

Universal Data Collection (UDC) Project Fact Sheet for HTC Providers



WHAT IS THE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

The Universal Data Collection (UDC) Project is a public health surveillance project coordinated and supported by the Centers for Disease Control and Prevention (CDC). It is designed to collect and organize routine clinical information obtained by federally funded hemophilia treatment centers (HTCs) across the United States and its territories.

Data are collected to help the bleeding disorders community determine rates and severity of disease complications, describe treatment and care patterns, monitor blood product safety, and determine issues for further study. The project was initiated in 1996, and data collection began in May 1998.

UDC consists of multiple components to provide information on specific target populations. These components include:

- UDC (original forms designed for hemophilia and expanded to include rare bleeding disorders)
- Female UDC (for women and girls with bleeding disorders)
- Baby UDC (for children under 2 years of age with bleeding disorders)
- Inhibitor Pilot Project (to monitor inhibitors in selected sites)

This fact sheet describes the original UDC component; the specialized components are described in separate fact sheets.

WHAT IS INVOLVED IN THE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

▪ *What information is collected?*

Basic information is collected on diagnosis, patient characteristics, and treatment products used. Information on the complications of bleeding disorders including joint disease, blood-borne infections, and inhibitors is also collected. Joint range of motion is measured, and a sample of blood is collected for blood-borne virus testing and storage for further study. People 14 years of age or older are also asked to complete a quality of life questionnaire.

▪ *How is this information obtained?*

A patient must give his or her written permission to participate in the study. Hemophilia Treatment Center (HTC) health care providers complete the data forms by reviewing the participant's medical record or by asking the participant questions. The quality of life questionnaire is completed by the participant. Each year, this information is updated to make sure it stays current.

▪ *How often is information collected from participants?*

Information is collected once a year during the patient's annual comprehensive care visit.

WHAT IS THE PURPOSE OF THE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

▪ *Why is the information collected?*

One of the major challenges facing researchers and scientists who work on rare disorders such as hemophilia is lack of access to uniform data. Through UDC, CDC can collect a consistent set of data to monitor the health of people with hemophilia and other bleeding disorders. The data are used to advance research for these conditions.



Another important aspect of the UDC program is ensuring that blood products used by people with bleeding disorders do not contain known viruses. Although the nation's blood supply is safer now than ever before, monitoring people with bleeding disorders for blood-borne infections is important to make sure that the blood supply remains safe.

Sharing outcomes and experiences on a national and international basis will lead to improved quality of care. Since many of the rare bleeding disorders have no specific therapies approved by the Food and Drug Administration (FDA), surveillance of bleeding events and treatments is expected to be helpful identifying new indications for presently licensed drugs, off-label use and practices, and risk factors to prevent complications in these rare disorders.

▪ *What is the information used for?*

The information collected through the UDC Project is used to:

- Measure rates of complications of bleeding disorders and to monitor trends over time.
- Identify high-risk populations for prevention programs.
- Identify issues that require further research.

WHO CAN PARTICIPATE IN THE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

A person can take part in the UDC Project if he or she receives care at a federally funded HTC and meets any of the following criteria:

- Was born with a bleeding disorder caused by a missing, reduced, or defective clotting protein with a functional level less than 50 percent.
- Has von Willebrand disease.
- Has a bleeding disorder because he or she has developed antibodies to a clotting protein (an acquired inhibitor).

HOW IS UNIVERSAL DATA COLLECTION (UDC) PROJECT INFORMATION KEPT CONFIDENTIAL?

The identity of individual participants is known only to the staff of their HTC. Information from individuals is recorded on a standard form and sent to CDC using a code number (no original medical records are sent) instead of a person's name. Participants' information is also protected by HIPAA (Healthcare Insurance Portability and Accountability Act) regulations. Further, the project is covered by a certificate of confidentiality that prevents the patient's identifying information from being disclosed even if ordered by a court of law. Finally, no individual data are released in reports or analyses; results are reported so that no particular individual can be identified.

WHO PROVIDES INPUT INTO WHAT DATA ARE COLLECTED AND ANALYZED?

