

INFECTED BLOOD INQUIRY

Statement of Dr Christopher Bunch, Caldicott Guardian on behalf of Oxford University
Hospitals NHS Foundation Trust

1. My name is Dr Christopher Bunch and I am a Consultant Physician at Oxford University Hospitals NHS Foundation Trust (the "Trust"), I am duly registered with the General Medical Council in relation to my clinical role. I was also appointed to the role of Caldicott Guardian for the Trust in 1998 and I remain in that role. I am currently Chairman of the UK Caldicott Guardian Council.

A Caldicott Guardian is a senior person within a health or social care organisation who makes sure that the personal information about those who use its services is used legally, ethically and appropriately, and that confidentiality is maintained. In the course of this role I am asked to advise on the release of confidential material on behalf of the Trust in a wide variety of settings and requests. This has required me to be familiar with the duties the Trust has in relation to information management over a number of years.

2. I have been asked to review and approve this summary in response to questions raised by the Inquiry, pursuant to a request under S.21(2) of the Inquiries Act 2005, providing information regarding the documentation, storage and archiving arrangements at the Trust, as well as describing the searches undertaken by the Trust in response to requests from the Infected Blood Inquiry, made between August 2018 and August 2019.
3. I do this as a suitably senior person in the Trust having been provided with information by colleagues, in particular within the Haematology and Haemophilia

clinical teams, given a significant amount of the searches relevant to the Infected Blood Inquiry naturally arise from the work of that department. I have not personally made the searches described. I note however that the longevity of the relevant search windows and Inquiry's key issues means that no one currently employed by the Trust has personal and direct knowledge of the materials being searched for. In addition, the very significant organisational changes, including different legal entities, corporate structures and interfaces with other organisations (which in turn have also changed), over the course of the 50 year window the Inquiry is exploring, has proved very challenging in trying to complete searches with confidence. By way of example, Oxford University Hospitals NHS Foundation Trust came into being as an amalgamation of the Churchill and John Radcliffe Hospitals. Previously the two were separately managed by the Oxford Area Health Authority. There is also a wide variety of historic systems in place that have made searching for particular materials difficult.

4. This process has presented a real challenge in terms of the Trust seeking to arrive at a place whereby those currently employed by the Trust feel confident that all relevant material has been found. We therefore continue to regard our duties as ongoing duties to search for and disclose material relevant to the Inquiry's key issues, and we will continue to do so throughout the duration of the Inquiry, alerting the Inquiry team to any new material or potential source of material, that comes to the Trust's attention.
5. In addition to addressing the specific sub-headings requested by the Inquiry, I set out below what the Trust has put in place to progress assisting the Inquiry in its important work, and the Trust remains extremely willing to take additional steps the Inquiry feels ought to be taken.

**Organisations and agencies that process information on behalf of the Trust
(where information is defined as material that may be relevant to the Inquiry)**

6. I have been advised that any relevant material held by the haemophilia service will have been archived on site at the Oxford Haemophilia and Thrombosis Centre (OHTC) or in a storage outbuilding close-by which has been searched. With regard to haemophilia, key basic patient information and treatment records

are shared with the National Haemophilia Database and the UK Haemophilia Doctors Association.

7. Additionally, the NHS Blood and Transplant service (NHSBT), has a blood donor centre in Oxford (owned and run by NHSBT). The National Blood service links with the NHSBT and the Trust.
8. The above paragraphs relate solely to the haematology department given a significant amount of the material relevant to the Infected Blood Inquiry naturally arises from the work of that department.

