NHD Dataset

Information required to: Register a Patient:

NHS number
NHD number (if known)
Forenames(s)
Surname
Previous surname
Date of birth
Gender
Post code
GP practice code
Ethnicity
Usually resident overseas (yes/no/unknown)
Date first seen
Reason seen (diagnosis/registration/clinical assessment/other)
Clinical bleeding history (no/yes/unknown)
Home delivery provider
Diagnosis
Factor Levels

Information required to: De-register a patient:

NHD number
NHS number
Forename
Surname
Date
Reason (transferred/lost to follow up/diagnosis is no longer current/moved away)

Adverse Events Reports:

Death event

Patient Details
Event Date
Factor Level
Cause of death
Confirmed by Autopsy?
Inhibitor present at Death - Yes/No
HIV \Positive - Yes/No
Hepatitis B Positive - Yes/No
Hepatitis C Positive - Yes/No

Allergic or Other Acute Event

Patient Details
Event Date
Factor Level
Type of Event: Anaphylaxis / Rigors / Rash / Shortness of breath
Infusion information:
    Product / Batch number
Additional Blood Products - Yes/No
Time between dose and event
Lifetime exposure days
Has this happened previously - Yes/No
Outcome
Do you consider this relationship to the concentrate to be:
    Definite / Probable / Possible / Unlikely / Unrelated

Thrombotic Event (including: Angina / Deep vein Thrombosis / Myocardial Infarction / Pulmonary Embolism / Thrombotic Stroke / Transient Ischemic Attack

Patient Details
Event Date
Factor Level
Event type
Patient received concentrate in previous 30 days? - Yes/No/Don't know
Was thrombosis associated with a central venous catheter? - Yes/No
Did the patient have surgery in the last 3 months? - Yes/No
Risk Factors:
    Thrombophilia
    Pregnancy
    Oral contraceptive pill
    Hormone replacement therapy
    Diabetes
    Smoking – Current / Former / Never
    Hyperlipidaemia

BMI > 30
Any personal past history of MI / Stroke / DVT / PE
Any first degree relatives with MI / Stroke
Any first degree relatives with DVT / PE
HIV positive
On HAART
Hypertension
Atrial Fibrillation

Infection Event (including: HIV / Hepatitis A, B and C / Parvovirus B19 / vCJD)

Patient Details
Event Date
Factor Level
Infection type:
Infusion information – Product / Batch number
Additional blood products - Yes/No
Last negative test date
First positive test date
Last exposure date
Do you consider this relationship to the concentrate to be:
Definite / Probable / Possible / Unlikely / Unrelated

Malignancy Event

Patient Details
Event Date
Factor Level
Malignancy diagnosis
Did the patient ever undergo radioactive synovectomy? - Yes/No / Don't know

In the last 10 years did the patient receive:	Plasma derived concentrate or FFP or Cryo
	Recombinant concentrate
	Both of the above
	None of the above
Is the patient	HIV \Positive - Yes/No
	Hepatitis B Positive - Yes/No
	Hepatitis C Positive - Yes/No

Poor Efficacy Event

Patient Details
Event Date
Factor Level
Event information

Other Event not specified above

Patient Details
Event Date
Details of the event

New inhibitor:

Patient Factor Level:
Patient Factor Level Units:
Reporting Consultant:
Coagulation Disorder:
Genotype:
Relatives with inhibitors?
Relatives Details:
Reason for test?
Is this the first ever inhibitor?
Date of last negative Inhibitor test?
Anti Human
- 1st Positive Level / Date:
- 2nd Positive Level / Date:
- Peak Inhibitor Titre / Date:
- Assay used:
- Lab Normal Range:

Anti Porcine
- 1st Positive Level / Date:
- Peak Inhibitor Titre / Date:

Any Change in Baseline FVIII/FIX? - Details:
Any Change in bleeding pattern?
Treatment before inhibitor development:
Additional Blood Products?
Estimate the following:
Time interval between first replacement and inhibitor:
Treatment days before inhibitor development:
Total Lifetime Exposure Days:
Factor Replacement details:
- From Date: To Date:
- Product: Units:
- Comment:

Concomitant Events
- From Date: To Date:
- Comment:

