Universal Data Collection Project

UDC Update

February 2002

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CDC ID Program (CINGA) Fixes and Improvements

A couple of problems were identified in the initial release of the CDC ID program and have been fixed in the new release. First, the EDIT function of the initial program did not work correctly. The new release replaces the EDIT function with a DELETE function. If an error is made in generating a CDC ID, the entire record can now be deleted and a new one created. Second, many people experienced problems printing the bar code labels because of font installation errors. The new release looks for the presence of the bar code font on the user's computer and, if it is not found, automatically installs it.

In addition, the new release contains a major improvement in printing functionality. The user can now select any number of patients in the database for printing either bar code labels or a data sheet listing of patients. Now, when you are preparing for a clinic with several UDC patients, you can select them and print all needed labels for all patients in one step.

By the time you read this newsletter, the updated version of the software should be available for downloading and installation on your computer. If you have not received email notification about this software, please contact Beverly Stokeling at BStokeling@cdc.gov for installation instructions.

Matching New and Old Data for UDC Patients

The CINGA program uses the same procedure to assign the CDC ID that the DOS CDC ID program used. This procedure was designed to create the same CDC ID every time that identical patient name and birth date information is entered. If, for any reason, a different CDC ID is assigned to a patient who has been previously registered in UDC, you must follow three simple steps to ensure that the new and old data will be correctly matched:

1. Use the labels with the **new** CDC ID created by the CINGA program on the patient's new ANNUAL FORM and LABORATORY FORM. Also, use the labels with the **new** CDC ID on the blood tubes and on the SHIPMENT NOTIFICATION FORM.
2. On the first page of the ANNUAL FORM, please write "This patient previously registered under ID ###-####-#####." Enter the patient's old CDC ID number in place of the #s.
3. Make a note in the patient's chart of the **new** CDC ID number. All future communications from CDC concerning this patient will use the **new** CDC ID.

Blood Safety

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If you have any questions about this procedure, please contact Mike Soucie by email at MSoucie@cdc.gov or by phone at (404) 371-5278.

Latest Change to UDC Consent Forms

CDC has provided a new number that patients can call if they have questions about their rights as a research subject: 1-800-584-8814. This information should be provided in addition to a local contact for human subject rights issues. The following is the suggested wording for this information:

> I know that my doctor (*insert name and phone number*) will be available to answer any questions I may have. I may also contact Dr. Mike Soucie in the Hematologic Diseases Branch of CDC at (404) 371-5278 for further information about this project. If I have any questions about my/my child's rights as a subject in a research study, I may contact (*insert name and phone number*). I may also call CDC at 1-800-584-8814 and leave a message, including my name and phone number, and someone will call me back as soon as possible.

HTC Directory Now On-Line

The long-awaited HTC Directory is now available for your use at www.ncid.cdc.gov. Not only is it easy to find, but easy to use! Once you are at this National Center for Infectious Diseases webpage, simply select "Bleeding and Clotting Disorders Surveillance" to access the HTC directory.

The directory allows you to:

- create lists of facilities and staff
- print mailing labels for staff
- search for facilities by name, HTC ID number, region, city, or state
- search for staff by name, contact type, job description, HTC ID number, or location
- generate national and regional UDC data reports

We are very excited to have the directory up and running! Much time has gone into designing a site that provides useful information in a functional, user-friendly manner. So please visit our new website and see all that it has to offer. We will be adding functions in the coming months.

UDC Cited in *The Hemophilia Bulletin*

Every few months, Dr. Carol Kasper of Orthopaedic Hospital of Los Angeles, California, publishes *The Hemophilia Bulletin*, a newsletter presenting topics of interest, including her own related personal accounts and opinions. The November 2001 issue cited data from the UDC report on viral hepatitis testing, which reported **no new infections with HIV, HAV, HBV, or HCV resulting from the use of blood products.** In order to come to this conclusion, we investigated UDC test results that changed from negative in the first year to positive in the second year. We discovered that the large majority of these "apparent sero-conversions" for anti-HAV and anti-HBsAg were true conversions due to vaccination, while nearly all false conversions were attributed to false-negative or false-positive tests.

