Community Counts!
CDC Public Health Surveillance for Bleeding Disorders

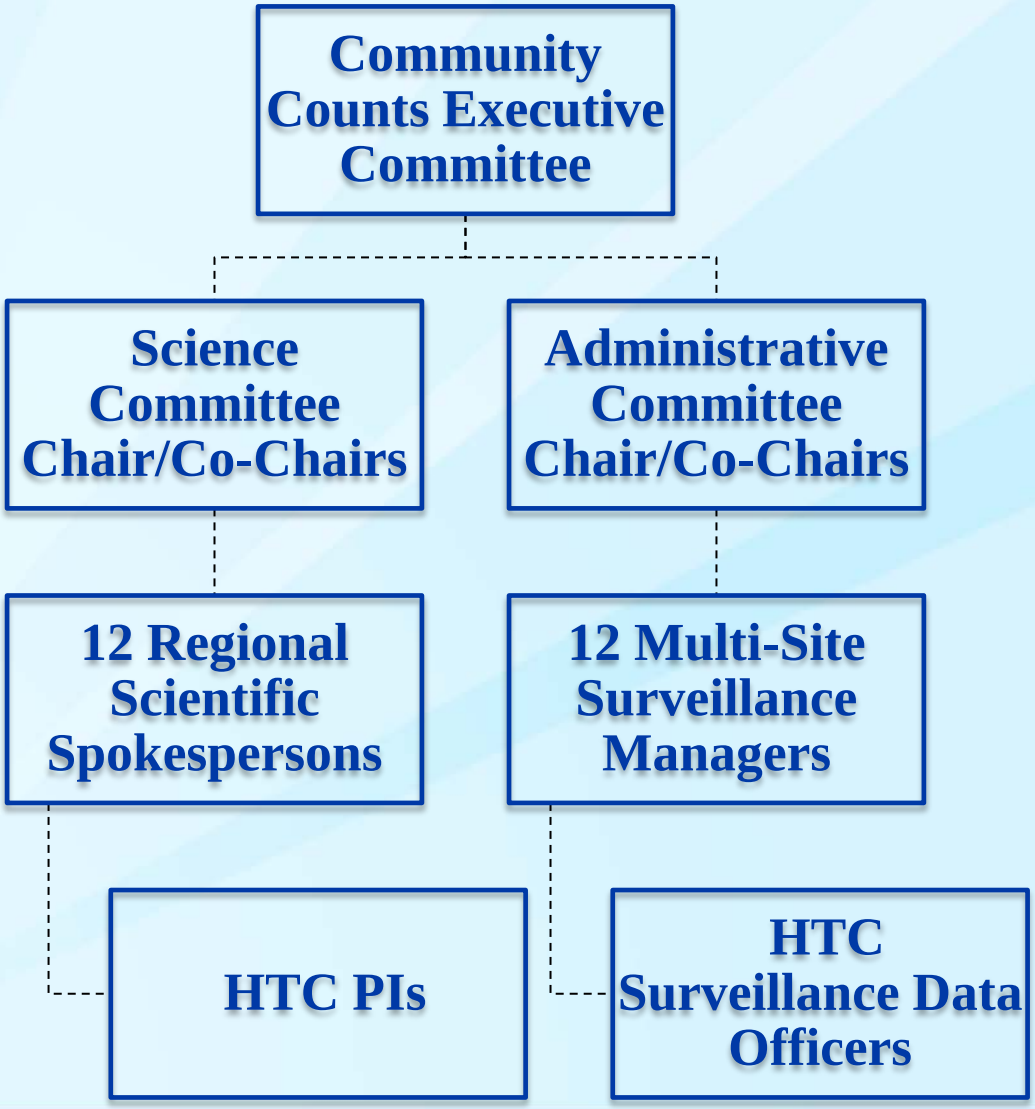
Responsibility and Funding

- The project is led by CDC/Division of Blood Disorders along with its partners the American Thrombosis and Hemostasis Network (ATHN) and the U.S. Hemophilia Treatment Center Network (USHTCN).
- Funded through cooperative agreement "Public Health Surveillance for the Prevention of Complications of Bleeding and Clotting Disorders" - Project period: 9/30/2011– 9/29/15
  - awarded to ATHN; ATHN issues subcontracts to regional core centers, which subcontract to 132 HTCs
  - Annual award approximately $3.9 million via congressional line item/mandate
- Applications for next 5 year cooperative agreement received and under review at CDC

