

Universal Data Collection

U.S. Department of Health
and Human Services
Public Health Service

Baby Visit



CDC ID

□□□ - □□□□ - □□□□□

GENERAL INFORMATION

Date of Visit

□□ □□ □□□□
month day year

Date Form Completed

□□ □□ □□□□
month day year

Form Completed by:

□□□□□□

Data entered by:

□□□□□□

CDC Use Only

DEMOGRAPHIC & CLINICAL INFORMATION

1. Zipcode: □□□ (first 3 digits)

2. Weight: □□ . □ kg

3. Length: □□□ cm

4. Head Circumference: □□ cm

5. Is this the FIRST visit to an HTC?

Yes No

6. Health Insurance (Check all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Straight commercial insurance | <input type="checkbox"/> Straight Medicaid |
| <input type="checkbox"/> Commercial insurance HMO | <input type="checkbox"/> Medicaid HMO |
| <input type="checkbox"/> Commercial insurance PPO | <input type="checkbox"/> CHAMPUS |
| <input type="checkbox"/> Straight Medicare | <input type="checkbox"/> State high-risk insurance plan |
| <input type="checkbox"/> Medicare HMO | <input type="checkbox"/> Uninsured |
| | <input type="checkbox"/> Other _____ |

7. Has the patient had an analysis of his or her genetic mutation since birth or the last visit?

Yes No

TREATMENT INFORMATION

8. Follow-up diagnostic hemophilia factor activity:

□□ . □ % check if < 1%

Date Obtained:

□□ □□□□
month year

9. Treatment type (check one):

- Episodic care
 Immune tolerance
 Prophylaxis
if prophylaxis,
 Continuous Intermittent

10. Central venous access device (CVAD) placed since birth or the last UDC visit:

Yes No Unknown

If yes, type of CVAD (check all that apply)

Port Catheter PICC

10a. CVAD complication since birth or the last UDC visit:

Yes No Unknown

If yes, type of complication (check all that apply)

- Infection Thrombus Mechanical
 Bleeding Other

11. Home infusion? Yes No

If yes, infused by (check all that apply)

- family member
 medical care provider

12. Highest inhibitor titer since birth or the last UDC visit:

(Bethesda units):

□□□□ . □ not done

Date Obtained:

□□ □□□□
month year

12a. Immune tolerance therapy since birth or the last UDC visit:

Yes No Unknown

If yes,

Date begun: Mo □□ Year □□□□

Status: Successful Unsuccessful
 Ongoing Unknown

BABY VISIT FORM

FORM COMPLETION: Complete this form at the first visit and at 6 month intervals for all visits made to the treatment center prior to age 2 years. If this is the first visit for which this form is being completed, substitute "during the previous 12 months" for the phrase "since the last visit."

Patient CDC ID: The unique 12-digit number generated for each patient by staff at the hemophilia treatment center (HTC) using the CDC ID computer program.

General Information: Enter the date of the visit and the date that this form was completed. Enter the initials of the person completing the form.

DEMOGRAPHIC INFORMATION

1. Zipcode of Residence: Enter the first three digits of the zipcode for the patient's residence (NOT for the HTC that the patient visits).

2. Weight & 3. Height: Enter the patient's weight in kilograms and height in centimeters without shoes and in light clothing; (2.2 lbs = 1 kg) (1 inch = 2.54cm). To convert pounds to kilograms divide by 2.2. To convert inches to centimeters multiply by 2.54.

4. Head circumference: Enter the patient's head circumference in centimeters. Measure the head by placing a flexible measuring tape just above the eyebrows and ears, and around the back of the head where it slopes up prominently from the neck. The goal is to measure the head at the spot where it has the largest circumference. The measurement is read to the nearest 0.3 cm.

5. Is this the FIRST visit to an HTC: If the current visit is the patient's first visit ever to an HTC, check YES. Count only actual visits to an HTC, not phone contacts or written correspondence. Otherwise, check NO.

