Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities

Public Health Surveillance for the Prevention of Complications of Bleeding Disorders

CDC-RFA-DD15-1507
Supporting Information

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Division of Blood Disorders Acceptance Testing for External Data Collection and Transfer Systems

CDC's Division of Blood Disorders (DBD) will work with collaborators who wish to submit data for DBD-sponsored surveillance projects. In most instances DBD will provide a data collection and submission system. Collaborators who wish to submit data via another route will be required to provide documentation about their system and participate in testing to ensure accuracy and completeness of data transfer (acceptance testing). DBD will initiate the acceptance testing procedure after the collaborator has provided documentation and indicated that they are ready to transfer records to DBD. This is an outline of the major components of DBD's acceptance testing process:

- DBD will request the collaborator to train DBD personnel on the use of their system.
- The collaborator will set up user accounts for DBD personnel that will be exactly like the user accounts set up for data entry by collaborators.
- The collaborator will provide, at a minimum, data dictionaries, edit checks and business rules, and mapping algorithms for generated variables, and quality assurance/quality control documentation.
- DBD will enter sample records into the collaborator's system and maintain a separate record of the data values entered into the collaborator's system.
- The collaborator will process the data entered by DBD and provide electronic records in a mutually agreeable, nonproprietary format (such as a comma-separated file) to DBD.
- DBD will compare the provided electronic records to the DBD record of data entered.
- The system will be considered to have met acceptance criteria if no data value discrepancies are detected between the electronic records and the DBD records except for key entry errors.

CDC-RFA-DD15-1507: Strategy 2, Activity 2 (Annual Minimal Patient-Level Data Elements)

GENERAL INFORMATION

Form completed by

Form submitted date

HTC ID

Subject ID

Year of visit at which information was collected

PATIENT INFORMATION

1. Year of Birth
2. Gender
3. Ethnicity
4. Race
5. Zip code of residence at time of visit (first 3 digits only)
6. Health Insurance status at time of visit (Insured, Uninsured, Unknown)
7. Primary bleeding disorder diagnosis
8. Baseline factor activity
9. VWF:RCof
10. VWF:Ag
11. History of HCV infection?
12. History of HIV infection

CDC-RFA-DD15-1507: Data Elements Currently Collected under DD11-1103/DD14-1409 for Strategy 2, Activity 3 (Longitudinal, Patient-Level Health Indicator Data)

Data Elements Collected About Each Participant upon Enrollment

ADMINISTRATIVE INFORMATION

Form completed by
HTC ID
Subject ID
Date of visit

Did this participant give permission to store his/her blood specimens for future testing? Yes/No

Did this patient participate in the Universal Data Collection (UDC) project?
Yes/No (skip to #1)/Unknown (skip to #ME1)

If your institution does NOT allow linkage to UDC data, skip to #ME1.

Did this participant give permission to link data from this project to his/her UDC data? Yes/No (skip to #ME1)

If yes, is the CDC ID known? Yes/No (skip to #ME1)

If yes, then: CDC ID/Date of last UDC visit:

PATIENT INFORMATION

ME1. Date of Birth (M/Y or D/M/Y)

ME2. Gender (Sex): □ Male □ Female

ME3. Ethnicity (check one): □ Hispanic, Latino/a, or Spanish origin
□ Not Hispanic, Latino/a, or Spanish origin
□ Unknown

ME4. Race (check one or more): □ American Indian/Alaska Native
□ Asian
□ Black or African American
□ Native Hawaiian or Other Pacific Islander
□ White
□ Unknown

1. Weight (most recent): __ __kg/Date collected/ Weight unknown

2. Height (most recent): __ __ cm/Date collected/ Height unknown

ME5. Zipcode: __ __ __ __ __

3. Health insurance:
□ Commercial insurance ..... □ Primary
□ Military Health Care (TRICARE/VA/Champ-VA) ..... □ Primary
□ Medicaid ..... □ Primary
□ Medicare ..... □ Primary
□ State programs ..... □ Primary

Data Elements Collected About Each Participant in Subsequent Years of Participation

ADMINISTRATIVE INFORMATION

Form completed by
HTC ID
Subject ID
Date of visit

PATIENT INFORMATION

1. Weight (most recent): __ __kg/Date collected/ Weight unknown

2. Height (most recent): __ __ cm/Date collected/ Height unknown

3. Zipcode: __ __ __ __ __

4. Health insurance:
□ Commercial insurance ..... □ Primary
□ Military Health Care (TRICARE/VA/Champ-VA) ..... □ Primary
□ Medicaid ..... □ Primary
□ Medicare ..... □ Primary
□ State programs ..... □ Primary

☐ Indian Health Service ..... ☐ Primary
☐ Other ..... ☐ Primary
☐ Uninsured
☐ Unknown

4. Patient education level: check the highest education level completed by the patient.

☐ None
☐ Pre-elementary
☐ Primary / Secondary
5. Enter grade 1-12 __ __
☐ GED or equivalent
☐ Technical school
☐ Some college
☐ 2-year college degree (Associates)
☐ 4-year college degree (Bachelors)
☐ Advanced degree (Masters, Doctorate or professional)
☐ Other
☐ Unknown

Patients <18 years old only; otherwise skip to #8.

6. Parental education level: check the highest education level completed by either parent.

☐ None
☐ Pre-elementary
☐ Primary / Secondary
7. Enter grade 1-12 __ __
☐ GED or equivalent
☐ Technical school
☐ Some college
☐ 2-year college degree (Associates)
☐ 4-year college degree (Bachelors)
☐ Advanced degree (Masters, Doctorate or professional)
☐ Other
☐ Unknown

Patients >/= 18 years old only; otherwise skip to #10.

8. Patient employment status (check one):

☐ Employed full-time (skip to #10)
☐ Employed part-time (skip to #10)
☐ Not employed
☐ Unknown employment status (skip to #10)

9. If not employed, check one of the following:

☐ Child or student
☐ Homemaker
☐ Able, but not currently working
☐ Disabled
☐ Retired
☐ Other
☐ Unknown

10. Diagnosis (check all that apply)

Clotting Factor Deficiency	Baseline clotting factor activity	Age or Date diagnosed
☐ VIII (8)	__ __ __.__ __% .. ☐ <1%	☐ Activity unknown	__ __/Unk
☐ IX (9)	__ __ __.__ __% .. ☐ <1%	☐ Activity unknown	__ __/Unk
☐ I (afibrinogenemia) (1)	__ __ __.__ __ mg/dL	☐ Activity unknown	__ __/Unk
☐ I (dysfibrinogenemia) (1)	__ __ __.__ __ mg/dL	☐ Activity unknown	__ __/Unk
☐ I (hypofibrinogenemia) (1)	__ __ __.__ __ mg/dL	☐ Activity unknown	__ __/Unk
☐ I (Factor 1, hereditary, unspecified)	__ __ __.__ __% .. ☐ <1%	☐ Activity unknown	__ __/Unk
☐ II (prothrombin) (2)	__ __ __.__ __% .. ☐ <1%	☐ Activity unknown	__ __/Unk

☐ Indian Health Service ..... ☐ Primary
☐ Other ..... ☐ Primary
☐ Uninsured
☐ Unknown

5. Patient education level: check the highest education level completed by the patient.

☐ None
☐ Pre-elementary
☐ Primary / Secondary
6. Enter grade 1-12 __ __
☐ GED or equivalent
☐ Technical school
☐ Some college
☐ 2-year college degree (Associates)
☐ 4-year college degree (Bachelors)
☐ Advanced degree (Masters, Doctorate or professional)
☐ Other
☐ Unknown

Patients >/= 18 years old only; otherwise skip to #10.

