Universal Data Collection Project

UDC Update

February 2004

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Have You Seen This? Patients with Elevated Liver Enzymes

We have had several reports of patients who have chronically elevated liver enzymes, but do not have symptoms or serologic evidence of hepatitis. We would like your help to find out how common this is among HTC patients. To do this, we are asking that you check your patient's most recent liver enzyme results (if available—i.e. there is no need to perform additional testing), and report to us the results of your check. You can report your findings to Mike Soucie via e-mail at msoucie@cdc.gov. For patients with elevated liver enzymes, include the most recent liver enzyme levels and, if the patient(s) has/have enrolled in UDC, the CDCID number(s). If you find that none of your patients have elevated enzymes, send an e-mail stating that you do not have any such patients .The findings will be used to assess the need for testing for new viruses such as TTV or SEN-V as a special study in UDC.

UDC Data Accepted for Publication!

The first publication using UDC data has been accepted by Blood, "Joint Range of Motion Limitations Among Young Males with Hemophilia; Prevalence and Risk Factors", will be published in April 2004. The paper examines limitations in joint range of motion among over 4,000 males with hemophilia aged 2 to 19 years. An important finding is that greater body mass index is related to greater extent of ROM limitation. This is a potentially modifiable risk factor. Copies of the paper will be sent to all HTCs when available.

We Have a New Name!

In case you hadn't heard, our branch has officially moved from the National Center for Infectious Diseases to the National Center for Birth Defects and Developmental Disabilities. As a result of our move, our name has changed from Hemotologic Diseases Branch to the **Division of Hereditary Blood Disorders**. Please note this change in our address and future correspondence.

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UDC Expands to Babies with Bleeding Disorders

As you know, eligibility for UDC begins at age 2 years. Unfortunately, bleeding and other problems such as the development of inhibitors often begin before this age. The UDC Working Group has helped us design data collection instruments to collect important data about these outcomes in infants. Last year, staff in 12 HTCs pilot tested the forms on 34 babies and provided feedback to CDC on data availability and ease of use of the forms. Based on this feedback we have modified the forms and sent them back out for further feedback before finalizing them.

There are two forms: the baby registration form which is completed one time for new enrollees; and the baby visit form which can be completed as often as every 6 months until the child reaches 2 years of age. No new registration form is required to continue a child's involvement in the UDC project after age 2 years. The data collection for these forms is focused on important aspects of childbirth, immunization information, detailed information on bleeding (particularly head bleeding), and data about the development of inhibitors. No blood sample for UDC is collected and no joint range of motion measurements are recorded on the forms.

The model informed consent for UDC has been modified to include a section specific to participants under the age of two and has already received approval by the CDC IRB. When the baby forms have been finalized, the forms along with the approved model consent will be made available to you for submission to your institutions' IRB. We anticipate finalizing the baby forms by the end of February. For those sites that plan to submit UDC data electronically, please note that Hemophilia of Georgia, Inc. has made arrangements with Ground Zero Software to add the baby forms to the Lab Tracker database as soon as the forms are finalized.

Quality of Life Questionnaire Added to UDC

Health-related quality of life (QOL) questionnaires are increasingly used to measure the impact that a particular disease has on an individual's sense of well being and health. QOL measurements assist in assessing treatment outcomes and identifying health needs. CDC, with extensive input from experts in the field, has developed a QOL questionnaire for UDC participants that combines three widely used standardized questionnaires—the SF 12 v. 2, CDC Healthy Days, and the EQ-5D—so that the health needs and issues of people with bleeding disorders can be compared with other groups who have chronic conditions. The ultimate goal of collecting this information is to help us identify and address areas to improve healthcare for our patients.

The questionnaire will assess general health concerns and the questions can be asked by either the social worker or nurse and should only take a few minutes to complete. The questions have been validated for use with patients who are 14 years old or older. We are evaluating tools designed to assess the QOL of younger children and tools that are being designed specifically for people with hemophilia for potential future use in UDC.

The latest version of the UDC model consent (in addition to the section specific to babies as mentioned above) contains a sentence about collecting QOL information on your patients who are 14 or older. We will be sending this new model consent and the QOL questionnaire to the UDC Contact at your center very soon. Once the consent and questionnaire are approved by your IRB, you can begin administering it to your UDC patients. Thank you for your help in gathering this important information. If you have any questions about the questionnaire or the revised consent form, you can contact Angela Ward at 404-371-5396 or by email at award19@cdc.gov.

Focus on the UDC Working Group

Members of the UDC Working Group perform a valuable service to ensure the continued success of UDC. The purpose of this advisory group is to provide CDC with input from hemophilia care providers and patients regarding this blood safety and joint complications surveillance system. The working group has provided insights and advice about all aspects UDC including identification and definitions of data collection elements, eligibility issues, patient recruitment, and interpretation and publication of collected data.

Continued feedback is an extremely important aspect of ensuring that the UDC remains responsive to the needs of the bleeding disorders community. The expertise of the healthcare providers is critical to the identification of data needs and proper interpretation of the findings. Consumer input is extremely important to ensure the continued participation of patients in the project.

The group provides input for the project in two ways: first, through monthly conference calls; and second, through annual meetings. On January 12 and 13, 2004, the UDC Working Group met with UDC staff at the offices of the Division of Hereditary Blood Disorders at CDC. During the meeting the work group reviewed the progress of enrollment in the UDC project, the data being collected as part of the project, advised us on possible additions to data collection activities, and provided feedback about the progress of UDC efforts in the group members' institutions or regions.

UDC Working Group Members

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Welcome to Our New Supplies Coordinator

Please join us in welcoming Alex Hunt, our first supplies coordinator for UDC. He is responsible for maintaining supplies for the project, and filling your supplies requests. If you have any questions, he can be reached at (404) 371-5254 or at ahunt1@cdc.gov.

Data Entry Corner

CINGA Backups

Recently, we have had several sites report that their computer had crashed and that they had to reinstall the CINGA program. If your computer crashes, it is possible that you will lose the file that contains all the ID numbers you have already generated in CINGA. CDC does not have access to the data you put into CINGA, so we cannot restore your file. For this reason, it would be a good idea to make a back up of this file--for most sites this will be the "IMPEXP.csv" file in your "C:\CINGA\DATA\" directory. Also, should you find that you have to reinstall the program, do not install it from any discs we have previously sent. The program has been modified and updated since that version was released. The current version of the program may be downloaded at http://www2.cdc.gov/ncbddd/cingaweb/index.htm. The password and username are available from Mike Soucie (msoucie@cdc.gov) or Beverly Stokeling (bstokeling@cdc.gov).

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