Community Counts: A US National Surveillance System for Bleeding and Clotting Disorders.

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Background

It is difficult to establish demographic and outcome data using hospital databases because many bleeding and clotting disorders are rare and hospital coding systems are imprecise. In order to identify outcomes requiring treatment, prevention or research, representative databases of at-risk populations are required.

Objective

Community Counts is an initiative of the Centers for Disease Control and Prevention (CDC) with the American Thrombosis and Hemostasis Network (ATHN) and the United States Hemophilia Treatment Center Network (USHTCN), consisting of 130+ clinics in 11 geographic regions. The objective of **Community Counts** is to develop a disease-specific national surveillance of bleeding and clotting disorders.

Materials and Methods

Community Counts collects patient level data across the United States (US) in three parts.

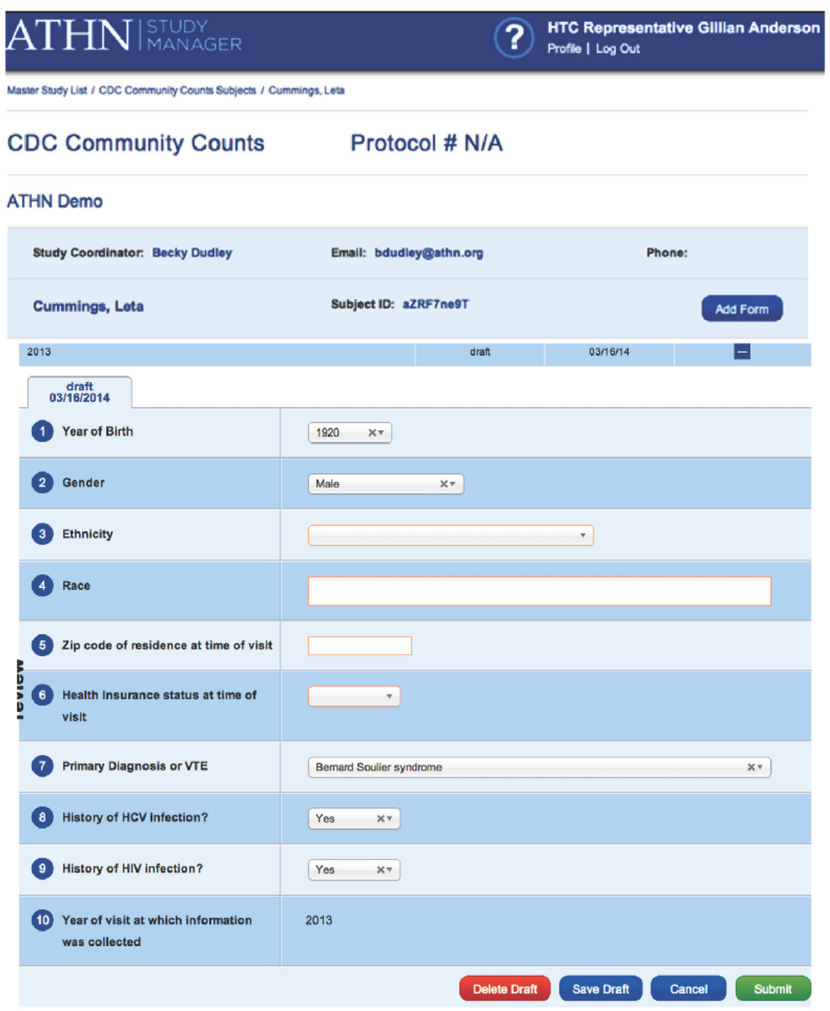
HTC Population Profile (HTC PP)—records all patients seen at the USHTCN including demographics, insurance, diagnosis, factor level, venous thromboembolism (VTE), and transfusion-acquired infections.

Mortality Reporting—reports cause of death for patients with bleeding disorders.

Registry for Bleeding Disorders—collects bleeding events including intracranial hemorrhage and hemarthroses, inhibitor formation, arthropathy, surgery, treatment regimens including prophylaxis, product use, mobility, pain, education, employment, genetics, family history and other medical conditions. Blood samples are collected for inhibitor and viral safety testing.

Community Counts is organized through ATHN with Administrative and Science Committees representing the USHTCN. The Executive Committee is formed by the Chair and Co-Chair of the two committees, and 2 representatives each from ATHN and CDC. ATHN maintains the secure collection and storage of the data via electronic case report forms and their infrastructure shown in *Figure 1*.

Figure 1. Community Counts HTC PP Case Report Form in ATHN Study Manager



Names and information included in Figure 1 are for demonstration purposes and do not represent actual persons.

Results

Data collection was initiated September 2012. As of March 31, 2014, 36,318 unique patients with 52,166 annual visits were entered into the HTC PP.

Thirteen point nine percent of patients were identified as Hispanic. Eighty-three point eight percent were identified as white race, 11.4% as black; and 2.7% as Asian. Diagnoses included: Hemophilia A (32.2%); von Willebrand disease (26.0%); VTE (18.8%); Hemophilia B (10.0%); and Inherited or Functional Platelet Disorder (7.2%), Rare Clotting Factor Deficiencies (4.6%), Connective Tissue Disorder (0.2%) and bleeding disorder with no laboratory diagnosis (1.0%) shown in *Table 1 and Figure 2*.

