

## 2. Data Management Working Party Report

### Membership

Dr Gerry Dolan	Chairman
Lorraine Birtwhistle	Haemophilia Nurses Association Representative
Dr Paula Bolton-Maggs	Rare Haemostatic Defects Working Party
Nancy Brodie	UK Haemophilia Data Managers Forum
Dr Peter Collins	Inhibitor Working Party
Lynne Dewhurst	Working Party Secretary
Bridget Emanuel	London Commissioners
Dr Charles Hay	Chairman UKHCDO
Prof Frank Hill	vCJD and Transfusion Transmitted Infections Working Party
Dr Sybil Hirsch	NHD Project Manager
Dr Rob Hollingsworth	Software Engineer
Prof Christopher Ludlam	Genetics Working Party
Mick O'Donnell	West Midlands Commissioner
Prof John Pasi	Von Willebrand's Working Party
Margaret Unwin	Haemophilia Society
Clifford Welch	Patient Representative
Dr Mike Williams	Paediatric Working Party

### Remit

The working group oversees the management and activities of the National Haemophilia Database and has special responsibility for the development of the database and the patient information system.

The group met twice during the year at Manchester Royal Infirmary and, in addition, several conference telephone calls were convened.

### The National Haemophilia Database

The National Haemophilia Database (NHD) has made considerable progress in 2005/6 and has been the cornerstone to major national Haemophilia service projects (Recombinant Rollout, National Procurement, vCJD Surveillance, etc.) and research. These projects illustrate the vital role that the NHD fulfils for the Haemophilia service and commissioning.

### Finance

Funding for NHD has been from grants from the Department of Health and an increasing proportion from commissioners. The latter funding stream now accounts for approximately 40% of financial support for the database and there is the opportunity to secure further support from commissioners.

Software support and software development continues to be provided on a consultancy basis. Finance for support of the Haemophilia Clinical Information System (HCIS) is provided from maintenance charges to Haemophilia Centres. Funding for the 2007 year is as yet not confirmed but it is hoped it will be again come from a combination of sources as above.

## Staffing

The NHD Project Manager, Dr Sybil Hirsch is responsible for core data collection and analysis and is assisted by our administrative assistant, Ms Lynne Dewhurst. Software support for NHD, HCIS and various projects is provided by a team (Paul Kane, Enis Muminovic and Amir Rowaichi) led by Dr Rob Hollingsworth. In recent months, a further administrative assistant Ms Jessica Smith has been appointed to develop work on the collection of data on potential exposure to vCJD in patients with haemophilia. This post has been funded by a grant from the DoH. There are future plans to expand the research capacity of the database and this may involve employment of extra research staff depending on the volume of research projects.

## Continued Development of the National Haemophilia Database

The NHD has undergone significant developments this year. This includes a large expansion of the available dataset, bringing the data up to date (previously one year behind) and large-scale validation exercises to validate and improve existing data held.

The major difficulties encountered during 2004 and 2005 in relation to centre access to the electronic NHD (caused by redevelopment of NHS IT infrastructure) have largely been resolved.

## NHD Dataset Expansion

The NHD dataset has been expanded to include patient specific data such as GP Practice Code, NHS number and Post Code. As well as these additional data items, for the first time the NHD is now recording product usage by individual patient. Previously product usage was only available by diagnosis. These additions open up whole new areas of potential audit, research and reports (patient usage, regional breakdowns, PCT specific etc.). The vCJD project has also resulted in an expansion of the dataset to store the vCJD related information.

It has been decided that next year we will have a transitional year moving towards reporting of data by financial rather than calendar year.

## NHD Data Brought Up to Date

This year we have taken steps to make the data held within the NHD current (data previously one year out of date). This has involved carrying out annual data collection and reports for both 2004 and 2005. This has been a major undertaking but has key benefits for both the quality and usefulness of the data within the NHD for commissioning and research purposes.

## New Technologies

New technologies such as web services have been developed in order to integrate the NHD more closely with the locally implemented Haemophilia Centre-based system (HCIS). These include automated services to notify centres of deaths of patients that they have registered as being seen at their centres, automated submission of NHD returns data, automated registration of patients on the NHD etc. HCIS and these technologies are the key to achievable increases in

detail levels of data available to the NHD. Centre use of the HCIS system is essential in order to continue to expand the dataset and detail of information collected for the NHD.