6. Health insurance: Check all sources of health insurance coverage for the patient. See *Data Forms Manual* for more detail about health insurance plans.
Commercial Insurance: Insurance provided through private or public companies and paid for either by employers or by individuals.

Medicare: Federal health insurance program available to persons who are either over 65 years old or disabled.

Medicaid (Medical Assistance, Title 19): State/federal health insurance program for certain needy and low income individuals.

CHAMPUS: Insurance offered by the federal government to persons who are in the military and their dependents.

State High Risk Insurance Plan: State-sponsored insurance plan for individuals who have difficulty purchasing insurance due to a pre-existing condition.

Uninsured: Persons without any health insurance coverage.

Other: Any other type of health insurance plan not listed above.

7. Has the patient had an analysis of his or her genetic mutation: Check YES, if the patient has undergone genetic testing to determine the specific genetic mutation responsible for his/her bleeding disorder. If they have not undergone testing or if it is unknown, check NO.

TREATMENT INFORMATION

8. Follow-up diagnostic hemophilia factor activity: For patients with factor VIII or factor IX deficiency due to hemophilia **only**, enter the most recently obtained factor activity and date performed. Do not enter factor levels for patients with von Willebrands disease.

9. Treatment type (check one): If the patient received treatment products only in response to bleeding complications since birth or the last visit, check EPISODIC CARE. If the patient is currently undergoing immune tolerance therapy (either initial or maintenance), check IMMUNE TOLERANCE. If the patient received treatment products to prevent bleeding or to prevent rebleeding, check PROPHYLAXIS. If you check PROPHYLAXIS and the patient was recommended to receive treatment products on a regular schedule to prevent any and all bleeding and this therapy was expected to continue indefinitely, check CONTINUOUS. If you check PROPHYLAXIS and the patient received treatment products on a regular schedule for a period of at least 28 days on at least one occasion since the last visit and this therapy was not expected to continue for an indefinite period of time, check INTERMITTENT. You should not check prophylaxis if the patient received treatment products for less than a period of 28 days.

10. Central venous access device (CVAD) since birth or the last UDC visit: If the patient had a central venous access device placed for delivery of factor since birth or the last UDC visit, check YES. If yes, indicate the type of device placed. PORT is an internal CVAD that is placed surgically under the skin of the chest or arm and is accessed using a needle. CATHETER can be either tunneled or non-tunneled, permanent or temporary and is inserted directly into a central vein such as the subclavian, jugular, or femoral. PERIPHERALLY INSERTED CENTRAL CATHETER (PICC) is inserted into a peripheral vein in the upper arm or leg and threaded into a central vein such as the subclavian or jugular vein. If a CVAD was not placed, check NO. If it is unknown whether a CVAD was placed, check UNKNOWN.

10a. CVAD complication since birth or the last UDC visit: If the patient had a central venous access device and experienced a complication with the access since birth or the last UDC visit, check YES. If yes, check all of the complications that were experienced. If a CVAD complication did not occur since birth or the last UDC visit, check NO. If it is unknown whether a CVAD complication occurred, check UNKNOWN.

11. Home infusion: Check YES, if patient receives treatment products intravenously outside of the medical setting. If YES, check whether the product is infused by a family member or a care provider. If patient receives treatment products only in a medical setting (e.g., HTC, emergency room), check NO.

12. Highest inhibitor titer since birth or the last UDC visit: If the patient had an inhibitor titer measured at or since the last UDC visit, enter the **highest** inhibitor titer measurement and the date that this measurement was obtained. Do not include values measured at the current visit. If less than 1, enter 0 (zero) in the box before the decimal point when entering the test result. If the patient did not have an inhibitor titer measured at or since the last UDC visit, check the box next to NOT DONE.

