

Witness Name: Professor Sheila M. Bird

Statement No.: WITN7586004

Exhibits: WITN7586004-008

Dated: 27 June 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR SHEILA M. BIRD

I, Sheila Macdonald Bird, will say as follows: -

Section 1: Introduction

1. I refer to my first written statement, WITN7586001, where I have laid out my qualifications and areas of research.
2. I am a member of the Statistics Expert Group, appointed to advise the Chair of the Infected Blood Inquiry. I co-directed the analyses for 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 9th November 2022.

Section 2: Purpose of this statement

3. I provide this witness statement to present research and findings that are relevant to the Inquiry's Terms of Reference. In particular, I present a research report exhibited at WITN7586005. These findings are in addition to the Statistics Expert Group report.

4. The exhibited report, [WITN7586005], provides a commentary on peer-reviewed papers from 1990/1991 in light of additional contemporaneous data and modern statistical analysis techniques.
5. Seroconversion describes the transition from the point of viral infection to when antibodies of the virus become present in the blood. Seroconversion marks the point at which the immune system reacts to the presence of a virus in the body. Once seroconversion has happened, an HIV test will detect antibodies and give a positive result.
6. In order to report accurately on the rate of seroconversion in HIV infected patients with bleeding disorders, contemporary estimates of the distribution of seroconversion dates and its median are required. Most recent reports utilise data gathered circa 1990. To ascertain if those estimates remain valid, I have interrogated both the published data and statistical methodology.
7. To illustrate some aspects of definition and data quality, later data were acquired from a subset of the National Haemophilia Database (NHD). There is a well-defined subset of patients with a bleeding disorder (PwBDs within sNHD3) who were alive at 1 January 1992 and had been exposed to pooled plasma prior to 1988 or to components prior to 1992, which I detail further in a previous report provided to the Inquiry, [WITN7586002].
8. The 1990 publication by Darby and co-workers concerned the HIV seroconversion-time and AIDS progression of 1,201 patients in the UK with haemophilia A or B who had been tested for HIV-infection and found to be seropositive by the end of September 1987. The underlying hazard was assumed to be the piece-wise constant over **three time-intervals** defined by 1st 30-month, next 48 months and a final 30 months: 1 January 1979 to 30 June 1981; 1 July 1981 to 30 June 1985 (prior to heat-treatment); 1 July 1985 to 31 December 1987.
9. There was some evidence that those aged under 25 years at first HIV seropositive test had a higher risk of HIV infection in the earliest 30 months

[0.30; 0.69; 0.01] than did older patients [0.054; 0.946; nil]. For the younger age-group, the estimated median seroconversion-time would have occurred by month $30 + 0.20/0.69 * 48 = \text{month } 44$ (August 1982). For the older age-group, median seroconversion-time would have occurred by month $30 + 0.446/0.946 * 48 = \text{month } 53$ (May 1983). Alternatively, without heed to age-group, the estimated median seroconversion-time occurred by month $30 + 0.34/0.83 * 48 = \text{month } 50$ (February 1983, see authors' Figure 1). Uncertainty-intervals about the estimated medians are not easily deduced from the published account.

10. Competent statistical methods were applied by Darby et al. (1990) to provide early answers on two salient issues: the HIV seroconversion-time and AIDS progression of 1201 patients with haemophilia A or B who had been tested for HIV-infection and found to be seropositive by the end of September 1987.
11. Statistical methodology has developed further since 1990 but refinement of methodology does not necessarily deliver inferential change. Statisticians are also concerned about data-quality and the potential for ascertainment bias, as outlined in report [WITN7586005].

Statement of Truth

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

Signed:

GRO-C

Dated: 27 June 2023

Table of exhibits:

Date	Notes/ Description	Exhibit number
08/12/2022	Written statement of Sheila Macdonald Bird	WITN7586001
01/09/2022	Statistics Expert Group Report	EXPG0000049
08/12/2022	"Status report on the slim National Haemophilia Database (sNHD3)" by Professor Sheila Bird, Infected blood Inquiry, Statistics Experts Group (SEG), in consort with Dr Matthew Gittins, Department of Statistics, Manchester University, and Ben Palmer, National Haemophilia Database on behalf of UKHCDO	WITN7586002
05/06/2022	"Estimating the median date of HIV seroconversion for people with bleeding disorders who were HIV-infected (whether within or outside of UK): brief commentary on early peer-reviewed papers which included covariate adjustment (e.g. by age-group at earliest known HIV-infected date)" by Professor Sheila M. Bird with support from Dr Matt Gittins, Centre for Biostatistics, University of Manchester.	WITN7586005
2001	Seaman & Bird, Statistics in Medicine 2001	WITN7586006
1990	Darby, Doll, Thakrar, Rizza & Cox (Statistics in Medicine 1990)	WITN7586007
1989	Darby, Rizza, Doll, Spooner, Stratton & Thakrar (British Medical Journal 1989)	WITN7586008
1989	Darby, Doll, Rizza & Spooner (Philosophical Transactions of Royal Society of London B 1989)	RLIT0000132