Method of searches undertaken by the Trust in response to requests made by the Inquiry August 2018-August 2019

9. Professor R.G. MacFarlane, Dr R. Biggs and Dr E. Bidwell pioneered comprehensive haemophilia care in the UK, initially working at the Oxford Blood Coagulation Research Unit (MRC) (1959-1968) on the Churchill site and then becoming the Oxford Haemophilia Centre on the Churchill Hospital site in September 1968. It is now known as the Oxford Haemophilia and Thrombosis Centre (OHTC). The secretariat of the UK Haemophilia Centre Doctors' Organisation (UKHCDO) was housed in the Oxford Haemophilia Centre until it moved to Manchester in 2002. Dr Charles Rizza who was the lead consultant in the Oxford Haemophilia service over a key period of time being explored by the Infected Blood Inquiry was secretary of UKHCDO.
10. At a practical level, OHTC has been based at the Churchill Hospital in a self-contained departmental building since 1968, i.e. all on one site. This includes the clinical staff, administration staff, a specialist haemostasis NHS laboratory within this building, a room for the paper 'haemophilia medical records' of all current patients and an archive room including the medical records of deceased patients with haemophilia and historic 'treatment books.'
11. The solicitor to the Inquiry wrote to Bruno Holthof, Chief Executive Officer on 20th August 2018 requesting OUHFT provide within 28 days "*all information and documents held by OUHFT in any form (paper, electronic, audio, video, microfiche etc.) excluding individual patient records, which are potentially relevant to the issues set out in the Inquiry's Terms of Reference.*"

12. The Trust sent an initial response on 13th September 2018 which included two ring binders containing a personal account of the events of that time period, written by Dr C. Rizza and a BMJ journal paper written in 1983 discussing non - A, non-B hepatitis at Oxford. The Trust also wrote to confirm that we held personal patient information in patient's records and also in several factor concentrate 'treatment books'. The Trust had initially understood that patient records were excluded from the August 2018 request.
13. Having reviewed this response the Inquiry wrote to the Trust on 20th September 2018 stating *"in our experience, given that the requested material spans over 40 years and includes a broad range of issues, potentially relevant documents and information can be stored in ways that have not been common practice for a number of years. We have also known individuals who have worked in an organisation for a number of years to be surprised at the nature of material that organisation holds.*
14. *We would, therefore, kindly ask that you perform a full and final check for the information specified in the Rule 9 request."* In addition, the letter stated that *"we would ask for the information within patients' notes concerning dates of diagnosis, when patients were informed of their diagnosis and treatments received for hepatitis C and HIV. We wouldn't consider records of this nature to be patient medical notes."*
15. The latter comment resulted in the Trust revisiting the question of patient records, given the request for patient diagnosis dates and treatments, which the Inquiry described as being records outside the medical records of patients. The Trust had circa 600 patients affected by matters being explored by the Infected Blood Inquiry, and we therefore considered how to satisfy this request, based on records held. Our understanding of what was required to be returned in late 2018 was:
 - a. the potential review of the 600 (approximation) sets of patient notes to extract and record the relevant information
 - b. copies of the treatment record books covering 40-50 years;
 - c. further search of OHTC to try and identify any further relevant information (this process is detailed in paragraphs 15 -22);

- d. manual search for historical documents that might have been stored in other areas of the Trust, where any of the 600 patients affected, may have received other treatment. We assessed that this included the need to check within GUM, HIV, hepatology, virology and blood transfusion areas. The electronically held Trust Board minutes (2013 to date) have been searched under search terms 'blood' and 'infected' and were found to have no items identified. Historic Trust Board minutes in hard copy running to 20 years (1993 to 2013), are in the corporate governance offices on the John Radcliffe site have not yet been manually reviewed. The Trust will need to additionally resource a manual review of 20 years of Trust Board minutes, to address 1993 to 2013 ;
 - e. any other searches that appeared necessary to extract relevant material, or as recommended by the Inquiry.
16. Following the announcement of the Infected Blood Inquiry a provisional search of the OHTC was carried out by the Unit Manager to identify what records were potentially still stored in the OHTC building at the Churchill site . It was identified that:
- a. archive material was kept in a secure records room within the OHTC;
The archive records consisted of
 - i. deceased patient records;
 - ii. archived laboratory results not in the patient notes and
 - iii. old treatment day books.
 - b. the specialist coagulation laboratory had workbooks going back to the 1970s;
 - c. miscellaneous material also found in the archive room in the OHTC required consideration – this was a mixture of paper documents, films, slides, minutes, litigation paperwork and random notes/pieces of paper that appeared to relate to a wide range of administrative issues.
17. Before becoming computerised , treatment information from the day books was collated and recorded alphabetically into “Black Books”. This information was further analysed and recorded in separate statistical data books. These black books and statistical data books were stored in the archive. Each book consisted of hundreds of pages of handwritten entries, double sided, and there were books covering 50 years.

