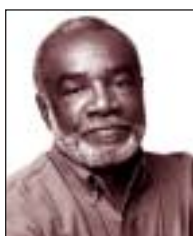




UDC

THE UNIVERSAL DATA COLLECTION PROGRAM

For People with Bleeding Disorders



Your Questions Answered

SAFER • HEALTHIER • PEOPLE

DEPARTMENT OF HEALTH & HUMAN SERVICES

UDC

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Frequently Asked Questions

What is UDC?

UDC is a voluntary program conducted by federally funded hemophilia treatment centers (HTCs) with support from the Centers for Disease Control and Prevention (CDC). The goal of UDC is to improve the health of people with bleeding disorders by monitoring and developing prevention strategies for two major health complications of bleeding disorders:

- Bloodborne diseases
- Joint disease

Why was this program created?

UDC was created based on the idea that widespread collection of health information from affected individuals will provide the best information to improve their health and decrease the complications of bleeding disorders. CDC worked closely with our partners, persons with bleeding disorders and HTC providers to create the program.

How is the program conducted?

During an annual comprehensive health exam at their HTC, participants are asked to provide a blood sample, have joint measurements taken, and provide basic information regarding their health. This information is then sent to CDC without names or other information that could identify an individual.

What will CDC do with this information?

CDC will use this information to identify areas for future studies to determine the best ways to reduce or prevent the complications of bleeding disorders. Also, by maintaining a collection of blood samples, CDC will be able to quickly investigate any potential problems, such as a new virus, that might be spread through blood products. If such a problem is identified, the HTCs can rapidly notify persons who may be at risk.

What methods are used to protect the confidentiality of participants?

Protecting the confidentiality of participants is an important concern to CDC and the HTCs. To ensure confidentiality, each treatment center assigns a computer-generated identification number to be used instead of the participant's name

on all UDC forms and blood samples. Should you decide to participate, only your treatment center will be able to match your identification number with your name.

How can I participate?

Persons who have an inherited bleeding disorder (i.e., hemophilia, von Willebrand disease, and other hereditary factor deficiencies) or an acquired inhibitor are eligible to participate through their HTC. Each year, as part of your annual comprehensive visit to your HTC, you will be given information about UDC and asked to participate. If you wish to participate, you will need to sign a consent form **each year**. 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 will these annual visits involve?

At each annual visit:

- A blood sample (about 2 teaspoons) will be taken and tested for bloodborne viruses (hepatitis A, B, and C viruses and human immunodeficiency virus [HIV]), and a small amount of this blood will be stored at CDC for future testing if necessary. If you test negative on any of these tests, they are repeated each year to make sure that you have not acquired any of these infections since the last time you were tested.
- Basic health information regarding your current and past medical treatment (e.g., current prophylaxis, immune tolerance therapy, and infusion practices) will be obtained from you or your medical chart.
- Range of motion measurements using standardized procedures will be taken on your elbows, shoulders, hips, knees, and ankles to determine any damaging effects on joint mobility resulting from bleeding into joints.

Why is UDC concerned with testing for bloodborne infections? Aren't blood products safe?

Yes. Today's blood supply and blood products are safer than ever, and no new viruses have been identified that can be

spread through blood products. In addition, all factor products undergo procedures to kill most viruses. Still, close monitoring of persons using blood products is important to protecting you and other members of the community from any potential infections.

Will I receive results from the testing on my blood sample?

Yes. CDC will provide your treatment center with your test results using your UDC participant identification number. Your treatment center can link this number with your name and provide you with test results. Tests for hepatitis A, B, and C viruses and HIV will be performed in the first year, and you will receive these results.

What if I test positive for one or more of these viruses?

If you have any test result indicating an infection, your treatment center will promptly notify you and provide counseling and if necessary, repeat testing and help develop a treatment plan with you.

What if I test negative for hepatitis?

If you test negative for antibodies for hepatitis A or B, you may not be protected from those viruses. Talk to your doctor about your results. You may need to receive hepatitis A and B vaccinations. Currently, there is no vaccine for hepatitis C.

What if something is found in the blood products that I use that does threaten my health?

CDC will alert your treatment center about any harmful substance that could be spread through blood products. Your treatment center will then notify you through your identification number. As a UDC participant, a sample of your blood will be stored at CDC for testing to determine whether you have been exposed to a potential bloodborne agent.

I use recombinant products, why would I need to provide a blood sample?

While there is no indication that viruses are spread through the use of recombinant products, it is important to monitor persons using them to make sure products remain safe.

Why are range of motion measurements taken of my joints?

Persons with bleeding disorders often experience bleeding into joints. This can cause joint disease and decreased joint mobility. It is important to know if you have joint disease, and, if so, how much it has affected your mobility.

Monitoring joint disease and how it affects different participants gives us information to identify patterns and develop new approaches to prevent or reduce joint disease.

If my disease is mild, should I participate in UDC?

Yes. Even persons with mild disease experience complications. If your disease is mild, your experiences are very different from those of persons with moderate to severe disease. These experiences have never been studied and need to be addressed. Your participation can help make this happen.

If I already know I have been infected with hepatitis or HIV, should I still participate?

Yes. You are an important part of our research efforts. The information you contribute can help us learn a great deal about persons with your complications. Even if you have been infected with hepatitis or HIV, it's important to continue to monitor any progression of your disease and its complications. The more information we have, the better our chances of finding answers. And, because you'll be providing a blood sample annually for storage at CDC, you will be able to be part of the "early warning system." That means that if a new infectious substance appears in blood products, you will be notified.

How will others, including my family, benefit from my participation?

CDC and the treatment centers are working to ensure the safety and well being of all people with bleeding disorders, including future generations. The more participants enrolled in the UDC program, the more information we can gather and the better our chances of finding solutions.

If I choose not to participate now, can I still receive services or treatment at my HTC?

Definitely, yes. Participation in UDC is voluntary and will not affect the treatment or services provided by your treatment center.

How long do I need to participate in UDC?

You will be encouraged to participate for as long as possible. Finding answers to complications and monitoring blood product safety is an ongoing process that requires access to the most current blood specimens. However, your agreement to participate is made on an annual basis and does not require you to participate throughout the length of the program.

Should you have additional questions, ask your nurse, doctor, or other treatment center staff member about UDC and your role as a participant.

The Centers for Disease Control and Prevention (CDC) is an agency of the Department of Health and Human Services. CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. For more information about the CDC's bleeding disorder programs, visit www.cdc.gov/ncidod/dastlr/hematology

Health Surveillance

Information for life.

Printed 10/2001