UDC Update
October 2001

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Expression of Sympathy

In light of the tragic events that took place on September 11th, we at CDC would like to extend our thoughts and deepest sympathy to all those whose lives were affected, as well as our admiration to all the health care providers and rescue workers who continue to respond to this crisis.

Out With the Old, In With the New

During the last week of August and the first week of September a packet of revised data forms, procedure manual replacement pages, and revised CDC ID software was sent out to UDC contact persons. This information was sent in a large brown padded envelope. Some of the packages did not reach their destinations intact. A list of items included in the packet is given below. Please check the list to make sure you received all of the items, and let Meredith Oakley (404/371-5277) know if you are missing anything!

- Memo
- CINGA2000 software discs (1 set; software manual included in replacement pages)
- Replacement Pages list, detailing the changes to the pages included in this replacement set (1 copy)
- "Key to Current Pages" (2 copies)
- Procedures Manual replacement pages (2 sets)
- Revised Annual Visit forms (1 packet)
- Revised Registration forms (1 packet)
- Revised Laboratory forms (1 packet)
- Revised Refusal forms (1 packet)
- Data forms masters for revised data forms (2 sets; these go in the red section of the procedures manual notebook)
- Revised order forms (1 packet)
- Revised Shipment Notification forms (1 packet)
- Avery 5160 laser labels
- Envelopes for returning data forms to CDC (1 packet)

Lost in Limbo! Those Mysterious Specimen Collection Dates

In order to prepare log-in sheets before the specimens arrive, the serum bank records the collection date for blood specimens from the shipment notification form rather than from the Laboratory form. Currently, our computer cannot match specimens without a collection date to their corresponding forms, and their results end up in computer limbo. So please remember to include the collection date on the notification form--there's a whole column reserved just for that!

The Need for Notification

It is very important that a **completed** notification-of-shipment form be faxed to the serum bank prior to sending specimens. Not only is this helpful to the serum bank, but more importantly, it is required by

law. For security reasons, the serum bank is required to account for shipments being received. Sporadic checks are done on shipments and if the serum bank has not been notified by fax of the shipment's pending arrival, it will be refused.

Update on limit of Detection of HCV PCR Test

Due to changes in technique, the limit of detection for hepatitis C RNA by PCR is now 1000 copies. Specimens with a reading of <1000 are reported as 'Not Detected'.

No ID Please

You may have noticed that the revised Refusal forms do not have a space for the 12-digit CDC ID number. In its place, is a space that requires only your 3-digit HTC ID. This is a reflection of the direction in which CDC's IRB regulations are heading. Collection of identifiers for persons who decline participation in a study will not be allowed. Therefore, we ask that you do not put the entire CDC ID number anywhere on new refusal forms. Put only your 3-digit HTC ID!

Rapid Return

Please send your corrected validation error reports back as soon as possible. We are trying to get the data currently in the system "cleaned up" as soon as possible; incomplete or missing information makes this task difficult. If you have any questions regarding validation error reports or would like to respond by phone, Evett Palmer is available to help you at 404-371-5251.

Trying Translations

Please take the time to print clearly when filling in questions that require a handwritten response. Illegible handwriting can be difficult for our data entry staff to decipher and often leads to errors. The few extra seconds needed to print legibly will save everyone time in the long run.

Transfer Patients

Please make sure that a new registration form (with your center number on it) is filled out and returned with the Annual form for any UDC patient who have transferred from another center.

Eliminate Error – Use Barcode Labels!

The new CDC ID software creates a label with both a numeric and barcode id. The purpose of these computer-generated labels is to eliminate transcription errors at both the data-collection and data-entry levels. While we realize that not all HTCs have the resources necessary to implement this software immediately, we encourage those who do have the equipment to begin using it. The barcode labels should be used in place of hand-writing the CDC ID or using other labels and should be affixed to all Annual and Registration forms in the upper right-hand corner. It is okay if the barcode label covers the words "CDC ID."

Nashville Here We Come!