18. At the end of 2018, all rooms in the OHTC were also searched independently by the Unit Manager and Lead Administrator. Any records or documents potentially relevant to the Infected Blood Inquiry were gathered up and transferred to the OHTC archive room to ensure they were held securely in case they were required by the Inquiry.
19. In January 2019 the search was widened to include areas outside of the OHTC that might potentially contain OHTC material - in the 1990s there was a major refurbishment of the Haemophilia Centre during which the service was temporarily relocated to porta-cabins. During the 2000s further major work was carried out; an external storage area, "Ruby Room", was demolished to make way for the National Haemoglobinopathy Reference Laboratory and the rear of the OHTC was remodelled.
20. As it was possible that material may have been moved during these refurbishments/remodelling, buildings adjacent to the OHTC were searched by the Unit Manager and Lead Administrator: many boxes were discovered containing miscellaneous material relating to the Haemophilia centre including:
- a. leaflets;
 - b. journals;
 - c. laboratory books;
 - d. research papers and notes;
 - e. patient leaflets.
21. This material was reviewed by two OHTC consultants in February 2019, along with the miscellaneous material that had been added to the OHTC archive room. Everything that might be of potential interest to the Inquiry, based on the Key Issues and Terms of Reference for the Inquiry, was kept (some highly relevant, some general background). This resulted in 12 cardboard boxes and 3 additional folders being ring-fenced in the secure archive room at OHTC.
22. The Trust recognised the need to ensure that these materials were scheduled, scanned and disclosed to the Inquiry team. We also continued to search for relevant materials. We identified a specific issue regarding the very limited resources the Trust had available to support this work in addition to running the OHTC day to day for patients. The greatest burden thus far had fallen on OHTC

consultants, and the very small number of those had meant that real pressure was felt in trying to support the search and disclosure process. The Trust made enquiries over a few months regarding funding third party administration support to deal with the practical impact of supporting the Inquiry workload at Oxford, and explored costing with various providers. Ultimately we sought help from the Trust's solicitors, to mobilise a process of reviewing, scheduling and scanning for disclosure the material we sent to them.

23. Following further consideration of whether there were any other potential areas across the Trust where relevant material may be held, the Medical Director's office issued a short letter to GUM, hepatology and the sexual health teams on 22 February 2019 to place them on notice of the need to specifically consider the work of the Infected Blood Inquiry and to search for and identify any relevant materials. Responses received largely confirmed no materials were held, save for material that duplicated that held by the haemophilia team already.
24. In May 2019, 29 boxes of miscellaneous material, the "black books", treatment record books, unfiled laboratory results and statistical data books were sent to DAC Beachcroft. Over the subsequent 2 months, these materials were meticulously reviewed, scheduled for the Inquiry's team to consider, and scanned and uploaded to the Inquiry's portal. The initial focus was on the thousands of pages of treatment books, and then moved on to the uncatalogued, miscellaneous items to be described, scheduled, scanned (or identified where scanning was not possible, for example slides), and uploaded to the Inquiry Portal. I understand the Inquiry team attended DAC Beachcroft in July 2019 to map the disclosed schedule to the original materials, and to then arrange for original materials to be couriered to the Inquiry team for further logging and analysis. Those materials currently remain with the Inquiry team.
25. The Trust team remains mindful and vigilant in relation to the ongoing duties around finding relevant material within the Trust premises or control, and on 17 July 2019, some historic treatment records (5 haemophilia treatment record books and a folder of 'monthly returns', spanning dates 1960 to late 1980s) were discovered by the Unit Manager in the OHTC Data Manager's office.
26. Following this discovery however, the Trust conducted another physical inspection of the main OHTC buildings, by the Lead administrator and Data

Manager and independently by the Unit Manager. Additionally, on the 19th July all OHTC staff were requested to check their offices and work areas for any documents that may be relevant to the Inquiry. The outbuildings were re-inspected by both the Unit manager and, independently, by the lead Haemophilia Nurse.

