

Witness Name: Professor Sheila M. Bird

Statement No.: WITN7586001

Exhibits: WITN7586002-003

Dated: 8 December 2022

## **INFECTED BLOOD INQUIRY**

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### **WRITTEN STATEMENT OF PROFESSOR SHEILA BIRD**

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I, Sheila Macdonald Bird, will say as follows:

#### **Section 1: Introduction**

1. I am an Honorary Professor at the University of Edinburgh and former Programme Leader at the Medical Research Council (MRC) Biostatistics Unit, Cambridge. I led the MRC Biostatistical Initiative in support of AIDS/HIV Studies in Scotland. Over the course of my career, I have championed the use of statistical methods in evaluating public policies. I have also worked on UK dietary exposure to BSE, on the design and interpretation of surveillance studies for abnormal prion protein and on the late sequelae of injection-related Hepatitis C virus infection.
2. I am one of the experts who was appointed to the Statistics Expert Group to advise the Chair of the Infected Blood Inquiry. I contributed to compiling the Statistics Expert Group report which was published in September 2022 [EXPG0000049] and I gave evidence as part of the Statistics Expert Group's panel hearing on Wednesday 9<sup>th</sup> November 2022.

## **Section 2: Purpose of this statement**

3. I provide this witness statement to present research and findings that I believe to be relevant to the Terms of Reference of the Inquiry, which are in addition to the Statistics Expert Group report. In particular, I present two reports which I exhibit as WITN7586002 and WITN7586003.
4. The Infected Blood Inquiry lacked relevant information on the survival-status to 31 December 2019 for those who had received a transfusion or had been treated with blood products in the UK. The Scottish National Blood Transfusion Service (SNBTS) and UK Haemophilia Centre Doctors' Organization (UKHCDO) facilitated the record-linkage and research that helped me, with others whom I acknowledge, to write the aforementioned reports.
5. The first of these short reports, WITN7568002, concerns the survivorship during 1992-2019 of a well-defined subset of 6,282 patients with a bleeding disorder, namely: those whose sex and age were known, who were born before 1992, first treated in the UK before 1992 (or for whom date of first treatment is missing), were alive at 1 January 1992 and were HIV -infected or HCV-tested or were known to have been at-risk because exposed to components pre-1992 and/or to pooled plasma pre-1988. In particular, having allowed for sex, age-band and bleeding disorder, attention focused on the hazard-ratio for all-cause mortality in three distinct epochs of follow-up (1992-1999; 2000-2009; and 2010-2019) for those who were HIV/HCV co-infected (versus HIV uninfected); and, in 2010-2019, for those who had tested HCV-antibody-positive (versus at-risk but HIV-uninfected and HCV-status unknown). Please see paragraphs 8 and 9 for further detail.
6. The second short report, with SNBTS and associated hospitals in the east and north of Scotland (WITN7568003), analysed how demography, transfusion-aspects and recipients' International Classification of Disease version 10 (ICD10) discharge-code at their index transfusion influenced the immediate (1<sup>st</sup> 4-weeks) through to longer-term (2<sup>nd</sup> decade post-transfusion) survivorship of

recipients of red blood cell (RBC) transfusion in SNBTS's 1999-RBC and 2004-RBC cohorts. Each cohort comprised over 13,000 RBC recipients.

### **Section 3: Reports based on Record Linkage**

7. Record linkage is the term used by statisticians, epidemiologists and others for the task of finding or producing a data set that joins up or matches records that refer to the same entity or person, from across a range of data sources. In this case, we are relying on existing data-bases about patients (SNBTS and NHD respectively) for whom sufficient identifying information is made available in confidence to National Records of Scotland (in the case of SNBTS) or other death-registers to enable the register to identify if the patient has died; and, if so, to provide the death-date and ICD10 cause of death. In all cases, the data we analysed were anonymised: in particular, the research-team did not have access to personal identifying information such as Community Health index number in Scotland or NHS number.

#### **3.1: Report on National Haemophilia Database record linkage and clinical consensus on cause of death:**

8. The Statistics Expert Group's report relied in part on a 'slimmed' National Haemophilia Database (sNHD), which is a slimmed version of the National Haemophilia Database which gave access to limited data-fields and was anonymised for analysis. The version of sNHD which SEG relied on pertained to 37,041 patients, including 7,078 deaths prior to 2020. However, since the SEG report was completed, an updated version of sNHD - sNHD3 - was created, and shared with the research-team on November 17th 2022. This updated version pertains to 37,416 patients with 7,123 dates of death prior to 2020. The vast majority of new patients were registered with NHD after 2020 although born before 1992.
9. We sought to analyse the records of patients who were born and NHD-registered before 1992, for whom date of first treatment with blood products is

either pre-1992 or is missing and who, according to NHD, had been HIV-infected, HCV-tested or exposed to pooled plasma prior to 1988 or to components prior to 1992 (prior to HCV testing of these treatments). The objective of this analysis was to establish the survivorship of these patients. In all, the number of persons in the well-defined cohort of patients with blood disorders whose survival during 1992-2019 was analysed totalled 6,282. Overall, this covariate-adjusted survival analysis contributes to our understanding of how many patients with blood clotting disorders are likely to have died as a result of infection (or co-infection) with hepatitis C.

10. Based on record-linkage and clinical consensus on cause of death, I exhibit a report on the survivorship in distinct epochs of follow-up (1992-2019) as WITN7586002.

### **3.2: Report on Scottish National Blood Transfusion Service record linkage pertaining to survival status of patients given blood transfusions:**

11. Further, because the Infected Blood Inquiry lacked information on survival-status for those who had survived for at least 10 years after transfusion in the UK, the Scottish National Blood Transfusion Service (SNBTS) initiated a record-linkage study to follow-up for mortality four 5-yearly cohorts of transfusion recipients (1999; 2004; 2009; 2019). I exhibit a report on mortality after transfusion - WITN7586003 - which focuses specifically on the 1999 and 2004 RBC-cohorts, as both contribute to our understanding of survival in the second decade after blood transfusion. *See also the Expert Report to the Infected Blood Inquiry: Statistics.*

### **3.3: Supporting data:**

12. The NHD and SNBTS data sets are not publicly available due to patient confidentiality and the required competencies which permitted record-linkages and analyses to be performed in the public interest. I was granted controlled access to the anonymised record linkage reports provided through specialist teams at SNBTS and the NHD with local statistician support, respectively from

the University of Edinburgh and the University of Manchester, and I am very grateful for their assistance. While their original data sets cannot be disclosed to support the reports which I exhibit below, I have directed and reviewed the analyses of these linked data to the best of my professional ability.

### **Statement of Truth**

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

GRO-C

Signed \_\_\_\_\_

Dated 8<sup>th</sup> December 2022

### **Table of exhibits:**

<b>Date</b>	<b>Notes/ Description</b>	<b>Exhibit number</b>
01/09/2022	Expert Report to the Infected Blood Inquiry: Statistics	EXPG0000049
29/11/2022	Status report on the slim-National Haemophilia Database, version 3 (sNHD3) by Sheila M. Bird, Matt Gittins and Ben Palmer	WITN7586002
29/11/2022	Scotland's covariate-adjusted survival to 31 December 2019 for 1999-cohort and 2004-cohorts by Sheila M. Bird, Vanda C.F.I. De Carvalho, Katherine Forrester, Amanda Stewart and Marc Turner	WITN7586003