12b. Immune tolerance therapy since birth or the last UDC visit: Check NO if the patient did not receive immune tolerance therapy since birth or the last UDC visit. Check UNKNOWN if it is not known whether or not the patient received immune tolerance therapy since birth or the last UDC visit. If the patient received immune tolerance therapy since birth or the last UDC visit, check YES. If yes, also check whether the therapy was SUCCESSFUL or UNSUCCESSFUL. Check SUCCESSFUL **only** if the patient can be effectively treated for a bleeding episode with a factor dosage appropriate to his/her hemophilia severity and its type. If immune tolerance therapy is no longer being given and the inhibitor is still present, check UNSUCCESSFUL. If immune tolerance therapy is still being given, check ONGOING. Check UNKNOWN, if the status of immune tolerance therapy is not known.

TREATMENT PRODUCTS

13. Treatment product(s) used since birth or the last visit: (check all that apply)

- NONE USED** **UNKNOWN**

Factor VIII, vWF, or Non-plasma Products

Factor IX, PCC, and Other Factor Products

Recombinant FVIII

- Advate
- Helixate FS
- Kogenate FS
- Recombinate
- ReFacto
- other, specify _____

Recombinant FIX

- BeneFIX
- other, specify _____

Monoclonal FVIII

- Hemofil M
- Monarc-M
- Monoclate P
- other, specify _____

Human FIX

- AlphaNine S-D
- Mononine
- other, specify _____

Prothrombin complex

- Bebulin VH
- Profilnine SD
- Proplex T
- other, specify _____

Human FVIII containing VWF

- Alphanate
- Humate P
- Koate DVI
- other, specify _____

Activated prothrombin complex

- Autoplex T
- FEIBA VH
- other, specify _____

Porcine factor VIII

- Hyate-C
- other, specify _____

Concentrates of other factors

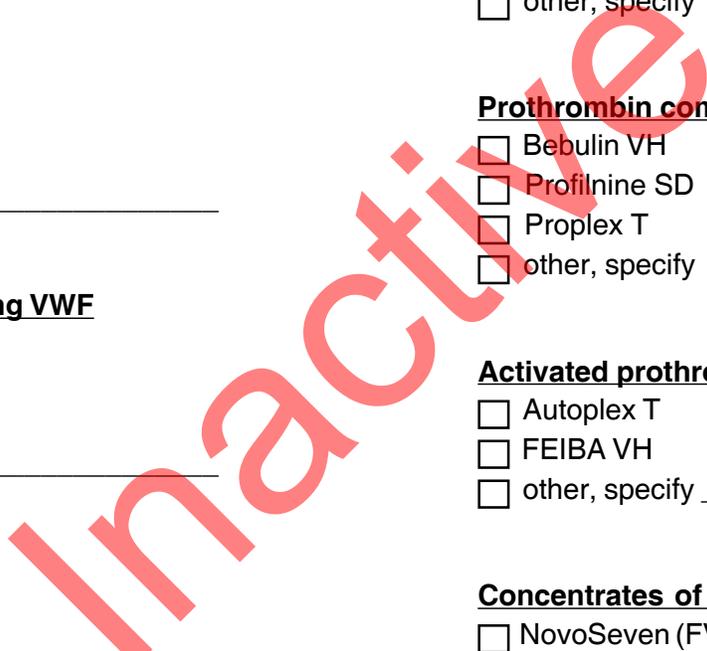
- NovoSeven (FVIIa)
- Fibrogammin P (FXIII)
- other, specify _____

Blood bank products

- cryoprecipitate
- fresh-frozen plasma, packed RBCs, or whole blood

Non-plasma and topical products

- Intravenous desmopressin (DDAVP)
- Nasal desmopressin (Stimate)
- Amicar
- Fibrin glue
- other, specify _____



BABY VISIT FORM

13. Treatment product(s) used since birth or the last visit: Check or enter all treatment products (including blood products, DDAVP, or Amicar) used by the patient since birth (if this is the first UDC visit) or the last visit. Check NONE USED, if the patient did not use any treatment products since the last visit. Check UNKNOWN, if you do not know whether the patient used treatment products since the last visit or if you are unable to determine which products were used.

