UDC UPDATES

September 1998
Vol.1 No.II Pg.1 Newsletter for the Universal Data Collection Project

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In This Issue:

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Introduction

In recent months, HTCs across the country have begun collecting data and specimens for UDC. During this implementation period, several questions and issues have arisen. This edition of the newsletter is intended to address these concerns. We hope that this information is helpful and facilitates involvement in this important project.

Label Makers

Many centers have expressed difficulty in using the label makers that we have provided for labeling the UDC blood specimen tubes. These devices are intended to aid those centers that do not have the capability to generate duplicate labels for each specimen. If your center does have the capability to generate labels that do not smear when wet, adhere well to the tubes when wet, and have legible font size and style for both written and faxed documents, please feel free to generate your own labels.

Mislabeled Blood Specimens

Blood specimens that arrive at the serum bank with inappropriate or incorrect identification numbers will be destroyed without testing. This includes specimens with ID numbers that have the wrong number of digits or transposed digits, as well as specimens that have had the wrong label applied. Although we realize that some mix-ups are inevitable, such specimens must be discarded to prevent the reporting of erroneous test results.

Additionally, please make sure to include the hyphens between the sections of the ID numbers. Hyphens are an integral part of the CDC ID number, and the computer will not recognize an ID number without hyphens. Serum bank technicians will not know to include hyphens if they are not included on the lab forms and specimens.

Plasma Preparation Tubes (PPT)*

Initial lots of PPT had a maximum shelf life from date of manufacture of 9 months, but in most cases the longest shelf life we were able to obtain was 6 months. Although the next lots of tubes should have up to 10 months of shelf life, tubes with even longer shelf life should be available after production begins in the United States. For now, small patient loads and short shelf life mean that many centers will not be able to use all of the tubes from their initial UDC supply before they expire. You are welcome to use your “extra” tubes for non-UDC bloodwork requiring plasma or to share them with other HTCs or other departments at your institution.

Check with your institution’s laboratory and/or central supply to see if they already stock PPT or if they are willing to obtain these tubes for you. Due to the newness of the product, the Becton Dickinson (BD) sales force is not actively marketing the PPT; however, these tubes can be easily ordered upon special request. Many institutions belong to purchasing consortiums which can obtain products with greater ease and at lower prices than available to individuals.

According to BD, few consortiums are currently purchasing these tubes, but the number is likely to increase with time. If you must obtain them on your own, distributors currently selling the tubes are CMS Fischer, VWR, Allegiance, and Bergon Brunswick. The BD item number for the PPT is 362788.

HIV Lab Schedule

The HIV laboratory at CDC is being restructured and is attempting to streamline its procedures. Consequently, reporting of HIV results is temporarily delayed. It currently takes an average of 3 weeks from the date of distribution before HIV results are returned. This change does not affect reporting of hepatitis results to the HTCs. The HIV lab anticipates that in a few months it will be returning HIV lab results within one week. We appreciate your patience during this time. In addition, when reviewing case reports, the sentence "No HIV results available to report" means that results are not yet available from the lab.

Use the Correct Air Bill for Shipment

You should receive two sets of Federal Express air bills in your UDC supply kit. When packing blood specimens please **be sure** to use the air bills addressed to Suzette Bartley at the CDC Serum Bank in Lawrenceville, GA, and **not** those addressed to Meredith Oakley at the Hematologic Diseases Branch. Specimens incorrectly addressed will not arrive at the serum bank in time to be processed that day.

Data Forms

Common Problems to Avoid

Incomplete data, violation of skip patterns, and incorrectly formatted entries will cause the data entry computer to generate a "Validation Error Report" requesting clarification of those items.

Please refer to the instructions printed on the back of the data forms as well as the Data Forms Manual when completing forms. Especially note the following most common problems:

Registration Form
#8, 9a, 10b, 11, 12a--Be sure to circle whether the patient's age is in days, months, or years.

Annual Form
Treatment Information #11--Provide an estimate of the number of bleeds that is based on infusion logs **or** patient recall, not **both**. Also, do not leave both columns blank even if there were no bleeds in a joint, muscle, or some other site. For each site enter a 0 (zero) in **either** the infusion logs **or** patient recall column, as appropriate, if no bleeds occurred.

Risk Reduction #23-28--If the patient is HIV negative or untested, no risk reduction information should be completed. These questions are optional for participants who find them too sensitive.

Joint Disease #31-32--The "not applicable" choice for the number of days of work or school missed because of lower and upper extremity joint problems is appropriate **only** for patients who neither work nor go to school. All patients who work and/or attend school should have a number (≥ 0 [zero]) for both questions.

Ranges of Motion #35--If there is hyperextension in either the knee or elbow, be sure to enter 0 (zero) for extension in that joint and enter the number of degrees of hyperextension in the joint as a positive number in the hyperextension box.

Data Forms

Some Clarifications

As the data forms have come into greater use, HTCs have asked for clarification of some items. If you have a question about a specific item, please ask your Regional Coordinator.

For example, HTCs have asked for clarification of the use of the terms "**blood product"**, "**factor**", and "**factor replacement products**" on all UDC data forms.

Factor replacement product and blood product are synonymous terms and refer to any product that contains blood or any blood component but are extended to include Benefix. These terms exclude DDAVP in any form and Amicar.