Responsibility and Funding

- CDC, ATHN and HTCN roles
  - CDC provides resources, scientific and programmatic guidance, laboratory testing, and technical assistance to ATHN and the HTCs to facilitate their efforts in collecting surveillance data. Maintains project data, performs analyses and develops reports.
  - ATHN serves as the coordinating center for the HTCs on all surveillance project related activities and provides the data platform to electronically record and transmit surveillance data to CDC. Provides training and technical assistance to HTC staff on data platform.
  - HTCs identify and enroll patients with eligible bleeding disorders at their centers, administer data collection, collect appropriate blood specimens, and contribute to the development, evaluation, testing and implementation of all surveillance instruments.

Project Organization Chart



Aims/Purpose:

- Monitor health indicators of importance to the bleeding disorders population
- Measure rates of complications of bleeding disorders and monitor trends over time
- Identify high risk populations for prevention programs
- Identify issues that require further study

Aims/Outcomes of Interest

- Bleeding events and complications
- Inhibitor development
- Treatment practices and patterns
- Blood-borne infections
- Chronic diseases of aging and co-morbid conditions
- Health service utilization
- Causes of death

Data Methods (Transparency)

- Data collected by HTC staff
- Definitions and instructions for collection of each data element provided
- Initial collection on paper with data entry and validation at CDC
- Planned transition to electronic data collection via ATHN data infrastructure (Study Manager)
- Data quality assurance procedures integrated into data platform and performed by CDC – will initiate HTC data audits in the near future

Structure/Data Parameters

- Community Counts has 3 components: HTC Population Profile, Mortality Reporting and the Registry for Bleeding Disorders Surveillance
- HTC Population Profile
  - Provides description of the overall HTC population
  - Individual, de-identified data collected annually
  - No patient authorization required
- Data elements
  - Race
  - Ethnicity
  - Gender
  - Year of Birth
  - Zip Code (3 digit)
  - Insurance Status
  - Year of Visit to HTC
  - HTC Identifier
  - Primary Bleeding or Clotting Disorder
  - Baseline factor level/VWD labs
  - VTE Occurrence
  - HCV Status
  - HIV Status
  - Unique Identifier

Structure/Data Parameters

- HTC Population Profile – included diagnoses

Factor Clotting Deficiency

- VIII (8)
- IX (9)
- I (fibrinogen)
- II (prothrombin)
- V (5)
- VII (7)
- X (10)
- XI (11)
- XIII (13)

- Von Willebrand Disease (VWD)
- Inherited or Functional Platelet Disorder
- Bleeding Disorder, no laboratory diagnosis
- Connective Tissue Disorder
- Venous Thromboembolism (VTE) without any of these diagnoses

Structure/Data Parameters

- Mortality Reporting
  - Describes the demographics, diagnoses and causes of death of decedents
  - Individual, de-identified data collected annually
  - No proxy/family authorization required

- Data elements
  - HTC PP elements
  - Age at time of death
  - HCV Status
  - Year of Death
  - Sources of Information about Death
  - Autopsy Information
  - Cause of Death (Primary and Contributing)
  - Category of Primary Cause of Death

Structure/Data Parameters

- Mortality Reporting- included diagnoses

Factor Clotting Deficiency

- VIII (8)
- IX (9)
- I (fibrinogen)
- II (prothrombin)
- V (5)
- VII (7)
- X (10)
- XI (11)
- XIII (13)

- Von Willebrand Disease (VWD)
- Inherited or Functional Platelet Disorder
- Bleeding Disorder, no laboratory diagnosis