Inactive

INFECTIOUS DISEASE INFORMATION

14. Status of hepatitis B vaccination (Check one)
(see explanation on reverse)

- Completed basic vaccine series
- Currently receiving basic vaccine series.
- Never received any doses of vaccine.
- Unknown.

14a. If vaccinated, check administration route and enter dates, if known.

- IM SQ - 1st Dose
 - IM SQ - 2nd Dose
 - IM SQ - 3rd Dose
- month year

HEAD INJURY AND BLEEDS INFORMATION

15. Number of head injuries since birth or last visit: **15a. If >0, number with skull fracture:**

16. Number of intracranial hemorrhages (ICH) since birth or last visit? **16a. If >0, fill in data below:**

ICH #1: (check all that apply)

- Site:** Intracerebral Subdural Subarachnoid Epidural Intra/periventricular Cerebellar
- Confirmed by:** Exam Xray Ultrasound MRI CT None Other (specify) _____
- Associated with:** Delivery Trauma Thrombocytopenia Procedural Spontaneous Other (specify) _____

ICH #2: (check all that apply)

- Site:** Intracerebral Subdural Subarachnoid Epidural Intra/periventricular Cerebellar
- Confirmed by:** Exam Xray Ultrasound MRI CT None Other (specify) _____
- Associated with:** Delivery Trauma Thrombocytopenia Procedural Spontaneous Other (specify) _____

ICH #3: (check all that apply)

- Site:** Intracerebral Subdural Subarachnoid Epidural Intra/periventricular Cerebellar
- Confirmed by:** Exam Xray Ultrasound MRI CT None Other (specify) _____
- Associated with:** Delivery Trauma Thrombocytopenia Procedural Spontaneous Other (specify) _____

17. Other bleed since birth or last visit? Yes No Unknown

17a. If yes, check the site(s) and enter the number of episodes of any other bleeding:

- | | | | |
|--|---|--|---|
| <input type="checkbox"/> Circumcision | <input type="text"/> <input type="text"/> | <input type="checkbox"/> Umbilicus | <input type="text"/> <input type="text"/> |
| <input type="checkbox"/> Oral / Nasal | <input type="text"/> <input type="text"/> | <input type="checkbox"/> Joint | <input type="text"/> <input type="text"/> |
| <input type="checkbox"/> Venipuncture / Heel stick / Surgical site | <input type="text"/> <input type="text"/> | <input type="checkbox"/> Gastrointestinal (upper or lower) | <input type="text"/> <input type="text"/> |
| <input type="checkbox"/> Soft tissue hematoma | <input type="text"/> <input type="text"/> | <input type="checkbox"/> Genitourinary, renal | <input type="text"/> <input type="text"/> |
| <input type="checkbox"/> Intramuscular hematoma | <input type="text"/> <input type="text"/> | <input type="checkbox"/> Pulmonary | <input type="text"/> <input type="text"/> |

LONG-TERM EFFECTS

18. Long-term effects due to bleeding since birth or last visit?

- Yes No Unknown

18a. If yes, Check all that apply (see reverse side):

- Focal Neurologic deficit(s)
- Seizure Disorder
- Hydrocephaly
- Neuropathy due to compartment syndrome
- Paralysis

BABY VISIT FORM--

INFECTIOUS DISEASE INFORMATION

14. Status of hepatitis B vaccination: Please complete this section according to the following guidelines:

- COMPLETED BASIC VACCINE SERIES: the completed basic series for hepatitis B is three doses of vaccine given within a 6-18 month period.
CURRENTLY RECEIVING BASIC VACCINE SERIES: patient has had at least 1 dose of vaccine within 12 months of the current visit but has not had the complete series.
NEVER RECEIVED ANY DOSES OF VACCINE: no evidence of vaccination is present in the medical record, and parent denies vaccination.
UNKNOWN: no record of vaccination in the medical record, and the parent is unsure whether or not the baby has received any doses of vaccine.