27. As a result of this further work, one box of index cards with patients' historic hepatitis B antibody results was found in the outbuilding. The OHTC consultant and lead nurse reviewed 5 of the patient's medical records and found that there were official paper laboratory reports that corresponded to the handwritten information on the index cards already for these patients in their individual medical records. These documents are in effect duplicates of those held within patient records, however we have included them in the disclosure schedule and process of disclosure to the Inquiry team.
28. One additional A4 folder was found in an office containing historic printed leaflets e.g. Haemophilia Society Survey reports from late 1960s and 1975; social implications of home therapy specialist interest group report 1976; these may be of interest to the Inquiry and have therefore also been included in the disclosure process. These additional treatment books/box of index cards/printed leaflets have been sent to DAC Beachcroft on 20 September 2019 to be added to the disclosure schedule.
29. On 20th September 2019, the Clinical Manager for OHTC found further boxes of potentially relevant material in the locked OHTC archive room. The area of the archive room had been previously overlooked as it seemed to contain historic medical records, and unrelated archived trial records. This was immediately notified to the OHTC consultants and in turn to the Inquiry team on 21 September. This new material is being added in detail to the ongoing disclosure schedule for the Inquiry but includes, in summary:
 - a. minutes from meetings for haemophilia directors from 1975 onwards ;
 - b. copies of costings for factor VIII and contracts for factor VIII;
 - c. significant information about the 8Y study - looking at LFT abnormalities in previously untreated patients;
 - d. minutes from the UKHCDO;
 - e. MRC progress reports (the MRC pre-dated the OHTC - and includes

- minutes about hepatitis monitoring);
 - f. minutes from the UK haemophilia centre directors 1968 -1976;
 - g. therapeutic materials made in Oxford
 - h. minutes from joint blood transfusion centre directors and UKHCDO meeting;
 - i. Haemophilia Working Party minutes.
30. The above additional materials have all been added to the 'live' schedule of Trust materials shared with the Inquiry and will also be disclosed to the Inquiry team following the same process as occurred in July/August 2019.
31. We continue to seek assurance that all physical searches have now been completed, such that the Trust, and the Inquiry, can have confidence that all relevant material has been identified and disclosed.

Information regarding the Trust's retention and destruction policies

32. In addition to the Trust's local policies (referred to below) the Trust works to national standards including the Information Governance Alliance Records Management Code of Practice for Health and Social Care 2016 ("the Code"). For ease of reference a copy of this Code of Practice is appended to this statement as exhibit **CB1**.
33. The Code sets out best practice guidance in relation to the management of records, and relates to all records held by the NHS, including records of staff, complaints, corporate records and any other records held in any format including both paper and digital records. The Code also applies to Adult Social Care records where these are integrated with NHS patient records. Appendix 3 of the Code of Practice sets out guidance in relation to the retention of different categories of records. The Trust takes a more robust approach than the Code sets out, with the application of a 6 month period of inactivity as the initial trigger to archive records.
34. A copy of the Trust's current Health Records Management Procedure is appended to this statement as **CB2**. This is version 6 of the protocol and unfortunately despite extensive searches not all earlier versions are available as versions 1, 2 and 4 were only held in paper form and have not been

retained. Versions 5 and 3 are appended to this statement as exhibits **CB3** and **CB4** respectively. Appendix 5 to this protocol sets out detailed guidance regarding the storage and retention of health records, which reflect the guidance set out in the Records Management NHS Code of Practice.