### Validation Exercises

Combined with these developments we have undertaken data validation exercises to validate and improve the quality of existing data within the NHD. This validation has included a national validation of patient factor levels by Haemophilia Centres, use of the NHS Strategic Tracing Service (NSTS) to validate and insert GP Practice Codes, NHS numbers, Date of Birth, Date of Death and Post Codes. Regular validation using NSTS will ensure NHD data is always up to date, accurate and complete.

### Service Level Agreement (SLA)

The NHD has been working closely with the Pan Thames Haemophilia Consortium (PTHC) to enhance the dataset, define data access mechanisms and design reports specifically tailored for commissioners. Pan Thames have requested monthly reports for specific data items. An early outcome of these discussions is that the NHD will now move to recording data in financial year format (for 06-07 onwards) to increase the usefulness of current NHD data for commissioners.

The reports and additional dataset items established by these discussions will enable commissioners to better plan, manage and forecast their commitments to the Haemophilia Service. Use of the NHD is the only way to obtain data that enables both long and short term planning, through activities such as analysis of trends, time activity comparisons, and identification of outliers. It is hoped that these reports will start during the current financial year and be extended and develop in the next financial year.

### The Haemophilia Clinical Information System (HCIS)

HCIS is recommended by the UKHCDO for centres who wishing to acquire a centre data management system. The rollout of the system continues and has been installed in 21 Haemophilia Centres to date with several more planned. The structured support for the system continues with an established user's forum, national training days and a comprehensive support web site.

The system continues to be enhanced to reflect the changing needs of centres e.g. Home Delivery. This year we will be looking closely at incorporating product bar code reading facilities and closer integration with home delivery providers to reduce the required workload for centres to deliver these services.

The web service technologies as described have dramatically eased the workload required to register patients on the NHD, submit annual returns and register patient deaths. We will be looking to make more use of these technologies during 2007 to provide functionality such as automated updates of the HCIS system.

A new genetics dataset established by the genetics WP is close to completion and this will be incorporated into HCIS, allowing electronic image storage of patient genetic reports.

## Automated Data Collection from the Haemophilia Clinical Information System

Following the successful pilot work in four centres for semi automatic data export for the 2003 returns, this system has been rolled out to almost all HCIS centres with great success. This facility has dramatically reduced the effort required to produce this years returns data requirements for 2004 and 2005.

## UKHCDO Website

The UKHCDO website is maintained at <http://www.ukhcdo.org>. The website is updated regularly and has details of all meetings and all relevant information for the working parties.

## Dataset Changes

Details of the updated dataset are given in Appendix I. Key changes to the dataset through 2005/6 are: - Collection of GP code. Next year we intend to move over to reporting by financial year rather than calendar year.

## Adverse event reporting

The monthly orange e-mail is being introduced in 2007 and this will allow real-time entry of adverse events. Early feedback on pilots has been positive and it is hoped that it will both speed up and enhance the completeness of adverse event reporting.

## Research Proposals

UKHCDO has acknowledged the potential of the database to support research in Haemophilia and related conditions in the UK. It has been agreed that the Working Parties and other researchers in the UK should have easier access to the database. A protocol for requesting data will be presented at this AGM for approval.

All requests for information will be processed in compliance with the Data Protection Act of 1998.

## Data Protection Act and Caldicott Inspection

A new patient information leaflet is about to be printed, and it has been agreed that we will post this to patients.

A Caldicott inspection was undertaken in February 2006. Two minor issues were raised and were immediately resolved with the inspector. We have also had further correspondence with the Data Protection Registrar confirming our compliance with DPA

## Freedom of Information Act

The Freedom of Information Act does not apply to registered charities and so we are not obliged to release old minutes under the provisions of the act. No requests of this sort have been received for nine months.

## Data Managers Forum

The group of Haemophilia Centre Data Managers continues to provide valuable feedback and support for the NHD and HCIS. Nancy Brodie continues in the role of chairman and is a member of the working party. Lynne Dewhurst continues as secretary.

## Summary

The changes in HCIS have greatly improved the ability to provide and collect data. This has allowed a catch up in the annual returns to the point where, with this double report, the data are up to date. This has been achieved despite a greatly expanded dataset and several other high pressure activities such as the national procurement project, 'recombinant for all' rollout and audit and the vCJD surveillance project.

I would like to pay tribute to Charlie Hay, Sybil Hirsch, Lynne Dewhurst, Rob Hollingsworth and colleagues and to all Haemophilia Centre Data Managers for their enormous efforts to maintain, develop and extend the UKHCDO database which remains the most comprehensive haemophilia database available.