Table 1, Figure 2. HTC Population Profile: Diagnoses of Patients

Diagnosis	Freq	Percent
Hemophilia A (FVIII)	11,690	32.19
Hemophilia B (FIX)	3,621	9.97
VWD	9,448	26.01
VTE	6,817	18.77
Bleeding Disorder, no laboratory diagnosis.	378	1.04
Other (rare clotting factor deficiencies, connective tissue, and inherited or functional platelet disorders)	4,364	12.02

Sixty-seven percent of the population was 30 years of age or younger; 63% were male; 95% were insured *(shown in Figures 3, 4, and 5)*. Among patients with a bleeding disorder, 4% were HIV positive and 13% were HCV positive. Among hemophilia A patients, 51% were severe and 48% were moderate or mild.

Figure 3. Hemophilia Treatment Center Patient Population: Age

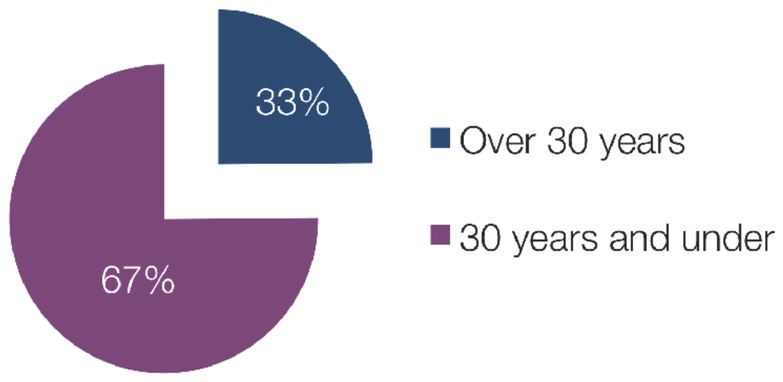


Figure 4. Hemophilia Treatment Center Patient Population: Gender

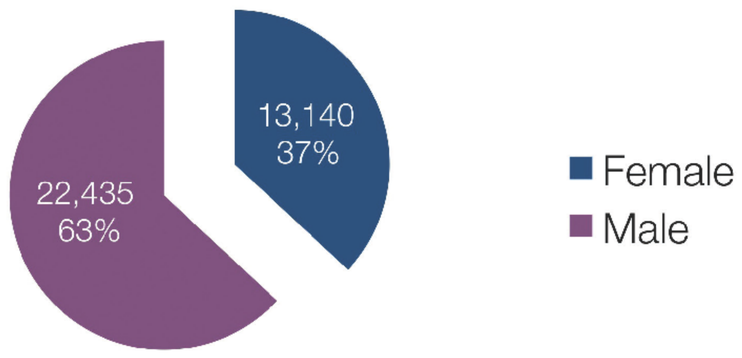
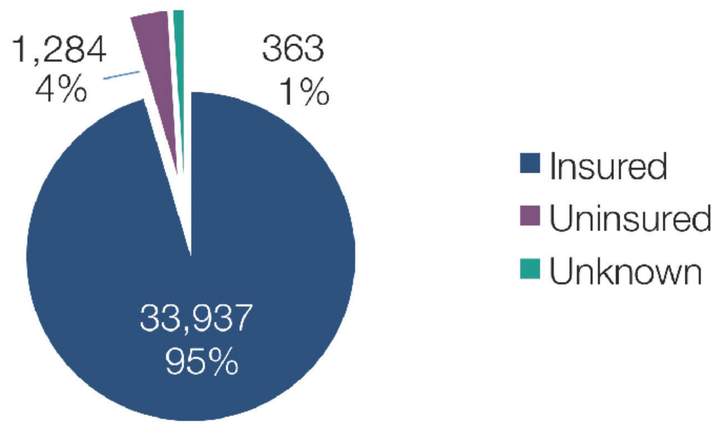


Figure 5. Hemophilia Treatment Center Patient Population: Insurance Status



One hundred forty-one (141) mortality reports have been submitted since submission began in September 2013. The causes of death reported are shown in Table 2. Data and blood specimen collection for the Registry for Bleeding Disorders started in December 2013; as of March 31, 2014, 88 centers have ethics committee approval with 267 Registry Initial Visit Forms and 608 specimens submitted to CDC.

Table 2. Causes of death among persons with bleeding disorders who received care at HTCs by diagnosis, October 2011- March 2014 (reports received as of March 31, 2014).

Cause of Death	Bleeding Disorder Diagnosis	
	Hemophilia (n=102)	Other (n=39)
Bleeding	18%	8%
Cancer	15%	23%
Cardiovascular	13%	15%
HIV-related	7%	0%
Kidney disease	3%	0%
Liver disease	15%	5%
Unknown	12%	18%
Other	19%	31%
Mean/median age at death (years)	52/54	48/52

Conclusion

Surveillance of bleeding and clotting disorders is critical to discover complications and plan prevention. **Community Counts** demonstrates the network capacity of hemophilia treatment centers in the US to track important treatment practices and outcomes, such as product usage and inhibitor formation, prophylactic regimens and joint disease, and bleeding and mortality.

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our vision. *To advance and improve the care of individuals affected by bleeding and thrombotic disorders.*

our mission. *To provide stewardship of a secure national database, adherent to all privacy guidelines, which will be used to support clinical outcomes analysis, research, advocacy and public health reporting in the hemostasis and thrombosis community.*

our values. *Improving clinical outcomes and care, facilitating continuity of care, fostering collaboration, maintaining confidentiality, conserving resources through a common infrastructure.*

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