

# Public Health Surveillance to Monitor Blood Product Safety

Coordinating Center for Health Promotion  
National Center on Birth Defects and Developmental Disabilities

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# Prevention Program

- CDC has established a public health surveillance system for product safety among persons with bleeding disorders
- Eligibility
  - Receive care at a federally supported comprehensive care clinic
  - Congenital deficiency of any of the clotting factor proteins below 50% of normal
  - Diagnosis of von Willebrand disease



# Prevention Program

Cooperative Agreement with national network of 135 specialized hemophilia treatment centers

- Participate in blood safety monitoring and surveillance efforts
- Collaborate with lay organizations to deliver consistent prevention messages
- Maintain a prevention evaluation network to assess the efficacy of these prevention services



# Hemophilia Treatment Centers



★ Hemophilia Treatment Centers

Source: UDC 1997 through August 2005



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# Universal Data Collection (UDC)

## Study Design

- National protocol approved by CDC IRB and the local institutional IRBs of all participating treatment centers
- Standardized data collection annually using tools designed with input from experts
- Portion of blood specimen is stored in the CDC Specimen Bank for future studies



# Universal Data Collection (UDC)

## Study Design

- Blood specimen is tested in CDC lab for known infectious disease agents (hepatitis A, B, C and HIV)
- Current and previous results compared to identify new infections
- New infections are investigated with help of state health departments and FDA for any link with blood product exposure



# Universal Data Collection (UDC)

## Privacy Issues

- All patients (or parents of minor children) give informed consent
- Data and specimens sent to CDC with an identification code
- Application for Certificate of Confidentiality has been submitted



# UDC Enrollment

- Since May, 1998, more than 19,000 people with bleeding disorders have been enrolled
- The overall national refusal rate is 7.5%
- More than 50,000 blood specimens have been collected from these patients and stored in the CDC Specimen Bank for future blood safety testing as needed





# Thalassemia Surveillance System

- Similar system has been set up in six centers providing comprehensive care to people with thalassemia
- About 200-300 patients using these clinics receive frequent transfusions
- Since 2004, more than 400 specimens from this patient population have been collected, tested and stored



# CDC Specimen Bank

- Created to provide a secure environment for specimens collected by CDC
- State-of-art facility located outside Atlanta
- Protected by a guard force and freezers are electronically monitored 24 hrs/day
- Directly receives and processes specimens and sends to CDC labs



# Testing and Investigation

- Testing algorithms are designed to minimize false negative tests (e.g., RNA on HCV-)
- All new infections are confirmed with repeat testing of new specimens
- Complete information on all blood and blood product exposures are obtained
- Epidemiologic investigation is conducted by state health department with CDC assistance as necessary



# Monitoring Results

- No new infections with hepatitis A, B or C or HIV have been attributed to blood or blood product exposure, 1998 - 2005
- Vaccination rates for hepatitis (especially for hepatitis A) among bleeding disorder patients have been improved
- Reassurance of product safety
- Reported in routine surveillance reports and in MMWR, January 3, 2003



# Special Studies

- Markers of parvovirus B19 exposure prevalence among 2-7 year-old children
  - Prevalence higher among hemophilic boys using plasma-derived vs. recombinant factor
- Prevalence of antibodies to West Nile Virus among bleeding disorder patients
  - Tested specimens collected during the mosquito seasons of 2002 and 2003
  - No evidence of product transmission



# Emerging Infections

- Comprehensive care centers monitor the health of patients with bleeding disorders and thalassemia
- Mortality is being tracked over time
- Unusual illnesses and/or changes in death rates may signal emerging infection
- Once tests are available, large serum bank allows quick testing to evaluate the scope of the problem



# Potential for Expansion

- System could be expanded to monitor other populations at risk (e.g., sickle cell)
- Necessary elements
  - Serial sample collection
  - Reporting mechanism
  - Patient follow-up for investigation
  - Resources for testing costs



# Conclusions

- CDC has established a surveillance system to monitor the health and infectious disease status of certain populations using blood and blood components
- The system could be expanded to include other patient groups
- A system of care that provides regular access to the population is crucial

