | 2 | 2 | 2 | 0 | 0 |
| Certain surgical contacts of patients diagnosed with CJD | 332 | 277 | 217 | 0 | 0 |
| Highly transfused recipients | 3 | 3 | 1 | 0 | 0 |
| **Total for 'at increased risk' groups where PHE holds data** | **550** | **449** | **346** | **3** | **1** |
| Patients with bleeding disorders who received UK sourced plasma products 1980 to 2001[b,e] | 3,636 | 3,275[c] | 2,671 | 0 | 1 |
| Recipients of human derived growth hormone[b] | 1,883 | 1,883 | 1,448[d] | 82 | 0 |
| **Total for all 'at increased risk' groups** | **6,069** | **5,607** | **4,465** | **85** | **2** |

a. An asymptomatic infection is when an individual does not exhibit any of the signs and symptoms of CJD in life but abnormal prion protein indicative of CJD infection has been found in tissue obtained at post mortem.

b. These are minimum figures. Central reporting for bleeding disorder patients is incomplete, and a small number of patients have opted out of the central UKHCDO database. A small number of 'at increased risk' growth hormone recipients are not included in the Institute of Child Health study. Not all of the 'at increased risk' growth hormone recipients have been notified. There is no central record of who has been informed.

c. These are the minimum number of people notified based on those patients who were seen for care after the notification exercise. It is likely that many more of the 'at increased risk' patients received their notification letter but as they were not subsequently recorded as being seen for care this cannot be confirmed.

d. Data is correct as of 31 December 2016. Information on non-CJD related deaths is currently not available.

e. Including a small proportion of individuals known to have been treated with UK plasma products 1980 to 2001, and presumed to have been treated 1990 to 2001.

## Statement of Truth

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

Signed.. GRO-C .....

Dated.....29th April 2022.....