7. Patient employment status (check one):

☐ Employed full-time (skip to #9)
☐ Employed part-time (skip to #9)
☐ Not employed
☐ Unknown employment status (skip to #9)

8. If not employed, check one of the following:

☐ Child or student
☐ Homemaker
☐ Able, but not currently working
☐ Disabled
☐ Retired
☐ Other
☐ Unknown

☐ V (5) .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
☐ V-VIII .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
(Combination 5 and 8)
☐ VII (7) .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
☐ X (10) .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
☐ XI (11) .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
☐ XIII (13) .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
☐ PAI-1 deficiency .....__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
(plasminogen activator inhibitor-1 deficiency)
☐ α2anti-plasmin deficiency .__ __ __.__ __% ☐ <1% ..... ☐ Activity unknown ... __ __/Unk
(α2-AP)

Von Willebrand disease (VWD) Age or Date diagnosed

☐ VWD Type 1 .....__ __/Unknown
☐ VWD Type 1C .....__ __/Unknown
☐ VWD Type 2A .....__ __/Unknown
☐ VWD Type 2B .....__ __/Unknown
☐ VWD Type 2M .....__ __/Unknown
☐ VWD Type 2N .....__ __/Unknown
☐ VWD Type 2, type unknown .....__ __/Unknown
☐ VWD Type 3 .....__ __/Unknown
☐ VWD type unknown .....__ __/Unknown
☐ VWD Other .....__ __/Unknown

VWF activity (lowest ever):
__ __ __.__ __% OR ☐ <lower limit of detection ☐ Unknown

VWF:Ag (same date as VWF activity above or lowest ever if VWF activity is unknown):
__ __ __.__ __% OR ☐ <lower limit of detection ☐ Unknown/Not collected on same date

FVIII Level (same date as VWF activity above or same date as VWF:Ag if VWF is unknown):
__ __ __.__ __% OR ☐ <1% ☐ Unknown/Not collected on same date

Inherited or Functional Platelet Disorder Age or Date diagnosed

☐ Bernard Soulier .....__ __/Unknown
☐ Glanzmann's thrombasthenia .....__ __/Unknown
☐ Grey platelet syndrome .....__ __/Unknown
☐ Hermansky-Pudlak syndrome .....__ __/Unknown
☐ Inherited thrombocytopenia .....__ __/Unknown
☐ Release defect .....__ __/Unknown
☐ Storage pool defect .....__ __/Unknown
☐ Hereditary platelet function disorder .....__ __/Unknown

Bleeding Disorder, no laboratory diagnosis

☐ Blood coagulation disorder with prolonged coagulation time .....__ __/Unknown
☐ Blood coagulation disorder with prolonged bleeding time .....__ __/Unknown
☐ Blood coagulation disorder with impaired clot retraction time .....__ __/Unknown

11. Age or Date of first bleed: Date/Date unknown/NA - has never had a bleed

12. Date of first treatment for bleeding with any source of clotting factor (including clotting factor concentrates, plasma or cryoprecipitate) or non-factor replacements such as Stimate (DDAVP) or an antifibrinolytic:

Date/Date unknown/NA - has never received treatment for bleeding

Patients <2 years of age only; otherwise skip to #14.

13. Method of delivery (check all that apply):

- □ Vaginal, unassisted
- □ Vaginal with forceps
- □ Vaginal with vacuum
- □ Vaginal, assistance unknown
- □ C-Section, Elective
- □ C-Section, Emergent/Non-elective
- □ C-Section, type unknown
- □ Unknown

14. Is there a history of this congenital bleeding disorder (including a known carrier) in any blood relative of this patient?

Yes/No/Unknown

15. Is the specific genetic mutation causing this patient's bleeding disorder known?

Yes/No/Unknown

16. In the past 12 months, where has the patient received services from the HTC (mark all that apply)?

- □ HTC's primary location
- □ HTC outreach clinic
- □ HTC telemedicine session or telemedicine clinic

If the patient has been diagnosed with a clotting factor deficiency, including VWD, answer question 17; otherwise, skip to question #28.

17. Most recent available inhibitor titer result:

□□□□□.□□ BU/mL □ Not detected Date drawn (MM/DD/YY)

□ No results available

18. Has the patient ever had a positive inhibitor titer? Yes (skip to #20)/No/Unknown

19. In the absence of a Bethesda assay, has the patient ever been diagnosed with or suspected to have an inhibitor based on clinical evidence?

Yes/No (skip to #28)/Unknown (skip to #28)

If yes, then

If the patient has more than one clotting factor deficiency, or vWD, answer question #20; otherwise, skip to #21.

20. To which factor was an inhibitor detected (mark all that apply)?

- □ FVIII (8)
- □ FIX (9)
- □ FI (fibrinogen)
- □ FII (2)
- □ FV (5)
- □ FVII (7)
- □ FX (10)
- □ FXI (11)
- □ FXIII (13)
- □ VWF
- □ PAI-1 deficiency
- □ α2anti-plasmin deficiency
- □ Unknown

9. Since the last surveillance visit, have any blood relative(s) of the patient been diagnosed with any of the same congenital bleeding disorder(s) as this patient (including new carrier diagnosis)? Yes/No/Unknown

10. Since the last surveillance visit, has the specific genetic mutation causing this patient's bleeding disorder been determined? Yes/No/Unknown

11. Since the last surveillance visit, where has the patient received services from the HTC (mark all that apply)?

- □ HTC's primary location
- □ HTC outreach clinic
- □ HTC telemedicine session or telemedicine clinic

If the patient has been diagnosed with a clotting factor deficiency including VWD, answer question #12 otherwise skip to question # 19.

12. Most recent inhibitor titer result:

□□□□□.□□ (BU/mL) □ Not detected Date Drawn: (MM/DD/YY)

□ No results available

21. Date inhibitor was first detected: Date/Date unknown

If the inhibitor was to FVIII or FIX answer #22; otherwise, skip to #28.

22. What was the highest historic inhibitor titer ever?
□□□□□.□□ BU/mL □ Unknown

23. Does the patient have a history of immune tolerance induction (ITI)?
Yes/No (skip to #26)/Unknown (skip to #26)

If yes,

24. Has the patient undergone more than one course of ITI?
Yes/No/Unknown

25. What was the highest historic inhibitor titer prior to initiation of the first course of ITI?
□□□□□.□□ BU/mL □ Unknown

26. Does the patient have a history of immune modulation therapy for treatment of an inhibitor? Yes/No/Unknown

27. For bleeding events requiring treatment, which of the following is/are currently used by this patient? Mark all that apply. If the patient is currently undergoing ITI, do not consider doses that are part of the ITI regimen; consider only doses used to treat bleeding events.

□ FVIII or FIX concentrates
If FVIII or FIX concentrates, then:
□ Routine doses and frequency
□ Increased doses or frequency or both
□ Unknown whether dose or frequency is routine or increased
□ Bypassing agents
□ Antifibrinolytics
□ Corticosteroids
□ Other
□ Unknown

28. Treatment regimen currently practiced by patient (check one):

□ Prophylaxis- Continuous
□ Prophylaxis- Continuous with by-passing agents plus ITI
□ Prophylaxis- Menstrual bleeding
□ Prophylaxis- Event-based, short-term or intermittent (skip to #35)
□ Immune tolerance induction without continuous prophylaxis with a by-passing agent (skip to #35)
□ Episodic (on-demand) (skip to #35)

*If patient does **NOT** use clotting factor concentrate for prophylaxis, skip to #35.*

If the patient has ever had a positive inhibitor titer, or been clinically diagnosed with an inhibitor, to FVIII or FIX, answer question #13; otherwise, skip to #19.