The UDC Working Group gives CDC regular input into what data are collected and how they are used. The working group is made up of physicians, nurses, a physical therapist, a social worker, a data coordinator, a regional coordinator for the HTC network, and a consumer. Representatives from the Medical and Scientific Advisory Committee (MASAC) of the National Hemophilia Foundation and the Hemophilia and Thrombosis Research Society (HTRS) also serve on the working group. There is also a working group that ensures that individuals with rare blood disorders are included in the UDC project. This working group was formed in 2007 to encourage national and international data collection on these rare conditions.

WHAT ARE THE SIGNIFICANT FINDINGS OF THE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

Some significant findings include:

- Overweight and obesity are associated with decreased joint range of motion.



- Youth with hemophilia enrolled in UDC are more likely to be overweight than the general population.
- Children who received only plasma-derived factor VIII have a higher rate of infection with human parvovirus B19 than both children who received no treatment product and children who received only recombinant factor VIII.
- Children who were positive for human parvovirus B19 had slightly less range of motion than those who were not positive for B19.
- Samples of blood from UDC participants from the early days of the West Nile virus epidemic (2002–2003; before the virus spread across the country) showed no evidence of spread of the virus through treatment products.
- No new infections of hepatitis A, hepatitis B, hepatitis C, or HIV have been found as a result of the use of blood products to treat hemophilia.
- Septic arthritis appears to be a rare complication of hemophilia and occurs primarily in target joints or as a result of joint surgery.
- Among deaths of people with bleeding disorders reported to CDC from 1997 to 2007, the most common causes were related to HIV (19%) and liver disease (22%). Hemophilia-related bleeding causes were less common (12%).

WHAT PUBLICATIONS HAVE BEEN GENERATED AS A RESULT OF THE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

- Ashrani AA, Key NS, Soucie JM, Duffy N, Forsyth N, Geraghty S, and the Universal Data Collection Project Investigators. Septic arthritis in males with hemophilia. *Haemophilia* 2008; 14(3):494–503.
- Kempton CL, Soucie JM, Abshire TC. Incidence of inhibitors in a cohort of 838 males with hemophilia A previously treated with factor VIII concentrates. *Journal of Thrombosis and Haemostasis* 2006;4(12):2576–81.
- Soucie JM, Cianfrini C, Janco RL, et al. Joint range of motion among young males with hemophilia: prevalence and risk factors. *Blood* 2004;103:2467–73.
- Soucie JM, Siwak EB, Hooper WC, Evatt BL, Hollinger FB. Human Parvovirus B19 in young males with hemophilia A: associations with treatment product exposure and joint range-of-motion limitation. *Transfusion* 2004;8:1179–84.
- CDC. Blood safety monitoring among persons with bleeding disorders—United States, May 1998–June 2002. *MMWR* 2003;51(51):1152–4.

WHAT FUTURE PUBLICATIONS OR ANALYSES OF DATA FROM THE UNIVERSAL DATA COLLECTION (UDC) PROJECT ARE PLANNED?

Manuscripts are in preparation describing:

- Factors influencing the rate of range of motion loss in youth with hemophilia.
- “Normal” ranges of motion for people without bleeding disorders.
- Bleeding symptoms and other characteristics of severe von Willebrand disease.
- Diagnosis and bleeding symptoms in children younger than 2 years with hemophilia.

In addition, numerous HTC investigators are looking at the UDC data to find out more about inhibitors, joint disease in severe von Willebrand disease, Factor VIII and IX deficiency in women, intracranial hemorrhage, use of prophylaxis, use of intravenous access devices, the progression of joint disease in persons who already have damaged joints, and causes of death.

The UDC Working Group is seeking proposals from investigators with clinical research questions that might be addressed using data collected as part of UDC. Investigators from any discipline who are affiliated with a federally supported hemophilia treatment center are encouraged to submit proposals using the “UDC Research Proposal Submission Template” found at <http://www.cdc.gov/ncbddd/hbd/surveillance.htm>.