Dr Gerry Dolan  
Chairman, Data Management WP  
November 2006

## Appendix I

## National Haemophilia Database – Data Set

We are required to collect the following Data by the DoH. In the past, they have also required us to collect data on HIV but not hepatitis C. We have recently been asked to collect detailed data on potential vCJD exposure including batch numbers and volumes used. This data collection is ongoing and since entries will have to include all registered patients, even those never treated with blood products as well as those affected, it involves more than 20,000 patients. Data entry into the database will commence shortly.

NB: It is important to note that, with a very few exceptions, we have never held central data on factor VIII/IX product batch numbers used by patients. Neither have we ever held data on hepatitis C status. Since these two items are the commonest focus of interest from patients requesting extracts from the database, it is important to emphasise this limitation in the historical dataset.

## Name

Patient Unique ID	Used to link patient records with other tables
Name	
Soundex	

## General patient information

FIELD NAME	EXPLANATION
Patient Unique ID	Used to link patient records with other tables
Sex	Male or Female
Basic factor level	Factor level for the diagnosed deficiency
DOB	
Year First Registered	Year first registered with the NHD
Inhibitor detected	Yes / No
Year Inhibitor First Detected	Year of first inhibitor detection
Inhibitor form received and date	
HB s AG Carrier	
Resident Overseas	Yes / No
Date of Death	
Cause of Death	
History of Jaundice/Hepatitis	Yes / No
NHS number	
Old NHS	
No Oxford Diagnosis	No longer used

Oxford Reg No	No longer used
Home Post Code	
GP Practice code	
Date of Death - Not known at Centre	Used if information is obtained from source other than a Haemophilia Centre
Cause of Death - Not known at Centre	Used if information is obtained from source other than a Haemophilia Centre

### Annual Treatment Record

FIELD NAME	EXPLANATION
Patient Unique ID	Used to link patient records with other tables
Treatment Year	
Centre	Centre from which treatment was issued
Regular Home Treatment	Yes / No
Regular Prophylaxis	Yes / No
No Inhibitor This Year	Yes / No
Inhibitor Present This Year	Yes / No
No Dose This Year	Yes / No
Visitor	Yes / No
Other Use	
Material used	
Volume of Material used	

### Record of Haemophilia Centres that each patient is registered at (patients can be registered at more than one Haemophilia Centre)

FIELD NAME	EXPLANATION
Patient Unique ID	Used to link patient records with other tables
Centre	Name of Haemophilia Centre
Gene Mutation Known	Yes / No
Gene Mutation Date	Date mutation detected
No Longer Seen	Yes / No – used when patients transfer
No Longer Seen - Date	Date
Date Registered	Date registered at individual Haemophilia Centres
Date first seen	Date first seen at individual Haemophilia Centres

## vWD results

<b>FIELD NAME</b>	<b>EXPLANATION</b>
Patient Unique ID	Used to link patient records with other tables
Date Code	
Centre	Name of Haemophilia Centre
Year First Seen	
Reason First Seen	
Date Form Completed	
Home Area	
VIII:C R	
VIII:C D	
VIII:Ag R	
VIII:Ag D	
VIII:RiCof R	
VIII:RiCof D	
VIII:RiCof Inhib R	
VIII:RiCof Inhib D	
2 DIE R	
2 DIE D	
BT mins R1	
BT mins R2	
BT mins D	
BT Method R	
BT Method D	
Severity Classification	
Family History	
Clinical Bleeding History	
Blood Group 1	
Blood Group 2	
Blood Group Date	
VWF:Ag	
VWF:Activity	
VWF:Ag Inhib	

Platelet Count	
RPA VW Type	
Multimeric Analysis	
Platelet VWF Levels	
Binding Assays	
Mutational Analysis	
VW(iii)	
Collagen	
Activity ac	
Ripa	

### HIV Test

Patient Unique ID	Used to link patient records with other tables
Date Code	
Centre	Name of Haemophilia Centre
Date of Sample	
Result	Pos / Neg
Date Form Completed	
Not Yet Tested	Yes / No
Date Last Negative	
Date First Positive	
Condition	
Date Condition Diagnosed	
Date of Last Report	
Reporting Centre	
CDSC Number	
Comment	

## vCJD Data

Patient Unique ID	Used to link patient records with other tables
At Risk Status	At risk or Not at risk
Reason at risk	
Patient notified date	
Assessor	
Assessment date	
Batch vial size, number and release date	
Batch first dose	
Batch last dose	
Batch Total dose	
Batch brand name	