13. Since the last surveillance visit, what was the highest inhibitor titer?
□□□□□.□□ BU/mL □ Unknown

14. Since the last surveillance visit, has the patient been on immune tolerance therapy (ITI) at any time? Yes/No (Skip to #17)/Unknown (Skip to #17)

If yes,

15. Please describe the patient's use of ITI since the last surveillance visit (mark all that apply):

□ The patient began ITI for the first time ever
16. What was the highest historic inhibitor titer prior to the initiation of the first course of ITI?
□□□□□.□□ BU/mL □ Unknown
□ The patient continued a course of ITI begun at or before the last surveillance visit
□ The patient began a new course of ITI following previous ITI

17. Since the last surveillance visit, has the patient been on immune modulation therapy for treatment of an inhibitor at any time? Yes/No/Unknown

18. Currently, for bleeding events requiring treatment, which of the following is/are used by this patient? Mark all that apply. If the patient is currently undergoing ITI, do not consider doses that are part of the ITI regimen; consider only doses used to treat bleeding events.

□ FVIII or FIX concentrates
If FVIII or FIX concentrates, then:
□ Routine doses and frequency
□ Increased doses or frequency or both
□ Unknown whether dose or frequency is routine or increased
□ Bypassing agents
□ Antifibrinolytics
□ Corticosteriods
□ Other
□ Unknown

19. Treatment regimen currently practiced by patient (check one):

□ Prophylaxis-Continuous
□ Prophylaxis-Continuous with by-passing agents plus ITI
□ Prophylaxis- Menstrual bleeding
□ Prophylaxis- Event based, short-term or intermittent (skip to #27)
□ Immune tolerance induction without continuous prophylaxis with a by-passing agent (skip to #27)
□ Episodic (on demand) (skip to #27)

*If patient does **NOT** use clotting factor concentrate for prophylaxis, skip to #27*

If on continuous prophylaxis or prophylaxis for menstrual bleeding then,

29. Date or age at which continuous prophylaxis or prophylaxis for menstrual bleeding was first started:

Date : □□/□□/□□□□

OR

Age: □□ □ Days/ □ mos/ □ years (check one) or

Approximate age (if specific age unknown):

□ <3 years of age

□ 3-6 years of age

□ > 6 years of age

OR

□ Date or age unknown

30. History of joint bleeds prior to first beginning continuous prophylaxis or prophylaxis for menstrual bleeding (check one):

□ Fewer than 2 bleeds total (that is, 0 or 1 bleed total) into the large joints (ankle, knee, hip, elbow or shoulder)

□ 2 or more bleeds total into the large joints (ankle, knee, hip, elbow or shoulder)

□ Unknown

31. Current clotting factor product used for continuous prophylaxis or prophylaxis for menstrual bleeding (check all that apply):

□ Advate	□ Hemofil M	□ Profilnine SD
□ Alphanate	□ Humate-P	□ Proplex T
□ AlphaNine SD	□ Hyate:C	□ Recombinate
□ Autoplex T	□ Koate-DVI	□ ReFacto
□ Bebulin VH	□ Kogenate	□ RiaSTAP (fibrinogen, FI)
□ BeneFIX	□ Kogenate FS	□ Wilate
□ Bioclate	□ Konyne 80	□ Xyntha
□ Corifact (FXIII)	□ Monarc-M	
□ FEIBA NF	□ Monoclate-P	□ Unknown
□ FEIBA VH Immuno	□ Mononine	□ Other, specify _____
□ Fibrogammin P (FXIII)	□ NovoSeven (FVIIa)	
□ Helixate	□ Novoseven RT (FVIIa)	
□ Helixate FS	□ Novo13 (rXIII-A2)	

32. Current prescribed clotting factor dose for continuous prophylaxis or prophylaxis for menstrual bleeding:

Dose 1: □,□□□.□□ Units or mg/dose

Dose 2: □,□□□.□□ Units or mg/dose □ N/A- no second dose

If on continuous prophylaxis or prophylaxis for menstrual bleeding then:

20. Since the last surveillance visit, has the patient started continuous prophylaxis or prophylaxis for menstrual bleeding for the first time ever?

Yes/No (skip to # 23)/Unknown (skip to # 23)

21. Date or age at which continuous prophylaxis or prophylaxis for menstrual bleeding was first started:

Date: □□/□□/□□□□

OR

Age: □□ □ Days/ □ mos/ □ years (check one) or

Approximate age (if specific age unknown):

□ <3 years of age

□ 3-6 years of age

□ > 6 years of age

OR

□ Date or age unknown

22. History of joint bleeds prior to first beginning continuous prophylaxis or prophylaxis for menstrual bleeding (check one):

□ Fewer than 2 bleeds total (that is, 0 or 1 bleed total) into the large joints (ankle, knee, hip, elbow or shoulder)

□ 2 or more bleeds total into the large joints (ankle, knee, hip, elbow or shoulder)

□ Unknown

23. Current clotting factor product used for continuous prophylaxis or prophylaxis for menstrual bleeding (check all that apply):

□ Advate	□ Hemofil M	□ Profilnine SD
□ Alphanate	□ Humate-P	□ Proplex T
□ AlphaNine SD	□ Hyate:C	□ Recombinate
□ Autoplex T	□ Koate-DVI	□ ReFacto
□ Bebulin VH	□ Kogenate	□ RiaSTAP (fibrinogen, FI)
□ BeneFIX	□ Kogenate FS	□ Wilate
□ Bioclate	□ Konyne 80	□ Xyntha
□ Corifact (FXIII)	□ Monarc-M	
□ FEIBA NF	□ Monoclate-P	□ Unknown
□ FEIBA VH Immuno	□ Mononine	□ Other, specify _____
□ Fibrogammin P (FXIII)	□ NovoSeven (FVIIa)	
□ Helixate	□ Novoseven RT (FVIIa)	
□ Helixate FS	□ Novo13 (rXIII-A2)	

24. Current prescribed clotting factor dose for continuous prophylaxis or prophylaxis for menstrual bleeding:

Dose 1: □,□□□.□□ Units or mg/dose

Dose 2: □,□□□.□□ Units or mg/dose □ N/A- no second dose

33. Current prescribed infusion frequency for continuous prophylaxis or prophylaxis for menstrual bleeding:

Frequency for Dose 1: □□.□□ □ time(s)/week
OR □□.□□ □ time(s)/month □ Unknown
Frequency for Dose 2: □□.□□ □ time(s)/week
OR □□.□□ □ time(s)/month □ Unknown
□ N/A- no second dose

34. Approximate percent of doses for continuous prophylaxis or prophylaxis for menstrual bleeding missed in the last 12 months:

□ <10% □ >50%
□ 10-20% □ Unknown
□ 21-50%

35. Treatment product(s) used since the last UDC visit (if applicable; otherwise, in the last 12 months) (check all that apply):

□ Advate
□ Alphanate
□ AlphaNine SD
□ Autoplex T
□ Amicar Syrup (Aminocaproic acid)
□ Amicar Tablet (Aminocaproic acid)
□ Bebulin VH
□ BeneFIX
□ Bioclate
□ FEIBA VH Immuno
□ Corifact (FXIII)
□ Cryoprecipitated AHF (Cryoprecipitate)
□ DDVAP (desmopressin IV or SQ)
□ FEIBA NF
□ Fibrin glue (Tissell, Artiss)
□ Fibrogammin P (FXIII)
□ Fresh-frozen plasma
□ Helixate
□ Helixate FS
□ Hemofil M
□ Humate-P
□ Hyate:C
□ Koate-DVI
□ Kogenate
□ Konyne 80
□ Monarc-M
□ Monoclate-P
□ Mononine
□ NovoSeven (FVIIa)
□ Novoseven RT (FVIIa)
□ Novo13 (rXIII-A2)
□ Packed RBCs
□ Platelets
□ Profilnine SD
□ Proplex T
□ Recombinate
□ ReFacto
□ RiaSTAP (fibrinogen, FI)
□ Stimate (Nasal desmopressin)
□ Topical thrombin (Evithrom, Thrombin-JMI)
□ Tranexamic acid (Cyclokapron, Lysteda)
□ Whole blood
□ Wilate
□ Xyntha
□ None (skip to #38)
□ Unknown
□ Other, specify _____

36. Has the patient experienced an anaphylactic or allergic reaction to clotting factor concentrate since the last UDC visit (if applicable; otherwise, in the last 12 months)?

