CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

Information for Providers

UDC

THE UNIVERSAL DATA COLLECTION PROGRAM

For People with Bleeding Disorders

SAFER • HEALTHIER • PEOPLE

DEPARTMENT OF HEALTH & HUMAN SERVICES

How does participating in the UDC program benefit hemophilia treatment centers (HTCs)?

As an HTC Provider, your practice stands to benefit greatly from the findings generated by UDC. This program will provide the most complete national portrait to date of the bleeding disorders population and its health complications, primarily bloodborne infections and joint disease. This information will form critical groundwork for future research to reduce and prevent these complications.

As a large data gathering and monitoring mechanism for persons with bleeding disorders, UDC will provide information to:

Determine the current level of bloodborne infections among members of the bleeding disorders population receiving care through federally funded HTCs by documenting hepatitis A, B, and C viruses and HIV infection.

Document seroconversions to bloodborne viruses. Monitoring persons who have participated in UDC for >1 year for bloodborne viral infections can identify potential problems with blood products. The prompt investigation of any seroconversions will facilitate the actions needed to minimize exposure to others.

Rapidly investigate new or suspected infectious agents. CDC will store a portion of each blood sample collected through UDC. These samples will allow CDC to rapidly investigate any new infectious agents suspected of contaminating blood products.

Document medical outcomes. UDC will map patterns, track trends, identify risk factors, and analyze treatment responses for the complications of bleeding disorders among patient subgroups.

Provide information about the severity and progression of joint disease. Standardized range of motion measurements taken annually on the UDC patient population (a large segment of the bleeding disorders community) will provide a rich source of information about the occurrence and natural history of joint disease, a common complication of bleeding disorders.

Naturally, a high degree of community participation will be necessary for UDC to fulfill its goals. As an HTC team member, you can play a crucial role in this program by enrolling as many persons as possible in UDC.

Why is it important for every HTC to participate in UDC?

Persons living in different areas of the country may have diverse clinical characteristics and outcomes. For UDC to generate an accurate portrait of the U.S. bleeding disorders population and its disease complications, every federally funded HTC should join in this effort. CDC's goal is to collaborate with our constituents to prevent the complications associated with bleeding disorders, and CDC has provided support to the HTCs to achieve this important public health goal. The success of UDC in identifying the best prevention strategies will ensure the continued support of Congress for these prevention efforts conducted by HTCs.

Is there a reason to be concerned about the safety of blood products?

Today's blood supply and blood products are safer than ever. While we are unaware of any new bloodborne pathogens, close monitoring of blood products is critical in protecting members of the bleeding disorders community from any possible new hazards.

Why does CDC need to maintain a central monitoring system for potential bloodborne infections?

A national system such as UDC can effectively monitor the occurrence of such rare events, which may be the only indication of a potential blood safety problem. An outbreak of hepatitis A in 1996 demonstrated the need for a centralized plasma storage bank and reporting mechanism to improve the ability of CDC and state and local agencies to respond to threats to blood product safety. Two patients living in different states became acutely ill with hepatitis A after being infused with factor concentrate. Without further investigation, these cases could easily have been ignored and determined to be the result of other, not blood, exposures. However, since both cases were reported to a national surveillance system (the Seroconversion Surveillance Project) the outbreak was linked to a particular lot of blood product concentrate. The product was removed from the market, thereby preventing further transmissions.

What are the advantages of maintaining such a plasma sample bank at CDC?

A national plasma specimen bank can improve the response time needed to evaluate potential threats to blood product safety. As new diseases of clinical importance are discovered and tests become available, access to banked specimens to investigate potential bloodborne infections will help provide urgently needed information quickly and efficiently.

Before UDC was in place, such investigations were cumbersome and emotionally difficult for providers, patients, and families.

As an example, in 1998, CDC initiated an investigation when a pharmaceutical company discovered that porcine-derived factor VIII contained porcine parvovirus. The product was pulled from shelves, and HTCs were asked to recruit patients who had used this product for participation in the investigation. HTC staff members had to review patient records to find this information, inform patients of the potential problem, and get their consent to provide blood samples to CDC. For patients, time was of the essence, since many of them required this product to control their bleeding. Yet the investigation, which ultimately determined that the virus was not transmissible to humans through this product, took almost one year to complete. This investigation complicated the effective health care management of these patients for a long period of time. Had UDC been in place, this investigation could have been completed within several weeks.

What is the difference between testing of blood samples for surveillance vs. clinical care?

The goal of viral surveillance testing is to determine whether or not a person is susceptible to an infectious agent and requires monitoring for future occurrence of the disease. Therefore, persons who test negative are retested in subsequent years to make sure they remain virus-free. Persons found to be free of the infection initially but who later test positive (seroconverters) will be studied to determine the source of their infection. Persons who initially test positive for a virus are not retested in subsequent years for surveillance purposes.