14a. If vaccinated, check administration route and enter dates, if known: If the patient has received any vaccinations for hepatitis B, check the box next to the appropriate route of administration, either intramuscular (IM) or subcutaneous (SQ), and enter the dates for each dose, if known.

HEAD INJURY AND BLEEDS INFORMATION

15. Number of head injuries since birth or the last visit: If the patient has experienced one or more head injuries **requiring treatment with factor** since birth or the last visit, enter the number of head injuries that required treatment with factor. If there has been no head injury that required factor treatment since birth or the last visit, enter 0 (zero).

15a. If >0, number with skull fracture: If the patient has experienced at least one head injury that required treatment with factor since birth or the last visit, enter the number of head injuries with an associated skull fracture that was documented by x-ray or other imaging study. If there has been no skull fracture since birth or the last visit, enter 0 (zero).

16. Number of Intracranial hemorrhages (ICH) since birth or the last visit: If the patient has experienced one or more ICHs since birth or the last visit, enter the number of ICHs. If there have been no ICHs or it is not known whether or not the patient has had an ICH since birth or the last visit, enter 0 (zero).

16a. If >0, fill in the data below: If the patient experienced one or more ICHs since birth or the last visit, check the appropriate boxes that indicate the site(s), the technique(s) used to confirm the ICH, and the factor(s) associated with the ICH for up to three of the events. Check all boxes that apply for each ICH occurrence. If the ICH is confirmed by an unlisted technique or associated with an unlisted factor, please check OTHER and use the space provided to write in the appropriate response.

17. Other bleed since birth or the last visit: If the patient experienced a bleed in one or more of the sites listed in 17a (see below) since birth or the last visit, check YES. If no bleeding at any of the listed sites occurred since birth or the last visit, check NO. Check UNKNOWN if it is not known whether bleeding occurred at any of the listed sites.

17a. Check the site(s) and enter the number of episodes of any other bleeding: If yes, check the box to the left of each site at which bleeding occurred since birth or the last visit. Enter the number of episodes of bleeding in the appropriate box(es) to the right of each site.

LONG-TERM EFFECTS

18. Long-term effects due to bleeding since birth or the last visit: If the patient, **as the result of a bleed**, developed any of the listed long-term effects since birth or the last visit, check YES. If no long-term effects from a bleed developed since birth or the last visit, check NO. If it is not known whether any long-term effects from a bleed developed since birth or the last visit, check UNKNOWN.

18a. If yes, check all that apply: Check the box next to any long-term effect from a bleed that has developed since birth or the last visit.

DEFINITIONS:

A focal neurologic deficit is an altered or decreased neurologic function, as a result of a bleed in the brain, spinal cord, nerve or muscle, and occurring in a specific location. It may result in an inability to speak, swallow, walk (balance), see or feel.

Examples include problems with:

1. Sensation (numbness or abnormal sensation).
2. Movement (weakness, increased or decreased muscle tone).
3. Speech (difficulty swallowing, hoarseness of voice).
4. Vision (vision loss, double vision, decreased visual fields).

Hydrocephaly - a condition characterized by abnormal accumulation of fluid in the cranial vault, accompanied by enlargement of the head, prominence of the forehead, atrophy of the brain, mental deterioration, and convulsions.

Paralysis - loss or impairment of motor function in a part due to lesion of the neural or muscular mechanism.

Seizure Disorder - a condition in which seizures (generalized or focal) recur, or are expected to recur, spontaneously/without new initiating factors **and** for which the participant has been placed on anti-convulsant medication or therapy.

Neuropathy due to compartment syndrome - A functional disturbance in an extremity due to a bleed into one of the the compartments located in the hand, forearm, upper arm, abdomen, buttock, or entire lower extremity.