Clinical studies

First 50 exposure days

NHD no
Ethnicity
Factor Levels
Family History of inherited bleeding disorders
Screened at Birth: Yes/No
If no, age at diagnosis: Months

Pregnancy and Delivery
Born at obstetric unit affiliated to Haemophilia centre: Yes/No
Gestation at delivery: Weeks
Mode of delivery
Duration of labour (if known): Hours

Peri-Natal History
Cranial USS performed? - Yes/No
If yes, at what age performed?
Indication – Routine / Bleeding (definite or suspected)
USS Result: Normal/Abnormal If abnormal, provide details:
Vitamin K given?
Route: IM/IV/PO
Was the child breast fed?

Prophylaxis
Prophylaxis with factor concentrate following delivery? - Yes/No
Indication – Preterm/Routine/Trauma
Bleeding during the 1st month of life - Yes/No
Severity – Minor (no treatment required) / Moderate / Severe (treatment required)
If bleeding, provide details:

All patients with severe haemophilia over the age of 10 who have up to 50 exposures will have the following data requested on a 3 monthly basis:

Exposure days
Day number
Date
Product Name Dose (IU) Weight (Kg)
If surgery was it by C/I
Was extravasation possible?
Intercurrent Infection: Yes/No

vCJD patient exposure assessment form

Name
NHD number
Date of birth
NHS number
Date first seen
Centre
Risk status:
Did the patient receive ANY UK sourced pooled factor concentrates or Antithrombin between 1980 and 2001? (Yes/No)
Did the patient receive ANY UK sourced pooled factor concentrates or Antithrombin between 1990 and 2001? (Yes/No)
Details of product and volume received: Brand
Batch number

Release date
First dose
Last dose
Total dose
Has the patient asked to know if they received the implicated batch(s)? Yes/No/Unknown)
Date patient notified
Assessor's name
Date of assessment

Hepatitis C Look-back Exercise

Has the patient been exposed to plasma components, platelets or red cells prior to September 1991?	Yes / No
Has the patient been treated with clotting factor concentrates prior to 1988?	Yes / No
Is the patient still alive?	Yes / No
What is the result of the hepatitis C test?	
Antibody	Unknown / +ve / -ve
Antigen/HCV RNA/HCV PCR	Unknown / +ve / -ve
Where did the patient contract the infection?	England / Scotland / Wales / N. Ireland / UK / Non-UK
Has Hepatitis C (HCV) been resolved?	Spontaneously / Following treatment / No
Hepatitis C Genotyping	1a / 1b / 2 / 3 / 4 / 5 / Unknown
What was the result of the patient's most recent liver function test?	Unknown / Normal / Abnormal
Cirrhosis	Yes / No / First Date (Year)
Liver failure	Yes / No / First Date (Year)
Hepatocellular carcinoma	Yes / No / First Date (Year)
Liver transplant	Yes / No / First Date (Year)
Treated for Hepatitis C	Yes / No
What was the outcome?	Successful / Unsuccessful / On-going / Pending
What was the treatment?	Interferon / Interferon + Ribivarin / Peginterferon +Ribavarin

Is the patient still under regular review at your centre? - Yes/No
Comments

Inhibitor Surveillance Data Collection

Test date
Was this done via a screening method? (Yes/No)
What was the result of the screening method test? (Positive/Negative)
Was this test done via a quantitative method? (e.g. Bethesda, Nijmegen modified) (Yes/No)
What assay was used?
What was the result of the test?
Does your Centre consider the result above to be Positive or Negative?
Next test date

Quarterly Treatment Data

Every quarter Haemophilia Centres are required to submit information to the National Haemophilia Database about the treatment issued to patients, including products delivered to the patient's home. The following information is collected:

Quarterly Returns Information

Patient information:

Patient's weight
Current inhibitor
Patient receives home delivery (Yes/No) Home delivery provider

Specific information for haemophilia A and B:

If the patient has had surgery with 2 or more nights as an inpatient – type of surgery; continuous infusion; total product usage for the first 2 weeks post-surgery
Family history of an inhibitor in a first degree relative
Malignancy diagnosed in this quarter
Auto-immune disease diagnosed in this quarter
Interferon received in this quarter

Treatment details

Name of product
Number of units issued