Yes/No (skip to #38)/Unknown (skip to #38)/None used (skip to #38)

25. Current prescribed infusion frequency for continuous prophylaxis or prophylaxis for menstrual bleeding:

Frequency for Dose 1: □□.□□ □ time(s)/week
OR □□.□□ □ time(s)/month □ Unknown
Frequency for Dose 2: □□.□□ □ time(s)/week
OR □□.□□ □ time(s)/month □ Unknown
□ N/A- no second dose

26. Approximate percent of doses for continuous prophylaxis or prophylaxis for menstrual bleeding missed in the last 12 months:

□ <10% □ >50%
□ 10-20% □ Unknown
□ 21-50%

27. Since the last surveillance visit, which treatment product(s) has the patient used? (check all that apply)

□ Advate
□ Alphanate
□ AlphaNine SD
□ Autoplex T
□ Amicar Syrup (Aminocaproic acid)
□ Amicar Tablet (Aminocaproic acid)
□ Bebulin VH
□ BeneFIX
□ Bioclate
□ FEIBA VH Immuno
□ Corifact (FXIII)
□ Cryoprecipitated AHF (Cryoprecipitate)
□ DDVAP (desmopressin IV or SQ)
□ FEIBA NF
□ Fibrin glue (Tissell, Artiss)
□ Fibrogammin P (FXIII)
□ Fresh-frozen plasma
□ Helixate
□ Helixate FS
□ Hemofil M
□ Humate-P
□ Hyate:C
□ Koate-DVI
□ Kogenate
□ Konyne 80
□ Monarc-M
□ Monoclate-P
□ Mononine
□ NovoSeven (FVIIa)
□ Novoseven RT (FVIIa)
□ Novo13 (rXIII-A2)
□ Packed RBCs
□ Platelets
□ Profilnine SD
□ Proplex T
□ Recombinate
□ ReFacto
□ RiaSTAP (fibrinogen, FI)
□ Stimate (Nasal desmopressin)
□ Topical thrombin (Evithrom, Thrombin-JMI)
□ Tranexamic acid (Cyclokapron, Lysteda)
□ Whole blood
□ Wilate
□ Xyntha
□ None (skip to #38)
□ Unknown
□ Other, specify _____

28. Has the patient experienced an anaphylactic or allergic reaction to clotting factor concentrate since the last UDC visit (if applicable; otherwise, in the last 12 months)?

Yes/No (skip to #30)/Unknown (skip to #38)/None used (skip to #30)

37. If yes, to which product was this reaction attributed (check all that apply)?

□ Advate	□ Hemofil M	□ Profilnine SD
□ Alphanate	□ Humate-P	□ Proplex T
□ AlphaNine SD	□ Hyate:C	□ Recombinate
□ Autoplex T	□ Koate-DVI	□ ReFacto
□ Bebulin VH	□ Kogenate	□ RiaSTAP (fibrinogen, FI)
□ BeneFIX	□ Kogenate FS	□ Wilate
□ Bioclate	□ Konyne 80	□ Xyntha
□ Corifact (FXIII)	□ Monarc-M	
□ FEIBA NF	□ Monoclate-P	□ Unknown
□ FEIBA VH Immuno	□ Mononine	□ Other, specify _____
□ Fibrogammin P (FXIII)	□ NovoSeven (FVIIa)	
□ Helixate	□ Novoseven RT (FVIIa)	
□ Helixate FS	□ Novo13 (rXIII-A2)	

38. Has the patient ever had a central venous access device (CVAD) placed?
Yes/No (skip to #42)/Unknown (skip to #42)

If yes, then
39. Did the patient have a CVAD in place at any time since the last UDC visit (if applicable; otherwise, in the last 12 months)? Yes/No (skip to #42)/Unknown (skip to #42)

40. Has the patient had a CVAD complication since the last UDC visit (if applicable; otherwise, in the last 12 months)? This includes complications from CVADs removed previous to this timeframe, such as post-thrombotic syndrome. Yes/No (skip to #42)/Unknown (skip to #42)

41. If yes, what kind of complication(s) (mark all that apply):

□ Bleeding	□ Thrombosis
□ Infection	□ Unknown
□ Mechanical	□ Other

42. Does the patient have a history of intracranial hemorrhage (ICH)?
Yes/No (skip to #49)/Unknown (skip to #49)

If yes, then
43. How many ICHs has the patient ever experienced?
__ __ Number/Unknown

44. Please provide the date or year of occurrence for each ICH.
ICH#1: Date/Date unknown
ICH#2: Date/Date unknown
ICH#3: Date/Date unknown

For ICH(s) that have occurred since the last UDC visit (if applicable; otherwise, in the last 12 months), complete the following for each:

29. If yes, to which product was this reaction attributed (check all that apply)?

□ Advate	□ Hemofil M	□ Profilnine SD
□ Alphanate	□ Humate-P	□ Proplex T
□ AlphaNine SD	□ Hyate:C	□ Recombinate
□ Autoplex T	□ Koate-DVI	□ ReFacto
□ Bebulin VH	□ Kogenate	□ RiaSTAP (fibrinogen, FI)
□ BeneFIX	□ Kogenate FS	□ Wilate
□ Bioclate	□ Konyne 80	□ Xyntha
□ Corifact (FXIII)	□ Monarc-M	
□ FEIBA NF	□ Monoclate-P	□ Unknown
□ FEIBA VH Immuno	□ Mononine	□ Other, specify _____
□ Fibrogammin P (FXIII)	□ NovoSeven (FVIIa)	
□ Helixate	□ Novoseven RT (FVIIa)	
□ Helixate FS	□ Novo13 (rXIII-A2)	

30. Since the last surveillance visit, has the patient had a central venous access device (CVAD) in place at any time?
Yes/No/Unknown

31. Since the last surveillance visit, has the patient had a CVAD complication? This includes complications from CVADs removed previous to the last surveillance visit such as post-thrombotic syndrome.
Yes/No (Skip to #33)/Unknown (Skip to #33)

32. If yes, what kind of complication(s) (mark all that apply)?

□ Bleeding	□ Thrombosis
□ Infection	□ Unknown
□ Mechanical	□ Other

33. Since the last surveillance visit, has the patient had an intracranial hemorrhage (ICH)?
Yes/No (Skip to #39)/Unknown (Skip to #39)

If yes, then
34. Since the last surveillance visit, how many ICHs has the patient experienced?
__ __ Number/Unknown

For ICH(s) that have occurred since the last surveillance visit, complete the following for each:

45. Date of occurrence:
ICH#i:
ICH#ii:
ICH#iii:

46. Was this ICH preceded by an episode of head trauma?
ICH#i: Yes/No/Unknown
ICH#ii: Yes/No/Unknown
ICH#iii: Yes/No/Unknown

47. Was the patient on continuous prophylaxis when the ICH occurred?
ICH#i: Yes/No/Unknown
ICH#ii: Yes/No/Unknown
ICH#iii: Yes/No/Unknown

48. When was the last infusion of factor given prior to onset of the ICH?
ICH#i: __ __ □ Days/ □ hours/ □ minutes □ More than 7 days □ Unknown
ICH#ii: __ __ □ Days/ □ hours/ □ minutes □ More than 7 days □ Unknown
ICH#iii: __ __ □ Days/ □ hours/ □ minutes □ More than 7 days □ Unknown

Patients <2 years of age only; otherwise skip to #52.