In contrast, the goal of clinical care testing is not only to determine susceptibility to disease but also to establish the level of infection for patients who test positive so that the level of their disease can be established, monitored, and managed over time. Therefore, persons testing positive for viral infections are likely to be retested for clinical care reasons.

How do I interpret UDC test results?

For a detailed description of algorithm testing and how to interpret the results, please refer to the companion piece accompanying this pamphlet entitled **"Surveillance Testing: Algorithms for Providers."**

What is the role of providers in recruiting patients for UDC?

Provide Information

As an HTC provider, your role is to inform patients about UDC and, to the extent possible, to answer their questions about the program. CDC has created an information packet for patients to help answer their questions about UDC. This packet includes a question-and-answer brochure and a brief fact sheet, both written in easy-to-understand language. You also must discuss the informed consent process with patients.

Obtain Consent

Patients agreeing to participate in UDC must provide written consent via a consent form. Each year, patients must indicate their willingness to continue their participation by signing a new consent form. How you tailor this discussion is up to you; however, it is important that all eligible patients be given the opportunity to participate in the program and to have their questions and concerns answered as completely as possible. Parental consent is needed for participating children younger than 18 years of age. Children younger than 18 but older than 7 years also sign an "assent" form showing their agreement to participate in UDC.

What are the HTC's responsibilities in implementing UDC?

Each HTC is expected to have trained professionals who can accomplish the following:

1. Provide patient information on the benefits of participating in UDC and on the confidentiality of all information collected for the program.
2. Obtain patient's consent to participate in UDC at each annual visit.
3. Collect routine clinical data.
4. Take and record standardized range of motion measurements on the patient.
5. Draw a blood sample and ship the specimen to CDC.
6. Respond to queries for data validation.
7. Provide feedback to the regional coordinator or to CDC regarding study procedures and problems.
8. Give test results to patients and offer counseling and/or medical management as necessary.

What are CDC's responsibilities?

CDC is committed to achieving UDC's goals with as little disruption to patient care as possible. Input from HTCs will continue to be solicited to improve the program's efficiency and effectiveness. Feedback, including sharing ongoing summaries of data, is recognized as a critical component. With input from the HTC and

patient communities, CDC will pose questions for further study to develop effective strategies to reduce or eliminate the complications of bleeding disorders. Upon identification of any seroconversions among patients, CDC will promptly launch investigations and share the results with the bleeding disorders community. The results of these investigations may suggest safeguards that could decrease risks and improve the safety of blood products.

Who is eligible to participate in UDC?

Any patient age 2 years or older with an inherited bleeding disorder (including von Willebrand disease and other factor deficiencies) is eligible to participate in UDC. This includes patients who have missing, reduced, or defective coagulation proteins and who have a functional factor level of less than 50 percent. Patients with an acquired inhibitor are also eligible.

What if my patient does not want to participate in UDC?

Providers should be prepared to address and ease emotional concerns of their patients, particularly concerns related to past blood safety issues**.** It is important to assure patients that their decision to participate in UDC will not impact the care they receive from your center. If a patient is unwilling to participate, providers should complete a patient refusal form and include the patient's reasons for refusal. This information will help us address these concerns in future patient educational materials.

Why aren't children younger than 2 years of age eligible to participate?

Younger children are not eligible to participate for several reasons. First, they have small veins which makes obtaining a blood sample difficult. Also, their joint mobility cannot be accurately measured. Because of the presence of maternal antibodies in young children, results from testing for bloodborne infections may not represent the true infection status of the child. Finally, children are often excluded from studies of this type by the institutional review boards of the sponsoring agencies.

How long will patients have to participate in UDC?

Improving the health and treatment of the bleeding disorders community and monitoring blood product safety is an ongoing effort and a commitment shared by Congress, CDC, and the HTCs. Also, close monitoring of any potential infectious threat to blood product safety is a continuing process and requires access to the most current blood specimens. Further, finding solutions to the complications of bleeding disorders takes time and requires the partici-

pation of as many members of the affected population as possible. Therefore, patients are encouraged to participate in the program for as long as possible. The more data collected, the better will be both our understanding of the community and its health problems and our chances of discovering solutions and learning where new services are needed.

Encouraging Full Participation in UDC

Encouraging patient participation and integrating a new program into your course of care is not easy. But, as with every new endeavor, the first step is the hardest. Once you begin the process, it becomes a part of your routine, part of your practice. If you have specific problems related to the implementation of the program, contact your regional coordinator for tips and possible solutions. The Hematologic Diseases Branch at CDC publishes a newsletter to address concerns and to share strategies from other HTCs. You can review past copies of this newsletter, a long with other information, through their website (listed below). The data you are collecting are contributing to the most comprehensive, national portrait of the bleeding disorders population available and helping to bridge gaps in our knowledge about these conditions.

To learn more about UDC, *contact your regional coordinator or the Hematologic Diseases Branch at CDC at 404-371-5903; or, visit our website at www.cdc.gov/ncidod/dastlr/hematology.*

Health Surveillance

Information for life.

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