Bruce Evatt, Mike Soucie, Sally Crudder, Sara Critchley, and Christy Cianfrini will be representing CDC's Hematologic Diseases Branch at November's annual NHF meeting. Christy is CDC's newest addition to the UDC project. She has been working with Mike in analyzing data for nearly 6 months now. She is looking forward to this excellent opportunity to interact with and learn about the bleeding disorder community as well as meeting all of you!

Blood Safety - Spread the News!

Blood safety monitoring is one of the central roles of UDC. It is essential that we communicate our findings, not only with you, the providers, but also with members of the bleeding disorder community. The accompanying article presents an overview of UDC's blood monitoring activities and results from the recent analysis of hepatitis seroconversions that were reported in the May 2001 surveillance report entitled "*Report on the Universal Data Collection Program: Special report summarizing the results from viral hepatitis testing of UDC participants.*" It is important that participants know how the data they provide are used and how valuable their participation in UDC is. We encourage you to share this information with your UDC patients. Please feel free to photocopy this article for distribution if you would like. The information presented in this article will also be available to you on our website: www.cdc.gov/ncid/dastlr/hematology.

CDC's Universal Data Collection Program: Blood Safety

Background

The safety of blood products is important for all people, especially those with hemophilia. The introduction of clotting factor concentrates in the 1970s greatly improved the treatment for hemophilia patients. Unfortunately, these products also introduced a new risk--the transmission of infectious diseases. While the risk of hepatitis from these products was recognized early on, the large number of persons with hemophilia who became infected with human immunodeficiency virus (HIV) in the early 1980's brought new questions to the safety of the blood supply. Prevention measures, including more sensitive donor screening methods, viral inactivation (viral killing) techniques, and the development of genetically engineered (recombinant) factor, were rapidly introduced to avoid future contamination. The use of these strategies has virtually eliminated the spread of viral diseases, including HIV and hepatitis, through the use of blood products.

A Blood Safety Monitoring System

Today, clotting factor concentrates are considered safe from contamination with known viruses. However, continued monitoring of blood products provides an additional measure to ensure their safety. With this in mind, the Centers for Disease Control and Prevention (CDC), in cooperation with federally funded hemophilia treatment centers (HTCs), established the Universal Data Collection Program (UDC). Persons with bleeding disorders are eligible to enroll in UDC at their participating HTC. As part of the program, clinical data and a blood sample are collected from participants each year during their annual clinic visit. A portion of the blood sample is tested for viral hepatitis (hepatitis A virus [HAV], hepatitis B virus [HBV], hepatitis C virus [HCV]) and HIV, and the remainder is stored for possible use in future blood safety investigations.

Since the program began in May 1998, nearly 9500 persons from 135 HTCs have been enrolled in UDC. As part of the program, each participant's annual test results are monitored for new infections with hepatitis or HIV. To date, no new cases of HAV, HBV, HCV or HIV infection have been found among UDC participants. Additionally, the monitoring has revealed that more than 90% of UDC participants under the age of 20 have been vaccinated against HBV. Since UDC began, 191 participants who were not immune to either HAV or HBV when first enrolled have been vaccinated.

How you can help protect yourself

The nation's blood supply is safer now than ever before. However, monitoring is important to make sure that it remains safe and to detect the appearance of any new infectious agent that may pose a threat to its safety. Members of the bleeding community can help protect themselves in two important ways:

1. **Get vaccinated.** Vaccination is a safe and effective way of protecting oneself against infection from HAV and HBV. CDC's Advisory Committee on Immunization Practices recommends HBV for all children and HAV vaccination for persons greater than 2 years of age who have hemophilia or other bleeding disorders. No vaccine is currently available against HCV.

2. **Participate in UDC.** Early identification of potential bloodborne diseases in the blood supply can help prevent further spread to others. Blood samples collected as part of the UDC program are stored in a national serum bank, and if a new disease is discovered, these stored blood samples can be tested to identify any potential threats to the safety of the blood supply.

For more information on UDC, contact your local HTC or visit the CDC website at www.cdc.gov/ncid/dastlr/hematology

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