49. Did the patient undergo head imaging within 30 days of birth?
Yes/No (skip to #51)/Unknown (skip to #51)

50. If yes, what type of imaging was done (mark all that apply)?
□ CT (computed tomography) □ Other
□ MRI (magnetic resonance imaging) □ Imaging type unknown
□ US (ultrasound)

51. Other than ICH, at what site(s) did the patient experience bleeding <u>within 30 days of birth</u> (mark all that apply and indicate what the bleed was associated with or if spontaneous: mark spontaneous. See definitions for more complete instructions):

	<u>Bleed Sites</u>		<u>Bleed was associated with:</u>	
□	Gastrointestinal	Associated With	□ Circumcision	□ Thrombocytopenia
			□ Delivery	□ Trauma
			□ Dental procedure	□ Venipuncture
			□ Iatrogenic	□ Other med procedure
			□ Injection site	
			□ Lancet stick	□ Other
			□ Surgery	□ Spontaneous
□	Genitourinary, Hematuria	Associated With	□ Circumcision	□ Thrombocytopenia
			□ Delivery	□ Trauma
			□ Dental procedure	□ Venipuncture
			□ Iatrogenic	□ Other med procedure
			□ Injection site	
			□ Lancet stick	□ Other
			□ Surgery	□ Spontaneous

35. Date of occurrence:
ICH#i:
ICH#ii:
ICH#iii:

36. Was this ICH preceded by an episode of head trauma?
ICH#i: Yes/No/Unknown
ICH#ii: Yes/No/Unknown
ICH#iii: Yes/No/Unknown

37. Was the patient on continuous prophylaxis when the ICH occurred?
ICH#i: Yes/No/Unknown
ICH#ii: Yes/No/Unknown
ICH#iii: Yes/No/Unknown

38. When was the last infusion of factor given prior to onset of the ICH?
ICH#i: __ __ □ Days/ □ hours/ □ minutes □ More than 7 days □ Unknown
ICH#ii: __ __ □ Days/ □ hours/ □ minutes □ More than 7 days □ Unknown
ICH#iii: __ __ □ Days/ □ hours/ □ minutes □ More than 7 days □ Unknown

	Bleed Sites		Bleed was associated with:	
☐	Genitourinary, Other	Associated With	☐ Circumcision	☐ Thrombocytopenia
			☐ Delivery	☐ Trauma
			☐ Dental procedure	☐ Venipuncture
			☐ Iatrogenic	☐ Other med procedure
			☐ Injection site	
			☐ Lancet stick	☐ Other
			☐ Surgery	☐ Spontaneous
☐	Head- Extracranial	Associated With	☐ Circumcision	☐ Thrombocytopenia
			☐ Delivery	☐ Trauma
			☐ Dental procedure	☐ Venipuncture
			☐ Iatrogenic	☐ Other med procedure
			☐ Injection site	
			☐ Lancet stick	☐ Other
			☐ Surgery	☐ Spontaneous
☐	Joint	Associated With	☐ Circumcision	☐ Thrombocytopenia
			☐ Delivery	☐ Trauma
			☐ Dental procedure	☐ Venipuncture
			☐ Iatrogenic	☐ Other med procedure
			☐ Injection site	
			☐ Lancet stick	☐ Other
			☐ Surgery	☐ Spontaneous
☐	Muscle	Associated With	☐ Circumcision	☐ Thrombocytopenia
			☐ Delivery	☐ Trauma
			☐ Dental procedure	☐ Venipuncture
			☐ Iatrogenic	☐ Other med procedure
			☐ Injection site	
			☐ Lancet stick	☐ Other
			☐ Surgery	☐ Spontaneous
☐	Nasal Mucosa (including Epistaxis)	Associated With	☐ Circumcision	☐ Thrombocytopenia
			☐ Delivery	☐ Trauma
			☐ Dental procedure	☐ Venipuncture
			☐ Iatrogenic	☐ Other med procedure
			☐ Injection site	
			☐ Lancet stick	☐ Other
			☐ Surgery	☐ Spontaneous

Bleed Sites		Bleed was associated with:	
☐ Oral	Associated With	☐ Circumcision	☐ Thrombocytopenia
		☐ Delivery	☐ Trauma
		☐ Dental procedure	☐ Venipuncture
		☐ Iatrogenic	☐ Other med procedure
		☐ Injection site	
		☐ Lancet stick	☐ Other
		☐ Surgery	☐ Spontaneous
☐ Soft tissue	Associated With	☐ Circumcision	☐ Thrombocytopenia
		☐ Delivery	☐ Trauma
		☐ Dental procedure	☐ Venipuncture
		☐ Iatrogenic	☐ Other med procedure
		☐ Injection site	
		☐ Lancet stick	☐ Other
		☐ Surgery	☐ Spontaneous
☐ Spine	Associated With	☐ Circumcision	☐ Thrombocytopenia
		☐ Delivery	☐ Trauma
		☐ Dental procedure	☐ Venipuncture
		☐ Iatrogenic	☐ Other med procedure
		☐ Injection site	
		☐ Lancet stick	☐ Other
		☐ Surgery	☐ Spontaneous
☐ Umbilicus	Associated With	☐ Circumcision	☐ Thrombocytopenia
		☐ Delivery	☐ Trauma
		☐ Dental procedure	☐ Venipuncture
		☐ Iatrogenic	☐ Other med procedure
		☐ Injection site	
		☐ Lancet stick	☐ Other
		☐ Surgery	☐ Spontaneous
☐ Other Site	Associated With	☐ Circumcision	☐ Thrombocytopenia
		☐ Delivery	☐ Trauma
		☐ Dental procedure	☐ Venipuncture
		☐ Iatrogenic	☐ Other med procedure
		☐ Injection site	
		☐ Lancet stick	☐ Other
		☐ Surgery	☐ Spontaneous

☐ None

52. Does the patient have a history of joint bleeds ever? Yes/No (skip to #56)/Unknown (skip to #56)

53. If yes, Date or age at first joint bleed:

Date: MM/DD/YYYY

OR

Age: □□ □ Days/ □ mos/ □ years (check one) or

Approximate age (if specific age unknown):

□ <3 years of age

□ 3-6 years of age

□ > 6 years of age

OR

□ Date or age unknown

54. If yes, indicate which joints have a history of bleeds ever and the cumulative number of bleeds into each:

□ Ankle, left	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Ankle, right	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Elbow, left	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Elbow, right	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Hip, left	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Hip, right	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Knee, left	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Knee, right	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Shoulder, left	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown
□ Shoulder, right	#bleeds:	□ 1-3	□ 4-19	□ >/=20	□ Unknown

55. Method of ascertainment (mark all that apply):

□ Paper logs □ Medical Chart

□ Electronic logs □ Other

□ Factor Dispensing Records □ Unknown

□ Routine Patient contact (non-contemporaneous patient verbal report)

56. How many treated bleeding events has the patient had since the last UDC visit (if applicable; otherwise, in the last 12 months)?

