



# Extract from the UK National Haemophilia Database: Explanatory note

## Introduction

1. You have requested information held by the National Haemophilia Database (NHD) about yourself or a relative, which has been provided in the enclosed report. This document details the information contained in the report and indicates any limitations that may apply. It has been developed as a result of the experiences of previous NHD report recipients, with the aim of giving you the best understanding possible when you read your report.

All the data held on the electronic database in relation to yourself or your relative is attached as requested. We hope you find this information useful.

2. We have also reviewed our old paper archives for any additional information that may not have been entered into the electronic database and any such information is included.

Please be aware that the Infected Blood Inquiry team was given full access to all the information and documents held by the National Haemophilia Database during 2018, and the UK Haemophilia Centre Doctors' Organisation (UKHCDO) is committed to supporting the work of the Inquiry and ensuring it achieves its objectives.

## History

3. The National Haemophilia Database was established by the UK Haemophilia Centre Doctors' Organisation (UKHCDO) in 1968 to provide basic information on the number of people in the UK with a bleeding disorder and how much treatment was being used in order to help with healthcare planning. This was a voluntary database and so hospitals could decide whether to submit information or not. The database was hosted at the Haemophilia Centre in Oxford prior to 2002 when it moved to its current location in Manchester. The NHD receives information from two sources:

- haemophilia centres
- patients via Haemtrack home therapy recording system (2008 and onwards)

The completeness and accuracy of information held on the NHD is dependent on each source being completed correctly. Consequently, the NHD team is unable to provide an answer on information that is missing or appears to be incorrect.

4. Treatment given in hospitals without a dedicated haemophilia centre may not be reported to the NHD. Therefore there is a high probability that information about such treatment is not included in the report. The hospital where you or a relative was treated should be contacted in such a case.

5. From 2005 onwards, the NHD has been significantly enhanced to record more information. However, during the 1970s-1990s only the minimal necessary information was collected, and this is detailed below:
- the diagnosis and severity of the bleeding disorder
  - type and brand of clotting factor treatment
  - adverse events (including cause of death)

Please note that during 1970s-1990s the following information was not generally recorded on the NHD:

- information on quantity of treatment product used and batch numbers
- reason for treatment

## HIV, Hepatitis, vCJD Related Information

The information in the NHD is only as good as the submissions made by the haemophilia treatment centres. It was not uncommon for submissions to be incomplete. The NHD is able to provide information submitted to it, but the hospital where you or your relative was treated should be contacted if you need complete information.

6. When HIV tests became available in 1985 information about HIV status was collected at the request of the Department of Health. During the 1980s and early nineties, UKHCDO conducted surveys of HIV positive patients on behalf of the Communicable Disease Surveillance Centre (CDSC). Some of the detail of this data was archived but not entered into the database. We have reviewed this archive and copies of any paper records that relate to you/your relative are included.
7. Information about Hepatitis C serology was not collected by the database until approximately 2010, when the database attempted to facilitate an exercise aimed to help Haemophilia Centres to identify people who might have been exposed to HCV (based on their reported treatment history) but might not yet have been tested. All potentially exposed patients should have been offered testing once the second-generation HCV antibody test became available in 1992. Between 1970 and 1984 data on hepatitis B and jaundice (if it occurred) was collected for various surveys. If information was submitted to the database about you or your relative, this will be included in your extract, including any information stored in the paper archive.
8. As a result of the emergence of variant Jacob Creutzfeldt Disease (vCJD) as a potential blood transfusion hazard in 2004, the Department of Health requested that a “lookback exercise” be conducted covering the potential risk period from 1980 to 2001 (subsequently revised to 1990-2001) to try to identify:
- who had been treated with factor concentrates manufactured in the UK
  - whether an individual had been given any batches that included donations from blood donors who had gone on to develop vCJD. These were called “implicated batches”.
  - In 2013 the guidance was revised, and the risk period was shortened to 1990 to 2001
9. Haemophilia centres contacted the people involved with a standard letter and spoke to them. Since there is no test or treatment for vCJD, patients were offered the option of being told or not told whether they had received a batch with a vCJD donation in it (an implicated batch). Many patients chose not to be informed and that decision would have been recorded in the hospital records and reported to the database. Your extract will include data on vCJD only if you or your relative were involved in that

lookback exercise and would indicate whether or not you / they were considered at that time to be ‘at-risk’ for public health purposes or / and had received an implicated batch and whether you / they had opted to be informed or not at the time. It is now thought that vCJD is unlikely to be transmitted through clotting factor concentrates and to date no patients with bleeding disorders have developed the disease.