35. Additionally the Trust has a Health Records Policy. Again, early versions 1, 2 and 3 were only held in hard copy and these were not handed over to the previous Health Records manager when coming into post, and have therefore not been retained by the Trust. A copy of the up to date policy is appended to this statement as **CB5**. Version 5 of this policy was not used widely and was superseded by version 6 which is appended to this statement as **CB6**.
36. We note that the Inquiry requires an account of any material known to have been destroyed with potential relevance to the Inquiry's Terms of Reference and/or List of Issues. This is a particularly difficult question to answer for the Trust, as whilst the retention and destruction of records policies are clear, it is apparent from the very significant volume of material already disclosed to the Inquiry team, that miscellaneous documents held within the OHTC service over the last 50 years, has not had the Trust's retention and destruction policy applied to it in any consistent way. For example, all deceased patient records have been retained, in case they are needed. The boxes of historical materials, including research papers and minutes of some (but clearly not all) meetings held within the service, all demonstrate that some materials have been retained far beyond the expected retention dates under the Trust's policy.
37. We cannot therefore know what the totality of material might have been within the (current corporate entity) of Oxford University Hospitals NHS Foundation Trust, over the last 50 years of its predecessor organisations and their respective control. As a result, we are unable to also know what material, if any, might have been lost from the control of the Trust, whether through formal destruction of material pursuant to Trust policy over the years, or through individuals moving to different organisations over the years. This is a frustrating, but perhaps understandable position for the Trust to be in given the time span for relevance covers some 50 years.

38. We can, however, indicate that any relevant material found has been shared with the Inquiry, and will continue to be shared in the event any further material is found.

Storage repositories used by the Trust

39. The Trust has centralised record libraries on each site. Additional information is stored in the following locations:
- a. The Oxford Haemophilia & Thrombosis Centre;
 - b. The Oxford Centre for Diabetes and Endocrine Medicine: these records are held both in hard copy and electronically, with approximately 14,000 records held. These records are archived after 2 years of inactivity;
 - c. Respiratory medicine;
 - d. Oral Surgery;
 - e. Medical Oncology;
 - f. Cardiac physiology: These records include implantable device records;
 - g. Genetics: These records are held both in hard copy and electronically. There are over 5000 records held;
 - h. Sexual health: These records are held in hard copy and electronically. There are over 5000 records held.

40. The Trust also has one contract with an offsite storage company (Restore Ltd) that is used to archive hard copies of medical documents. This company is on the NHS list of accredited suppliers of storage services and complies with relevant guidance. The requirement to comply with relevant national guidance is part of the terms and conditions of the contract with the supplier. There are approximately 1,822,632 medical records stored with Restore Ltd, although this figure is subject to change given that there is daily movement of records.

Information regarding archiving of documents/records by the Trust

41. The Trust has adopted an archiving process relating to patient records, where patients have not attended the Trust in the previous 6 months. These records

are then moved to an off-site storage location at Restore Ltd. This archiving process does not include haemophilia medical records (which may include outpatient reviews, details of emergency treatments and correspondence). All haemophilia records for adult patients are kept on site at OHTC, and the department also stores notes of all deceased adult patients at OHTC.

42. In order to conduct this exercise, the following process is undertaken:

- a. identification of correct patient on hospital electronic paper record system;
- b. review of the last date of attendance;
- c. review of future appointment dates;
- d. all records are tracked (location recorded electronically within the patient record system) to the off-site storage company (Restore Ltd);
- e. correct boxing of records for collection by off-site storage company. All notes are bar-coded and stored against a Restore registration number which can be cross-referenced against the Trust's number. These arrangements are audited once a year by the Trust's internal auditors.

43. Corporate Health Records transfer original documents offsite. The Trust is not required to retain copies as the original documents can be obtained from the off-site archive on the same day. For the same reason, Corporate Health Records do not transfer any hard copy material into electronic format.

CB1: WITN4196002
CB2: WITN4196003
CB3: WITN4196004
CB4: WITN4196005
CB5: WITN4196006
CB6: WITN4196007

Statement of Truth

I believe that the facts stated in this statement are true

Signed

DocuSigned by:
GRO-C

**Position
or office
held**

Caldicott Guardian

**Print Full
Name**

Chris Bunch

Date

24 September 2019