

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



WHAT IS THE FEMALE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

The Female Universal Data Collection Project is a component of the Universal Data Collection (UDC) Project, a public health surveillance project coordinated and supported by the Centers for Disease Control and Prevention (CDC). It was designed to collect and organize routine clinical information obtained by federally funded hemophilia treatment centers (HTCs) across the United States and its territories. The aim of the Female UDC Project is to provide descriptive information such as bleeding symptoms and treatment of women and girls, with a special emphasis on reproductive health issues. The data forms are being piloted and are expected to be finalized by January 2009.

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

▪ *What information is collected?*

Information is collected on diagnosis; bleeding symptoms, with an emphasis on menorrhagia and menopause-related bleeding; reproductive history; treatments; and surgical interventions. Joint range of motion is measured on severe patients (e.g., those with type III von Willebrand disease or severe factor deficiency), and a sample of blood is collected to be tested for ferritin, hepatitis, and HIV. Females 14 years old or older are also asked to complete a quality of life questionnaire.

▪ *How is this information obtained?*

A patient must give her written permission to take part 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 FEMALE UNIVERSAL DATA COLLECTION (UDC) PROJECT?

▪ *Why is the information collected?*

UDC was not designed to collect adequate information about bleeding symptoms and complications among women and girls with von Willebrand disease or other bleeding disorders. The female form was designed to capture this information.

▪ *What is it used for?*

The information collected through the Female UDC Project will be used to:

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



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

A woman or girl can take part in the Female UDC Project if she receives care at a federally funded HTC, is 2 years of age or older, and meets any of the following criteria:

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

HOW IS FEMALE 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 Female 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 social worker, a regional coordinator for the HTC network, and a consumer.

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>.

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

None to date. Data collection has not yet begun.

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

None to date. Data collection has not yet begun.