__ __ __ Number/Unknown

57. Method of ascertainment (mark all that apply):

□ Paper logs □ Medical Chart

□ Electronic logs □ Other

□ Factor Dispensing Records □ Unknown

□ Routine Patient contact (non-contemporaneous patient verbal report)

39. Since the last surveillance visit, has the patient experienced any joint bleeds?

Yes/No (Skip to #44)/Unknown (Skip to #44)

If yes,

40. Since the last surveillance visit, has the patient experienced his/her first joint bleed ever?

Yes/No (Skip to #44)/Unknown (Skip to #44)

41. If yes, Date or age at first joint bleed:

Date: MM/DD/YYYY

OR

Age: □□ □ Days/ □ mos/ □ years (check one) or

Approximate age (if specific age unknown):

□ <3 years of age

□ 3-6 years of age

□ > 6 years of age

OR

□ Date or age unknown

42. Indicate which joints have experienced bleeds since the last surveillance visit and the total number of bleeds into each joint since the last surveillance visit:

Location of Bleed	**Number of Bleeds**	
□ Ankle, left	__ __ bleeds	□ # unknown
□ Ankle, right	__ __ bleeds	□ # unknown
□ Elbow, left	__ __ bleeds	□ # unknown
□ Elbow, right	__ __ bleeds	□ # unknown
□ Hip, left	__ __ bleeds	□ # unknown
□ Hip, right	__ __ bleeds	□ # unknown
□ Knee, left	__ __ bleeds	□ # unknown
□ Knee, right	__ __ bleeds	□ # unknown
□ Shoulder, left	__ __ bleeds	□ # unknown
□ Shoulder, right	__ __ bleeds	□ # unknown

43. Method of ascertainment (mark all that apply):

□ Paper logs □ Medical Chart

□ Electronic logs □ Other

□ Factor Dispensing Records □ Unknown

□ Routine Patient contact (non-contemporaneous patient verbal report)

44. Since the last surveillance visit, how many treated bleeding events has the patient had?

__ __ __ Number/Unknown

45. Method of ascertainment (mark all that apply):

□ Paper logs □ Medical Chart

□ Electronic logs □ Other

□ Factor Dispensing Records □ Unknown

□ Routine Patient contact (non-contemporaneous patient verbal report)

58. Other than ICH and joint bleeds, at what site(s) has the patient experienced bleeding in excess of that expected for a person without a bleeding disorder since the last UDC visit (if applicable; otherwise, in the last 12 months)? Mark all that apply and indicate what the bleed was associated with or if spontaneous: mark spontaneous. See definitions for more complete instructions):

Bleed Sites		Bleed was associated with:	
☐ Gastrointestinal	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Genitourinary, Hematuria	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Inject ion site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Genitourinary, Other	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Inject ion site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Head- Extracranial	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous

46. Other than ICH and joint bleeds, since the last surveillance visit, at what site(s) has the patient experienced bleeding in excess of that expected for a person without a bleeding disorder? Mark all that apply and what the bleed was associated with or if spontaneous: mark spontaneous. See definitions for more complete instructions.

Bleed Sites		Bleed was associated with:	
☐ Gastrointestinal	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Genitourinary, Hematuria	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Inject ion site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Genitourinary, Other	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Inject ion site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Head- Extracranial	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous

Bleed Sites		Bleed was associated with:	
☐ Joint	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Muscle	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Nasal Mucosa (including Epistaxis)	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Oral	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Soft tissue	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous

Bleed Sites		Bleed was associated with:	
☐ Joint	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Muscle	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Nasal Mucosa (including Epistaxis)	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Oral	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous
☐ Soft tissue	Associated With	☐ Circumcision	☐ Surgery
		☐ Delivery	☐ Thrombocytopenia
		☐ Dental procedure	☐ Trauma
		☐ Iatrogenic	☐ Venipuncture
		☐ Injection site	☐ Other med procedure
		☐ Lancet stick	
		☐ Menses	☐ Other
		☐ Post-partum	☐ Spontaneous

Bleed Sites

☐ Spine — Associated With — Bleed was associated with:

☐ Circumcision ☐ Surgery
☐ Delivery ☐ Thrombocytopenia
☐ Dental procedure ☐ Trauma
☐ Iatrogenic ☐ Venipuncture
☐ Injection site ☐ Other med procedure
☐ Lancet stick
☐ Menses ☐ Other
☐ Post-partum ☐ Spontaneous

☐ Other Site — Associated With — Bleed was associated with:

☐ Circumcision ☐ Surgery
☐ Delivery ☐ Thrombocytopenia
☐ Dental procedure ☐ Trauma
☐ Iatrogenic ☐ Venipuncture
☐ Injection site ☐ Other med procedure
☐ Lancet stick
☐ Menses ☐ Other
☐ Post-partum ☐ Spontaneous

☐ None

59. Does the patient have a history of any invasive joint procedure(s)?
Yes/No (skip to #61)/Unknown (skip to #61)

60. If yes, mark all procedures performed and the joint(s) on which each was performed:

	Ankle		Elbow		Hip		Knee		Shoulder	
	left	right	left	right	left	right	left	right	left	right
☐ Synovectomy, *arthroscopic*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Synovectomy, *open*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Synovectomy, *radioisotopic*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Synovectomy, *type unknown*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Surgical fusion/ arthrodesis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Joint replace-ment/arthroplasty	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Other invasive joint procedure	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Bleed Sites

☐ Spine — Associated With — Bleed was associated with:

☐ Circumcision ☐ Surgery
☐ Delivery ☐ Thrombocytopenia
☐ Dental procedure ☐ Trauma
☐ Iatrogenic ☐ Venipuncture
☐ Injection site ☐ Other med procedure
☐ Lancet stick
☐ Menses ☐ Other
☐ Post-partum ☐ Spontaneous

☐ Other Site — Associated With — Bleed was associated with:

☐ Circumcision ☐ Surgery
☐ Delivery ☐ Thrombocytopenia
☐ Dental procedure ☐ Trauma
☐ Iatrogenic ☐ Venipuncture
☐ Injection site ☐ Other med procedure
☐ Lancet stick
☐ Menses ☐ Other
☐ Post-partum ☐ Spontaneous

☐ None

47. Since the last surveillance visit, has the patient had an invasive joint procedure due to his/her bleeding disorder? Yes/No (Skip to #49)/Unknown (Skip to #49)

48. If yes, mark all procedures performed since the last surveillance visit and the joint(s) on which each was performed:

	Ankle		Elbow		Hip		Knee		Shoulder	
	left	right	left	right	left	right	left	right	left	right
☐ Synovectomy, *arthroscopic*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Synovectomy, *open*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Synovectomy, *radioisotopic*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Synovectomy, *type unknown*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Surgical fusion/ arthrodesis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Joint replace-ment/arthroplasty	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
☐ Other invasive joint procedure	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

61. Check the statement which best describes how pain, loss of motion or weakness due to joint disease affects the patient's current overall activity level:

- □ Unrestricted school or work and unrestricted recreational activities
- □ Unrestricted school or work with limited recreational activity levels
- □ Limited school or work and limited recreational activity levels
- □ Limited school or work, limited recreational activity levels, and limited self-care activity levels
- □ Requires assistance from another person for school or work or self-care, and unable to participate in recreation
- □ Unknown

62. In the last 12 months, has the patient experienced chronic pain related to his/her bleeding disorder? Yes/No (skip to #66)/Unknown (skip to #66)

63. If yes, about how often in the last 12 months did the patient experience chronic pain related to his/her bleeding disorder?
Every day/Most days/Some days/Unknown

64. In the last 12 months, has the patient been prescribed or used opioids for the treatment of chronic pain related to his/her bleeding disorder in the outpatient setting? Yes/No (skip to #66)/Unknown (skip to #66)

65. If yes, about how often in the last 12 months did the patient use opioids for chronic pain related to his/her bleeding disorder?
Every day/Most days/Some days/Never/Unknown

