

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



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

The Baby UDC 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 project is to provide descriptive information on the complications of bleeding disorders that are specific to infants and toddlers.

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

▪ *What information is collected?*

Information is collected on diagnosis, patient characteristics, and treatment products used. Important information includes the number and location of bleeds experienced by the child, especially head bleeds; issues related to birth, delivery, and treatment within the first 24 hours of birth; use of intravenous access devices; and vaccinations. Unlike regular UDC, joint range of motion is not measured and a blood sample is not collected.

▪ *How is this information obtained?*

The child's parent or guardian must give written permission for the child to take part in the study. HTC health care providers complete the data forms by reviewing the participant's medical record or asking the participant's parent or guardian questions.

▪ *How often is information collected from participants?*

Information is collected as often as every 6 months, until the child turns 2 years old, at which time he or she becomes eligible to take part in the regular or Female UDC Project.

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

▪ *Why is the information collected?*

The complications of bleeding disorders that affect infants and toddlers are different from those of older children and adults and have not been well studied. Understanding the impact of delivery and routine procedures on infants with bleeding disorders, as well as their experiences in the first 2 years of life, is important in determining the diagnosis at an earlier age and potentially preventing bleeding complications that could affect quality of life. By monitoring health practices and outcomes, useful information can be obtained on issues such as early bleeding that can lead to joint disease, port infections, intracranial bleeding, inhibitor development, and other complications.

▪ *What is the information used for?*

The information collected through the Baby UDC Project is 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 BABY UNIVERSAL DATA COLLECTION (UDC) PROJECT?

A child can take part in the Baby UDC Project if he or she receives care at a federally funded HTC, is younger than 2 years of age, 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 his or her body has developed antibodies to a clotting protein (an acquired inhibitor).

HOW IS BABY 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 the 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. It 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) are also part of the working group.

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

More than 700 babies have taken part in the Baby UDC so far. However, as data collection for the Baby UDC Project began only 4 years ago, data are just now being analyzed.

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

None to date.

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

Two manuscripts are currently being prepared. One describes methods of delivery, diagnosis, and sites of first bleeds. The other focuses on the mode of delivery, severity of hemophilia, onset and timing of bleeds, role of prophylaxis (if any), and role of the HTCs in the management of 634 neonates and toddlers with hemophilia enrolled in UDC. A third paper looking at the relationship between intracranial bleeding, inhibitors, and other aspects of treatment is planned. We anticipate much interest in these data and expect many proposals from HTC investigators.

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>.