## Mandatory Treatment Safety Reporting Requirements

- 10 There has been an increased requirement for treatment safety monitoring (pharmacovigilance) and reports to the European Medicines Agency and Health Protection Agency are produced from NHD information. Adverse events considered to be treatment product-related are also reported to the manufacturer.

A list of the data *currently* collected in 2018 may be viewed on the website [www.UKHCDO.org](http://www.UKHCDO.org).

### Your Extract:

What is provided about you, or your relative, will vary depending on the date of diagnosis and treatment history and what was reported by the Haemophilia Centre to the Database. Hospitals without a Haemophilia Centre will generally not report to the database and so we are unlikely to have records of treatment administered in these non-specialist hospitals.

### The pages of your extract will each have a title heading, which are explained below:

- 01-03:** The first three pages contain demographic and diagnostic data: your name, haemophilia centre, bleeding disorder diagnosis and severity.
- 04:** This section is a record of treatment by year and haemophilia centre and includes the brand of product and, where available, the number of units administered during the year / quarter. As a broad generalisation, batch numbers have never been collected except where they relate to a specific adverse event that was investigated at the time.
- 05:** Although labelled “Hep C data”, this is very old data, collected before the hepatitis C virus was identified and before hepatitis C tests became available in 1992. It is derived from an early attempt to collect information on people who developed jaundice. Most people who contract hepatitis C do not develop jaundice and for them this data will not be available. This information was only collected between 1974 and 1984 and not all haemophilia centres sent in information about every episode of jaundice. (see also 10).
- 06:** This contains data on von Willebrand’s disease blood results for people with this condition.
- 07:** This shows HIV data for those people who have been tested and results reported to the NHD. People who were not treated with blood products or treated with blood products only outside the period of risk for HIV (1980-86) or only treated with recombinant products are likely not to have been tested because they are not at risk from their treatment. In some cases, the date of the HIV test may be earlier than 1985, when the HIV test became available. In that case, the sample will have been a stored and the frozen sample tested when the HIV test became available, so the result may have given an indication of the time of infection but would only have become known in 1985/86, when the test became available. Some of these stored samples tested retrospectively give an indication of the time of infection but only

a few centres had such stored samples available for testing. If further paper reports not included in the electronic record are available, copies of these will be included with the printout from the electronic database. Any reference in those paper records to any third party will be redacted in accordance with GDPR.

- 08:** This gives data on any biopsies or autopsy results conducted for variant Jacob Creutzfeldt Disease (vCJD). Very few records will include such data. It should be emphasised that no one with a bleeding disorder has developed vCJD and the consensus at the moment is that this condition is not transmitted by clotting factor concentrates.
- 09:** This section gives data on potential vCJD risk, as derived from the vCJD lookback exercise which began in 2004. If the box labelled “at risk” says “yes” then this means that the person was treated with UK plasma products or concentrates during the period of risk, which was 1990-2001 (originally 1980-2001 but subsequently revised). If the person is known to have been treated with a batch of clotting factor concentrate known to have included a plasma donation from a donor who later went on to develop vCJD, then the batch number, the date of first and last dose of treatment and number of units used will also be included. Where the “at risk” column says “no” it means that the patient was not treated with UK plasma concentrates during the period of risk. Where the “patient notified” column says “no”, that means that they were asked if “they wanted to know whether they had received an implicated batch” and had declined. This conversation should also be documented in the patient’s hospital record.
- 10:** This section includes hepatitis C test data submitted to the database by haemophilia centres in the course of the HCV lookback exercises conducted in 2010 and 2018 (ongoing). The objective of these exercises was and is for the database to identify patients potentially at risk of HCV, based on treatment records submitted to the database during the period of risk, and for the database to help the haemophilia centres to ensure that all patients potentially at risk have been tested and offered treatment, where that was appropriate.
- 11:** This section will be included with your extract only if an adverse event has been reported to us by your Haemophilia Centre in relation to your bleeding disorder itself or to treatment given to you or your relative. Centres report adverse events to us as they occur and these are then investigated further.

The adverse events collected have changed over the years but currently include: allergic or other acute event; intracranial haemorrhage; death and cause of death, new infections (e.g. HIV, hepatitis); factor VIII, IX or VW inhibitor; malignancy (cancer); neurological event (e.g. multiple sclerosis, CJD and vCJD); poor efficacy of treatment; thrombosis; any other unusual event not specified above. Adverse events thought to be treatment-related are also reported back to the manufacturer so that they can fulfil their regulatory requirement to investigate drug side effects further. We also report safety information to the European Medicines Agency who regulate and license new drugs in the EU.

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