Factor refers only to products that replace or replenish specific clotting factors, regardless of product origin. It excludes whole blood, cryoprecipitate, and plasma as well as DDAVP and Amicar.

Registration Form

#6--Acquired inhibitors should be classified under "other."

#14--Symptomatic carriers should be included as household members who have a bleeding disorder.

#15--Analysis of genetic mutation refers to analysis done on DNA taken from the study participant himself/herself.

Annual Form

#8--(Treatment type). The instructions given in the Data Forms Manual are correct. This question is asking about treatment with **blood products** only.

#9--If factor IX inhibitor levels are measured in units other than Bethesda units, write in the value and unit on the form.

#14--Whole blood, packed RBCs, and platelets should be written in as "other" next to blood bank products.

Although DDAVP and Amicar are not actually factor replacement products, they have been listed under question 14 ("Factor replacement products used...") for convenience. Their use by study participants should be recorded in question 14 under the category "Non-plasma products".

#35--"Lifts" should be included as orthotics.

Correction to the UDC Procedures Manual

Appendix B (p. 63): the last two sentences should read as one-"Should the shipment change...after you have sent the fax, notify the serum bank by phone or fax promptly."

Call for Comments/Questions

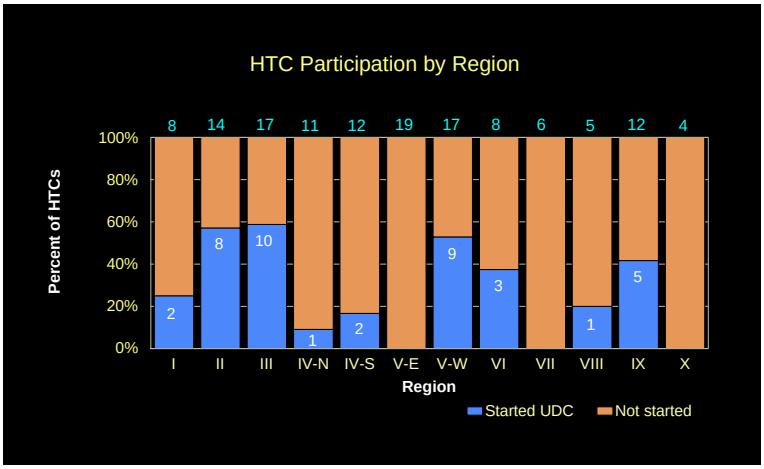
Many HTCs that have not yet begun UDC, are seeking information from participating centers about their experience with implementing the program. In this newsletter, we hope to provide a forum for such exchange of information as well as answer common questions asked by participating centers.

To accomplish this we need HTCs that have questions for other centers to specifically define them to their Regional Coordinator. The Coordinator will then evaluate these questions and communicate them to us. We will ask participating centers for their input on these questions and publish their responses in subsequent issues of the Newsletter. With participation from all centers, we can better facilitate everyone's experience with UDC.

* Use of trade names is for identification only and does not constitute endorsement by CDC or the U.S. Department of Health and Human Services.

During the past four months, HTCs across the country have begun UDC. Below are results of preliminary analyses using data collected at these centers.

Fig. 1 As of August 31, UDC has begun in 41 centers representing 9 regions. However, each week, more centers are beginning UDC. The numbers in white are the number of participating HTCs in each region. The numbers in blue represent the total number of federally-funded HTCs in each region.



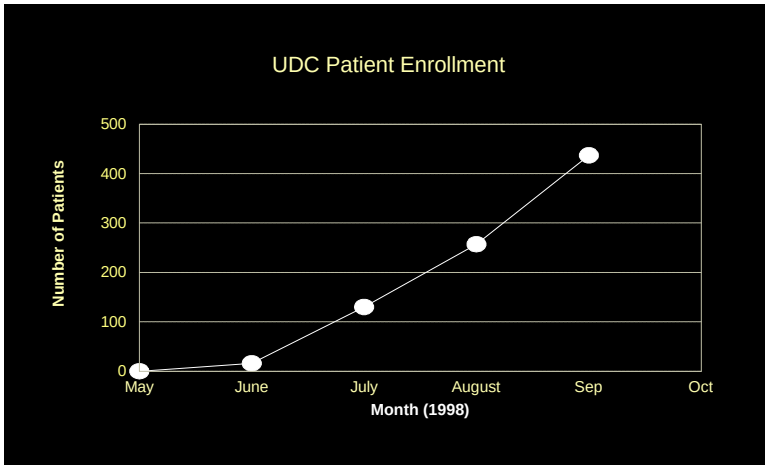


Fig. 2 The first patients were enrolled in UDC during May 1998. Since that time, the number of participants has steadily increased. More than four times the number of patients enrolled in May were recruited into UDC in June and July. We expect these numbers to rise even more rapidly in the fall, when centers who do not hold summer clinics begin enrolling patients.

Fig. 3 This pie chart shows the distribution of bleeding disorders among the 347 participants who were enrolled in UDC between May 1st and August 31st. Approximately 72% of the participants had factor VIII deficiency, 15% had factor IX deficiency, and 10% had von Willebrand Disease. Most of the patients with von Willebrand Disease had either the type 1 or type 3 pattern.