Dr. Kasper was not surprised at the number of false sero-conversions seen among UDC patients. Pointing to her own experience in studying hemophilia patients for hepatitis B antibodies in the 1970s, she noted that it was common to find antibody levels hovering right around the detectable limit in patients who had had hepatitis B in the past. If antibody levels dropped below the detectable limit, the patient falsely tested negative. Similarly, and in accordance with what was seen in UDC patients, many of Dr. Kasper's most frequently transfused patients also had these "peek-a-boo" antibodies.

Dr. Kasper also raised an interesting point related to the reported prevalence of antibodies to HAV among UDC participants. While anti-HAV levels among non-HAV-vaccinated adults with von Willebrand Disease (vWD) are similar to the age-matched general population, antibody levels among non-HAV-vaccinated adults with hemophilia are much higher, suggesting HAV transmission through blood products in the past was more common than Dr. Kasper (and probably many others) had previously thought. vWD patients usually need blood products less frequently than patients with hemophilia, and they used to receive single-donor products rather than concentrates from pooled plasma.

We always look forward to feedback on UDC issues. Thank you for sharing your thoughts and experiences with us, Dr. Kasper!

Why Lab Results Sometimes Take Longer Than Expected

As a result of your efforts, nearly 10,000 individuals have enrolled in UDC over the past four years! During this period, laboratory testing for exposure to viruses has uncovered no factor-related infections—attesting to the high level of safety of today's blood products. UDC testing has also led to the identification of susceptible individuals who have subsequently received immunizations. As you can see, laboratory testing has been a valuable component of the UDC project.

We would like to take this opportunity to clarify some issues related to the reporting of UDC test results. The testing of many individuals in a population for surveillance purposes demands a high degree of accuracy so that no true infections are missed and so that potentially alarming, false-positive results are minimized. The laboratories conducting the UDC testing are reference labs and, as such, are able to examine samples in greater detail when there may be questionable or inconsistent findings. However, this intense examination requires more time to complete than routine testing.

After discussing these issues with the laboratories, we have determined that, in most cases, CDC can expect to receive results within four weeks. However, in some cases, results reporting will be delayed. Therefore, you should expect to receive UDC test results within six to eight weeks of submission. If your patient has clinical symptoms and if results are needed on a more urgent basis, we suggest that you submit a specimen to your clinical laboratory as well. Thank you for your continued support and patience on behalf of the UDC project.

Evett's Corner

Conversion to New Data Forms by March 1

In early September, each UDC contact was mailed a packet that included revised data forms. While the majority of HTCs have begun using these forms, some have not yet made the transition. Sites that have not submitted new forms have been contacted by Evett Palmer. Different procedures are used to enter old and new forms into the database. To eliminate the need for two separate systems, **ONLY NEW FORMS WILL BE ACCEPTED AFTER MARCH 1**. After this date, old forms will be returned to you. While we encourage all sites with the capabilities in place to use our CINGA ID software, the software is not necessary in order to use the new forms. Old labels may be used on the new forms. Therefore, all sites, regardless of whether they are using CINGA, should be able to switch from old to new forms without difficulty. If for some reason you did not receive the revised forms or if there are other issues that prevent your use of the new data forms, please contact Meredith Oakley at (404) 371-5277.

Responding to Validation Error Reports

Please take the time to promptly respond to the validation error reports. Simply write the corrections on the validation error form itself and fax it to our office at (404) 371-5423. Validation error reports are sent out once a week until they are corrected. In addition, errors not corrected after two weeks are followed up by a phone call from one of our staff to the UDC contact. The simplest way to avoid receiving multiple copies of error reports and follow-up phone calls is to make your error corrections and transmit them to CDC within one week. For your convenience, Evett Palmer will be glad to handle your corrections over the phone. She can be reached at (404) 371-5251.

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