Community Counts-Inhibitor Surveillance

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Community Counts!

CDC Public Health Surveillance for Bleeding Disorders
Community Counts - 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
Inhibitors

• Major complication causing significant morbidity among people with hemophilia

• An antibody created by the patient’s immune system that inactivates the clotting factor replacement treatment making treatments ineffective

• Increased bleeding complications and increased risk of death

• Little is known about prevalence and incidence of inhibitors in the U.S.

Lessons from the Hemophilia Inhibitor Research Study (HIRS)

• Prospective study conducted by the CDC at 17 US hemophilia treatment centers, beginning in 2006, funded by the CDC Foundation with grants from Pfizer and Baxter

• All people with hemophilia at risk for inhibitor

• Clinical signs may not be evident – importance of screening

Lessons from the Hemophilia Inhibitor Research Study (HIRS)

• CDC inhibitor testing methodology breakthrough:
  – Developed and validated a modified NBA allowing testing of infused patients using heating step
    • true inhibitors may be missed if heating step is not used
  – Developed a means of confirming newly detected inhibitors using alternative testing methods

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Importance of Inhibitor Screening

• A screening test is needed to know if a patient has an inhibitor
• Regular screening is important for early detection of inhibitors
• Early detection increases the chances of eradicating an inhibitor
Goals of Community Counts Inhibitor Surveillance

• Establish nationally representative estimates of inhibitor incidence and prevalence
• Identify inhibitor trends over time
• Identify potential inhibitor “outbreaks”
• Characterize factors that might influence inhibitor development
MASAC Recommendation on Inhibitor Testing and Surveillance

• Annual screening
• Education efforts to emphasize risk and regular testing
• Standardized inhibitor testing methods including heat-treatment
• Participation in Community Counts
Community Counts Registry – Inhibitor Surveillance
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.
Centralized Inhibitor Testing

• HTCs submit plasma specimens from eligible participants to CDC for inhibitor testing during their annual surveillance visit.

• 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 – if first test indicates an elevated inhibitor, **CDC requests a follow-up specimen sent within 30 days**
Centralized Inhibitor Testing

For elevated inhibitor titers detected locally at the HTC as a part of clinical practice and not during the annual surveillance visit

• Contact CDC

• Please send a new plasma specimen to CDC for confirmation of local results within 30 days
Inhibitor incident case surveillance

• The inhibitor incident case form collects additional information after a participant is confirmed by CDC as having a new, elevated inhibitor titer

• Collects information about treatment product history, including product switches and infusion logs; bleeding events; surgeries and procedures; infections; and other medical history that occurred 4 months prior to the detection of the elevated inhibitor titer

• Please submit incident case forms and accompanying infusion logs via ATHN Study Manager **within three months** of a CDC confirmed elevated inhibitor titer
Resources


• **Community Counts - Centralized Inhibitor Testing and Surveillance Guidance** – project document


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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.