HTC Population Profile for Bleeding Disorders Surveillance

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On behalf of Science Committee
Surveillance Project = 2 Projects

- HTC Population Profile
- Registry
Objective

Provide a broad description of the population of patients seen at hemophilia treatment centers from which the registry data is derived.
Which Patients?
Diagnoses Included

1. Clotting factor Deficiency:
   • Factor II-XI,
   • Factor XIII,
   • Fibrinogen
2. Von Willebrand Disease
3. Inherited platelet disorders
4. Connective tissue disorders
5. Bleeding disorder, no laboratory diagnosis
6. Venous thromboembolism
Which Patients?
Diagnoses Excluded

1. Other or Non-hematologic disorders
2. Acquired bleeding disorders
What does it mean to be seen at an HTC?

- Clinical encounter can:
  - be a comprehensive, consultation, non-office visit, office visit, or study visit.
  - occur through a primary clinic, outreach clinic, or telemedicine (video) clinic

- HTCs must be:
  - part of the US Hemophilia Treatment Center Network (USHTCN)
  - have a fully executed subcontract agreement with their regional core center.
All Patients with inherited bleeding disorders and venous thrombosis

All HTC Patients

HTC Population Profile

Registry data collected
What data will be submitted?

• No HIPAA identifiers
  — All 18 HIPAA identifiers are removed
  — Although individual data is collected, it is considered a HIPAA compliant de-identified dataset
Data Elements

- Race
- Ethnicity
- Gender
- Year of Birth
- Zip Code (3 digit)
- Insurance Status
- Year of Visit to HTC
- HTC Identifier

- Primary diagnosis
  - Baseline factor level/VWD labs
  - VTE occurrence
- HCV Status
- HIV Status
- Unique Identifier
How will the data be collected?

• The population profile will be a new form in ATHN Study Manager

• Data that is already contained in WebTracker will pre-populate the new form
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**The “Form” – When Data is in WT**
# The “Form” – As Submitted

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6. Health Insurance status

Report whether the patient had health insurance at the time of the visit during which information was collected. Check the category that applies.

**Insured** - If the patient was covered by one or more of the following health insurance types: Medicare, Medicare HMO, Medicaid, Medicaid HMO, Commercial indemnity, Commercial PPO, Commercial HMO, State high risk insurance pools, Indian Health Service or TRICARE (military).

**Uninsured** - If the patient did not have health insurance. Patients receiving product support from pharmaceutical companies without any other coverage should be considered uninsured.

**Unknown** - If it is not known whether the patient had health insurance at the time of the visit during which information was collected.
7. Primary Bleeding or Clotting Disorder Diagnosis

This reflects the primary diagnosis of the patient. The system will report the primary diagnosis recorded for the patient. Confirm only one primary bleeding or clotting disorder diagnosis is recorded.
7a. **Baseline factor activity**

For patients with deficiency of clotting factors FI-FXIII including factor VIII or factor IX deficiency, enter the value that most accurately reflects the patient's baseline factor activity level (the level of clotting factor activity which best represents the patient’s inherent clotting factor activity).
7b. - 7d. Baseline factor FVIII activity, Von Willebrand factor activity, Von Willebrand factor antigen level

For patients with a primary diagnosis of von Willebrand disease record the following if known:

b. The lowest ever Von Willebrand factor activity (VWF:RCoF)

c. The Von Willebrand factor antigen level (VWF:Ag) from the same day as the VWF:RCoF

d. The baseline FVIII level, from the same day as the VWF:RCoF
HTC Population Profile Data
Entry Tools

7. Patients without a Bleeding Disorder with Venous Thromboembolism (VTE)
This section is reserved for patients without a bleeding disorder with a diagnosis (either primary or other) of a VTE who are being seen by the HTC for diagnosis, care or management of a VTE or its sequelae.

If patient does not have a primary diagnosis indicated above in sections marked Clotting Factor Deficiency, Von Willebrand Disease, Inherited or Functional Platelet Disorder, Connective Tissue Disorder, or Bleeding Disorder, No Laboratory Diagnosis, but does have a diagnosis (primary or other) of one or more VTE events described in 7e. (below), check the VTE check box.
7e. Historical VTE Events Experienced

For patients with a primary diagnosis of “Venous Thromboembolism (VTE)”, check all types of VTE events described below EVER experienced by the patient:

- Pulmonary embolism (PE)
- Thrombosis, abdominal vein (thrombosis of the mesenteric, portal or renal veins)
- Thrombosis, deep venous
- Thrombosis, deep venous of lower extremity or pelvis
- Thrombosis, deep venous of upper extremity or upper thorax
Feasibility Assessment

Completed by:
14 HTCs (5 Beta sites, 9 volunteer sites)
- 10 regions represented
- Diversity in size and staffing
- Range of staff using WebTracker
- Mixture of WebTracker utilization

Each site reviewed 5-10 patients with a diversity of diagnoses and recorded:
- If the data elements were in WebTracker
- How long it took to find them in WebTracker or from all sources
Feasibility Review

Time to find complete HTC Population Profile data from all sources.

- $\leq 1$ minute, 26%
- 2-5 minutes, 47%
- 5-10 minutes, 14%
- $>10$ minutes, 10%
Lessons Learned

History of HIV and HCV infection:
- Not easily found for ~ 20% of the subjects
- Absence most common in subjects with diagnosis other than hemophilia A, B or VWD

Change made:
- These questions are not required for other diagnoses.
Lessons Learned

Insurance status:
Not found in WebTracker for 37% of subjects
— Capturing this data on all patients will be emphasized in training with HTC staff on this project and others.
Data Transmission

• Since mid August, the ATHN beta sites have been submitting HTC Population Profile data to CDC.

• The CDC has validated the data transmission!
How Many Patients Included?

Target Goal:
15,477 in Year 2 of the project (October 2012 – September 2013)

This target equals approximately 85% of patients physically seen nationally each year at an HTC for an annual comprehensive care evaluation as reported in the 2010 Hemophilia Data Set.
Next Steps

• Local HTC personnel complete training
• Obtain access to the ATHN study manager
• Start submitting data!