

Synchronizing the Network and Information Infrastructure to Meet Future Public Health Needs

CDC Strategic Direction

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ATHN Data Summit

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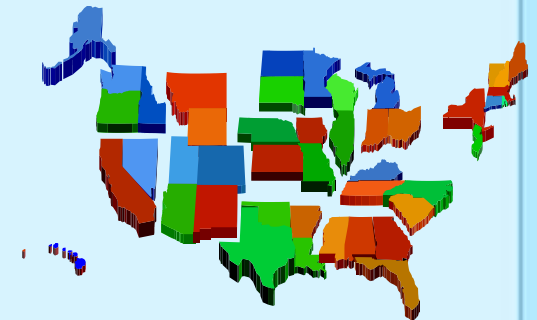


CDC/HTC Cooperative Agreement

“Prevention of the Complications of Bleeding Disorders Through Hemophilia Treatment Centers”

Current Agreement Ends Sept 2011

New Agreements Sept 2011



Bleeding Programs Highlights

2010

- **Single FOA**
- **Limited eligibility**
- **Administratively complex**
- **Limited ability to support research**
- **Limited population coverage**

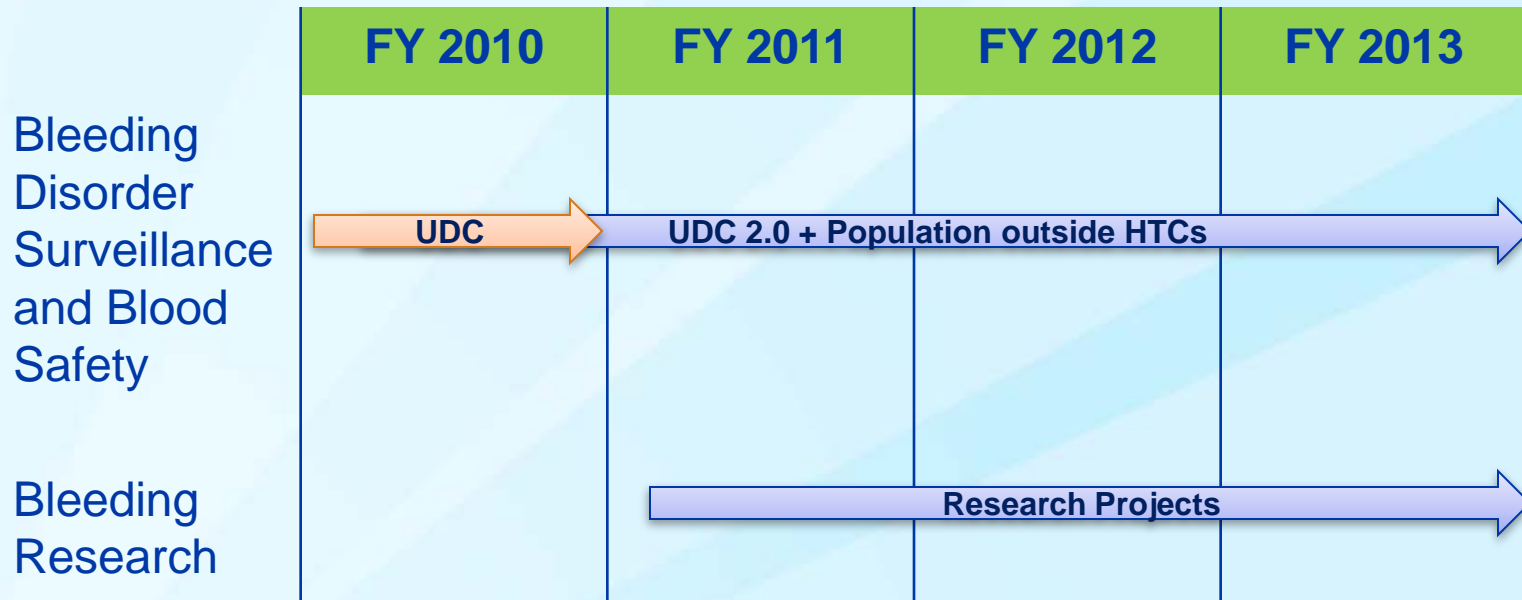
2011-2013

- **Multiple FOAs/ modules**
- **Expanded eligibility**
- **Administratively more efficient**
- **Support hypothesis-driven PI -initiated PH research**
- **More information about the population**

Bleeding

-Surveillance-

We are here



Planning for new Cooperative Agreement(s) – Timeline

- Fall 2009 /Winter 2009-2010
 - DBD Strategic Planning
 - DBD Program Review
- Summer-Winter 2010
 - Formal Evaluation of Bleeding Surveillance System (UDC)
 - Community Engagement: Stakeholder Meeting, Webinars, and Discussions
- Spring-Summer 2011
 - RFA development, review, approvals within CDC
 - Publication of RFA in Federal Register
 - Review Applications and Approval
- Sept 30, 2011 end of current Cooperative Agreement and beginning of new Cooperative Agreements

UDC Evaluation Findings

□ **UDC:**

- Supports a broad public health program
- Powerful health outcomes data collection network
- Enables large numbers of observations on rare diseases
- Supports improvements in standards of care for bleeding disorder populations
- Has capacity to expand to support health outcomes surveillance on other blood disorders

□ **UDC surveillance function:**

- Needs to be expanded and add focus
- Aspects of laboratory surveillance may be outdated
- Utility of information collected is not maximized

Evaluation cont.