66. In the last 12 months, has the patient visited a hospital emergency room for a bleed or other complication of his/her bleeding disorder?
Yes/No (skip to #68)/Unknown (skip to #68)

67. If yes, how many emergency room visits did the patient have due to his/her bleeding disorder in the last 12 months?
__ __ (Number)/Unknown

68. In the last 12 months, has the patient been admitted to a hospital as an inpatient due to a bleed or other complication of his/her bleeding disorder?
Yes/No (skip to #71)/Unknown (skip to #71)

69. If yes, how many inpatient admissions did the patient have due to his/her bleeding disorder in the last 12 months?
__ __ (Number)/Unknown

70. How many nights total did the patient spend as an inpatient due to his/her bleeding disorder in the last 12 months?
__ __ (Number nights)/Unknown

71. In the last 12 months, how many days has the patient missed from school or work due to his/her bleeding disorder?
__ __ __.__ __ (Number)/Unknown/NA

49. Check the statement which best describes how pain, loss of motion or weakness due to joint disease affects the patient's current overall activity level:

- □ Unrestricted school or work and unrestricted recreational activities
- □ Unrestricted school or work with limited recreational activity levels
- □ Limited school or work and limited recreational activity levels
- □ Limited school or work, limited recreational activity levels, and limited self-care activity levels
- □ Requires assistance from another person for school or work or self-care, and unable to participate in recreation
- □ Unknown

50. Since the last surveillance visit, has the patient experienced chronic pain related to his/her bleeding disorder? Yes/No (skip to #54)/Unknown (skip to #54)

51. If yes, since the last surveillance visit, about how often has the patient experienced chronic pain related to his/her bleeding disorder?
Every day/Most days/Some days/Unknown

52. Since the last surveillance visit, has the patient been prescribed or used opioids for the treatment of chronic pain related to his/her bleeding disorder in the outpatient setting?
Yes/No (skip to #54)/Unknown (skip to #54)

53. If yes, since the last surveillance visit, about how often has the patient used opioids for chronic pain related to his/her bleeding disorder?
Every day/Most days/Some days/Never/Unknown

54. Since the last surveillance visit, has the patient visited a hospital emergency room for a bleed or other complication of his/her bleeding disorder?
Yes/No (skip to #56)/Unknown (skip to #56)

55. If yes, since the last surveillance visit, how many emergency room visits has the patient had due to his/her bleeding disorder?
__ __ (Number)/Unknown

56. Since the last surveillance visit, has the patient been admitted to a hospital as an inpatient due to a bleed or other complication of his/her bleeding disorder?
Yes/No (skip to #59)/Unknown (skip to #59)

57. If yes, since the last surveillance visit, how many inpatient admissions has the patient had due to his/her bleeding disorder?
__ __ (Number)/Unknown

58. Since the last surveillance visit, how many nights total did the patient spend as an inpatient due to his/her bleeding disorder?
__ __ (Number nights)/Unknown

59. Since the last surveillance visit, how many days has the patient missed from school, or work due to his/her bleeding disorder?
__ __ __.__ __ (Number)/Unknown/N/A

72. Does the patient have a history of HBV (hepatitis B virus) infection (active or resolved)? Yes/No/Unknown

ME8. Does the patient have a history of HCV infection (active or resolved)? Yes/No/Unknown

ME9. Does the patient have a history of HIV infection? Yes/No/Unknown

73. Does the patient have a history of vaccination for hepatitis A?
Yes/No (skip to #75)/Unknown (skip to #75)

74. If yes, what is the status of vaccination?
Completed basic vaccine series/Incompletely vaccinated/Unknown

75. Does the patient have a history of vaccination for hepatitis B?
Yes/No (skip to #77)/Unknown (skip to #77)

76. If yes, what is the status of vaccination?
Completed basic vaccine series/Incompletely vaccinated/Unknown

If patient is female, skip to #80.

77. If male, has the patient undergone circumcision?
Yes/No (skip to #84)/Unknown (skip to #84)

If yes, then

78. Did excessive bleeding occur with the circumcision? Yes/No/Unknown

79. Was the circumcision performed under clotting factor concentrate coverage? Yes/No/Unknown

If patient is male, skip to #84.

80. If female, in the last 12 months, has the patient been prescribed iron replacement treatment (other than in pregnancy)? Yes/No/Unknown

81. If female, in the last 12 months has the patient experienced menstrual bleeding requiring a change in hygiene protection every 2 hours or more frequently?
Yes/No/Unknown

82. If female, has the patient undergone a hysterectomy?
Yes/No (skip to #84)/Unknown (skip to #84)

83. If yes, then age or date hysterectomy was performed:
__ __ Age/Date/Date unknown

60. Since the last surveillance visit, has the patient received any doses of hepatitis A vaccine?
Yes/No (skip to #62)/Unknown (skip to #62)

61. If yes, what is the status of the vaccination?
Completed basic vaccine series/Incompletely vaccinated/Unknown

62. Since the last surveillance visit, has the patient received any doses of hepatitis B vaccine?
Yes/No (skip to #64)/Unknown (skip to #64)

63. If yes, what is the status of the vaccination?
Completed basic vaccine series/Incompletely vaccinated/Unknown

If patient is female skip to # 67.

64. If male, since the last surveillance visit, has the patient been circumcised?
Yes/No (skip to #71)/Unknown (skip to #71)

If yes then,

65. Did excessive bleeding occur with the circumcision? Yes/No/Unknown

66. Was the circumcision performed under clotting factor concentrate coverage? Yes/No/Unknown

If patient is male skip to # 71.

67. If female, since the last surveillance visit, has the patient been prescribed iron replacement treatment (other than in pregnancy)? Yes/No/Unknown

68. If female, since the last surveillance visit, has the patient experienced menstrual bleeding requiring a change in hygiene protection every 2 hours or more frequently? Yes/No/Unknown

69. If female, since the last surveillance visit, has the patient undergone a hysterectomy?
Yes/No (skip to # 71)/Unknown (skip to #71)

70. If yes, what was the age or date that the hysterectomy was performed?
__ __ Age/Date/Date unknown

84. Has the patient ever been diagnosed with any of the following conditions?

Cancer

84i.	Hepatocellular carcinoma (HCC)	Yes/No history of/Unknown
84ii.	Leukemia (any type)	Yes/No history of/Unknown
84iii.	Cancer other than HCC and leukemia	Yes/No history of/Unknown

Bone disease

84iv.	Fracture of a bone	Yes/No history of/Unknown
84v.	Osteopenia	Yes/No history of/Unknown
84vi.	Osteoporosis	Yes/No history of/Unknown

Cardiovascular disease

84vii.	Acute ischemic stroke (AIS)	Yes/No history of/Unknown
84viii.	Atrial fibrillation	Yes/No history of/Unknown
84ix.	Coronary artery disease	Yes/No history of/Unknown
84x.	Congestive heart failure	Yes/No history of/Unknown
84xi.	Myocardial infarction	Yes/No history of/Unknown
84xii.	Transient ischemic attack (TIA)	Yes/No history of/Unknown

Kidney disease

84xiii.	Chronic kidney disease/CKD	Yes/No history of/Unknown
84xiv.	Kidney stones (renal urolith, nephrolith, nephrolithiasis)	Yes/No history of/Unknown
84xv.	Nephrotic syndrome	Yes/No history of/Unknown

Liver disease or failure

84xvi.	Ascites	Yes/No history of/Unknown
84xvii.	Cirrhosis	Yes/No history of/Unknown
84xviii.	Hepatic fibrosis or	Yes/No history of/Unknown
84xix.	Splenomegaly	Yes/No history of/Unknown
84xx.	Varices (esophageal or gastric)	Yes/No history of/Unknown