Structure/Data Parameters

- Registry for Bleeding Disorders Surveillance
  - Subset of patients with eligible disorders (same diagnoses as Mortality Reporting) and is a more detailed data collection on patient characteristics, diagnoses, treatments, and complications – patient authorization obtained
  - Voluntary participation; patient authorization required
  - Includes blood specimen collection based on risk for infectious disease and inhibitors
- Data elements
  - HTC PP elements
  - Inhibitors
  - Bleeds
  - Intracranial hemorrhage
  - Education/Employment
  - Insurance
  - CVAD
  - Mobility/Pain
  - Joint disease
  - Genetics
  - Family History
  - Product use
  - Prophylaxis
  - Surgeries
  - Other Medical Conditions

Structure/Data Parameters

- Centralized inhibitor testing is component of the Registry
- Plasma specimens are sent to CDC laboratory for Factor VIII and Factor IX inhibitor testing – HIRS testing methodology
- Eligibility
  - Participants at any age with FVIII (hemophilia A) or FIX deficiency (hemophilia B), or Type 3 VWD are eligible for submission of a plasma specimen to be tested for inhibitors IF they have ever been treated with clotting factor concentrate or blood products, or if the treatment product history is unknown.
- An elevated inhibitor titer is defined as:
  - ≥0.5 Nijmegen Bethesda Units (NBU) for FVIII
  - ≥0.3 Nijmegen Bethesda Units (NBU) for FIX
- Confirmatory testing also performed by CDC laboratory

Structure/Data Parameters

- The Inhibitor Incident Case Form collects additional information after a participant is confirmed by CDC as having a new, elevated inhibitor titer

- Form collects information about treatment product history, including product switches and infusion logs; surgeries and procedures; infections; and other medical history that occurred 4 months prior to the detection of the elevated inhibitor titer.

Access to Data

- Data initially available to CDC, ATHN, and HTCN through proposal process
- Envisioned: non-public web interface for HTCN to query data and public access data sets per CDC policy

Publications and Achievements

- Accomplished:

Enrollment and Participation-

As of April 30, 2015

- HTC Population Profile
  - 129 HTCs submitting forms
  - 48,062 unique patients; 86,848 total forms
- Mortality Reporting
  - 74 HTCs submitting forms
  - 405 total forms received
- Registry for Bleeding Disorders Surveillance
  - 88 HTCs submitting forms
  - 3,882 forms received
  - Over 6,400 specimens received

Publications and Achievements

- Accomplished:

Poster presentations-

- "Utilizing National Electronic Data Infrastructure to Longitudinally Follow the United States (US) Bleeding Disorders Population"; American Public Health Association Annual Meeting 2013.
- "Community Counts: Preliminary Report of a National Surveillance System for Bleeding and Clotting Disorders"; Thrombosis and Hemostasis Summit of North America 2014.
- "Community Counts: A US National Surveillance System for Bleeding and Clotting Disorders"; World Federation of Hemophilia Annual Meeting 2014.
- "U.S. Surveillance of Prophylaxis Use Among Persons with Hemophilia A Receiving Care at Hemophilia Treatment Centers (HTCs)"; International Society of Thrombosis and Hemostasis Congress 2015.

Publications and Achievements

- Planned:

Proposed Standard Reports & Analyses for Public:

- HTC Population Profile report (1st now available at cdc.gov)
- Inhibitor surveillance report
- Registry surveillance report
- Mortality surveillance report
- Special topic reports/data snapshots

Methods Manuscript Under Development

- "Community Counts: A National Surveillance System For Bleeding And Clotting Disorders"

Providing Safety and Efficacy Data on Products

- **Strengths**
  - Standardized data on large numbers of patients
  - Quality checks on data
  - Listing of all products used
  - Centralized lab testing (viral and inhibitor)
  - Central confirmatory testing of local results
  - Blood specimen repository for safety investigations
  - Longitudinal data accumulates over time
- **Weaknesses**
  - Annual testing interval
  - Voluntary participation on an ongoing basis (may be gaps in individual data)
  - Retrospective collection of exposure data on new cases of inhibitors