□ **UDC Scope:**

- UDC is more than a surveillance system
- Surveillance function
- Registry
- Intramural & extramural epidemiological, clinical, and laboratory research programs

□ **Recommendations**

- Revitalize and prioritize healthcare outcomes surveillance
- Reconsider repeat testing criteria, assays used, and justification for serological blood safety surveillance

Stakeholder Meeting

- ❑ **Held October 22, 2010 in Atlanta**
 - Federal Partners
 - CBO including bleeding, clotting and hemoglobinopathies
 - HTC providers and Regional Coordinators
 - Provider and other professional organizations
- ❑ **Purpose to obtain input on health monitoring efforts**
 - Identify current and emerging threats
 - Identify health indicators of greatest concern
 - Consider whether current systems are monitoring the most appropriate populations

Wider Community Feedback

- ❑ **Webinars December 14 & 17, 2010**
- ❑ **Purpose**
 - To share information from stakeholder meeting
 - Obtain further input and comments on current surveillance efforts
- ❑ **Participants**
 - Open to blood disorders community

Monitoring Complications and Health Indicators

What are the important indicators for overall health of the population with bleeding disorders that we should monitor over time?

- PTSD
- Depression
- Quality of life (QOL)
- Substance abuse
- Pain
- Participation in the community and society
- Workplace barriers
- Disabilities
- Joint disease
 - ROM (range of motion)
 - Gait
- Iron deficiency
- Immunization
- Inhibitors
- Intracranial hemorrhaging (ICH) at all ages

- Neuro-developmental testing
- Obesity
- Cost of care
- Availability of care
- Health insurance (gaps in care)
- Functionality
- Age of diagnosis
- Health Care patterns with Women with bleeding disorders: burden, cost, quality- are we identifying them, where are they receiving care, is the care appropriate
- Women's reproductive issues
- Patient adherence to treatment
- Over-treating (treating for pain vs. treating for bleeds)

- Aging
 - Chronic conditions
 - Functionality
 - Diagnosis and treatment of conditions general to the population among persons with bleeding disorders
 - How does a bleeding disorder alter the treatment of conditions of aging such as heart attacks or tumors
- Provider practices related to screening
- Provider education as related to appropriate diagnosis
- Provider practices and association with outcomes

Responses: Scope and Representativeness

- ❑ **Are the participants we are monitoring (UDC) representative of the population served by HTC?**
 - Many more women are cared for in HTCs than are captured in UDC.
 - Other conditions that are seen include ITP, acquired bleeding disorders, clotting disorders, platelet disorders, thrombosis.
 - Chronic conditions like hemophilia are seen more often and are more likely to be captured than conditions that do not result in repeated visits to the HTC

Responses: Scope and Representativeness

- **Are there populations with bleeding disorders outside of the HTC who we should be monitoring?**
 - It was suggested that those who are not cared for in HTCs may be:
 - older
 - geographically distant from the HTCs
 - insurance barriers
 - language or other cultural barriers.

Responses: Blood Safety

□ Emerging Threats:

- inhibitors, parasitic infections, non-lipid- enveloped viruses, prions, allergic reactions, iron burden (transfused populations), long term side effects upon major organ systems, accumulation of non-biologic compounds/toxicity, continuous factor level & hypercoagulability/thrombosis

□ Who to monitor:

- different populations have different levels of risk; participants suggested stratifying by risk when deciding how often and for what to monitor. No one opposed this strategy.
- Several participants said everyone should be tested upon enrollment.

NEXT STEPS

New Research RFA:

- ❑ **Public Health Research for the Prevention of Complications of Bleeding Disorders**
- ❑ **Support investigator initiated projects to provide new information on the complications and outcomes of bleeding disorders**
- ❑ **Priority Areas:**
 - Joint disease
 - Women with bleeding disorders
 - Prophylaxis Use
 - Inhibitors
 - Chronic conditions
 - Neonates, infants, children
 - Emerging issues

Funding expected to begin September 2011

Surveillance RFA

- ❑ **New**
 - Funding Opportunity Title: Public Health Surveillance for the Prevention of Complications of Bleeding and Clotting Disorders
 - Due: June 2, 2011
- ❑ **Enhancing activities, while improving efficiency**
- ❑ **More focused surveillance and monitoring**
- ❑ **Non-research**
- ❑ **2 modules**

Module A: Patients receiving care in Non-HTCs

- ❑ Purpose: Characterize populations with bleeding disorders receiving treatment outside of HTCs**
- ❑ Small pilot studies to determine if what we see in UDC is consistent outside of the HTC system**
- ❑ Are there gaps or needs that should be addressed, prevention initiatives implemented?**
- ❑ Basic data collection**
 - Demographic characteristics**
 - Health Service Utilization**

Module B: Patients receiving care in HTC's

□ Continue to:

- Monitor trends and rates of complications
 - Joint disease
 - Reproductive complications among women with bleeding disorders
 - Intracranial hemorrhage and other bleeding episodes
- Characterize risk factors contributing to complications
- Characterize and monitor health status as measured by health indicators: obesity, immunizations, quality of life, chronic diseases of aging, co-morbid conditions and mortality
- Monitor treatment practices and patterns and correlate with clinical outcomes

Module B: HTC's

- ❑ **Expand and improve upon UDC to include:**
 - Other bleeding disorders
 - More focused risk factor collection based on feedback and emerging issues
 - Include inhibitors
- ❑ **Collect aggregate data on patients receiving care**
 - Bleeding- provide denominator
 - Clotting- characterize population and assess feasibility for future projects

Module B: HTCs

- **Improved Blood Product Safety**
 - Seroconversions of emerging, as well as known, pathogens
 - Inhibitor development and other markers of treatment complications
 - Repository of blood samples
 - Blood-borne pathogens
 - Other treatment product safety issues
 - Markers (or potential markers) of complications

Summary



- *Building upon, enhancing, evolving*
- *More efficient and more focused*
- *Distinct objectives for surveillance and research*
- *Addressing and identifying new and emerging issues*

Thank You

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