Thrombosis

84xxi.	Deep vein thrombosis (DVT)	Yes/No history of/Unknown
84xxii.	Pulmonary embolism (PE)	Yes/No history of/Unknown

Other

84xxiii.	Anxiety	Yes/No history of/Unknown
84xxiv.	Depression	Yes/No history of/Unknown
84xxv.	Diabetes mellitus (other than gestational diabetes)	Yes/No history of/Unknown
84xxvi.	Hypertension	Yes/No history of/Unknown
84xxvii.	Iron deficiency anemia	Yes/No history of/Unknown
84xxviii.	Pseudotumor	Yes/No history of/Unknown

71. Since the last surveillance visit, has the patient been diagnosed with any of the following conditions?

Cancer

84i.	Hepatocellular carcinoma (HCC)	Yes/No history of/Unknown
84ii.	Leukemia (any type)	Yes/No history of/Unknown
84iii.	Cancer other than HCC and leukemia	Yes/No history of/Unknown

Bone disease

84iv.	Fracture of a bone	Yes/No history of/Unknown
84v.	Osteopenia	Yes/No history of/Unknown
84vi.	Osteoporosis	Yes/No history of/Unknown

Cardiovascular disease

84vii.	Acute ischemic stroke (AIS)	Yes/No history of/Unknown
84viii.	Atrial fibrillation	Yes/No history of/Unknown
84ix.	Coronary artery disease	Yes/No history of/Unknown
84x.	Congestive heart failure	Yes/No history of/Unknown
84xi.	Myocardial infarction	Yes/No history of/Unknown
84xii.	Transient ischemic attack (TIA)	Yes/No history of/Unknown

Kidney disease

84xiii.	Chronic kidney disease/CKD	Yes/No history of/Unknown
84xiv.	Kidney stones (renal urolith, nephrolith, nephrolithiasis)	Yes/No history of/Unknown
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84xvi.	Ascites	Yes/No history of/Unknown
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84xviii.	Hepatic fibrosis or	Yes/No history of/Unknown
84xix.	Splenomegaly	Yes/No history of/Unknown
84xx.	Varices (esophageal or gastric)	Yes/No history of/Unknown

Thrombosis

84xxi.	Deep vein thrombosis (DVT)	Yes/No history of/Unknown
84xxii.	Pulmonary embolism (PE)	Yes/No history of/Unknown

Other

84xxiii.	Anxiety	Yes/No history of/Unknown
84xxiv.	Depression	Yes/No history of/Unknown
84xxv.	Diabetes mellitus (other than gestational diabetes)	Yes/No history of/Unknown
84xxvi.	Hypertension	Yes/No history of/Unknown
84xxvii.	Iron deficiency anemia	Yes/No history of/Unknown
84xxviii.	Pseudotumor	Yes/No history of/Unknown

85. Does the patient have a history of having ever undergone any of the following procedures?

85i.	Coronary angioplasty or stent placement	Yes/No history of/Unknown
85ii.	Coronary artery bypass graft (CABG)	Yes/No history of/Unknown
85iii.	Dialysis (peritoneal or hemodialysis)	Yes/No history of/Unknown
85iv.	Heart valve replacement or repair	Yes/No history of/Unknown
85v.	Kidney transplant	Yes/No history of/Unknown
85vi.	Liver transplant	Yes/No history of/Unknown
85vii.	Peripheral revascularization (including carotid revascularization)	Yes/No history of/Unknown

86. In the past 12 months, has the patient undergone surgery?

Yes/No (stop)/Unknown (stop)

If yes, then

87. List all surgical procedures that the patient has undergone in the past 12 months and the date (month & year) each was performed:

a. _____Date:

b. _____Date:

c. _____Date:

d. _____Date:

e. _____Date:

72. Since the last surveillance visit, has the patient undergone any of the following procedures?

72i.	Coronary angioplasty or stent placement	Yes/No/Unknown
72ii.	Coronary artery bypass graft (CABG)	Yes/No/Unknown
72iii.	Dialysis (peritoneal or hemodialysis)	Yes/No/Unknown
72iv.	Heart valve replacement or repair	Yes/No/Unknown
72v.	Kidney transplant	Yes/No/Unknown
72vi.	Liver transplant	Yes/No/Unknown
72vii.	Peripheral revascularization (including carotid revascularization)	Yes/No/Unknown

73. Since the last surveillance visit, has the patient undergone surgery?

Yes/No (stop)/Unknown (stop)

If yes, then

74. List all surgical procedures that the patient has undergone in the past 12 months and the date (month & year) each was performed:

a. _____Date:

b. _____Date:

c. _____Date:

d. _____Date:

e. _____Date:

CDC-RFA-DD15-1507: Strategy 2, Activity 4 (Patient-Level Mortality Data Elements)

GENERAL INFORMATION

Form completed by

Form completed date

HTC ID

Subject ID

PATIENT INFORMATION

1. Age at time of death
2. Gender
3. Ethnicity
4. Race
5. Primary bleeding disorder diagnosis
6. Baseline factor activity
7. VWF:RCof
8. VWF:Ag
9. History of HBV infection?
10. History of HCV infection?
11. History of HIV infection?
12. Year of death
13. Sources of information about the death
14. Was an autopsy performed?
15. Type of autopsy performed
16. Primary cause of death
17. Contributing causes of death
18. Primary cause of death, categorized

CDC-RFA-DD15-1507: Regional Organization of the United States Hemophilia Treatment Center Network (USHTCN)

The USHTCN is currently organized into these eight regions by the The Health Resources and Services Administration (HRSA):

1) New England, including the states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York and Puerto Rico and the Virgin Islands.

2) Mid-Atlantic, including the states of Delaware, Maryland, Pennsylvania, Virginia, West Virginia and the District of Columbia.

3) Southeast, including the states of Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.

4) Great Lakes, including the states of Indiana, Michigan, and Ohio.

5) Northern States, including the states of Illinois, Minnesota, Wisconsin, North Dakota, and South Dakota.

6) Great Plains, including the states of Arkansas, Iowa, Louisiana, Kansas, Missouri, Nebraska, Oklahoma, and Texas.

7) Mountain States, including the states of Alaska, Arizona, Colorado, Idaho, Montana, New Mexico, Utah, Wyoming, Oregon, and Washington.

8) Western States, including the states of California, Hawaii, Nevada and American Samoa, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, Guam, the Marshall Islands, and the Republic of Palau.

The Regional Coordinators and Regional Directors of each of these regions, as well as the HTCs that are part of the USHTCN, are listed in the HTC Directory at https://www2a.cdc.gov/ncbddd/htcweb/Dir_Report/Dir_Search.asp. The HTC Directory is organized according the regional structure that existed prior to 2012 under which there were twelve regions. The regions listed in the HTC Directory correspond to the current HRSA regions as indicated below.

Current HRSA Regional Designation	Previous Regional Designation
New England	Region I and Region II
Mid-Atlantic	Region III
Southeast	Region IV-North and Region IV-South
Great Lakes	Region V-East
Northern States	Region V-West
Great Plains	Region VI and Region VIII
Mountain States	Region VIII and Region X
Western States	Region IX

CDC-RFA-DD15-1507: Strategy 3, Activity 1 and 2 (Specimen Form Elements)

GENERAL INFORMATION

HTC ID

Subject ID

CDC ID

Specimen collection date

Manner of collection of plasma specimen

Reason for submitting plasma

PATIENT INFORMATION

1. Date of Birth
2. Gender
3. Diagnosis
4. History of HCV infection?
5. History of HIV infection?
6. Most recent inhibitor titer result
7. History of inhibitor?