NIH Clinical Center CIO Newsletter

April 2008

28th Edition

This is the twenty-eighth edition of a monthly broadcast email to the CRIS user community about CRIS capabilities and issues. In addition to the text version in this email, I've attached a PDF version that can be printed. I look forward to receiving your comments or suggestions at CIOnewsletter@cc.nih.gov

Topics of the Month

- CIO Remarks
- Pharmacy Go-Live
- New Progress Note to Document Consent
- New DTM Blood Products Labeling
- Privacy Officer
- Information Systems Security Officer
- Security Requirements
- User Training
- CRIS Support

CIO Remarks

At their September, 2007 meeting, the members of the Medical Executive Committee (MEC) decided that all CRIS Prescriber Training should be made available on-line and should be readily accessible from areas other than the DCRI Training Room. On its face, this may seem a very basic and simple effort for DCRI staff to complete. After all, the training materials were already computer-based, so what would be the issues on extending them to any user, from any site?

First the new requirements were to provide a training format offering the following advantages:

1. 24-hour access to course material
2. Remote access (outside of DCRI Classroom and/or NIH campus)
3. Optional completion prior to arrival at NIH
4. Enhanced online tutorials
5. Ensure all access is secured and that no information is saved on the user's workstation

Second there were many logistical and technical challenges to overcome during the design and the succeeding implementation to meet these requirements requested by the MEC.

1. Identification of a process to create external user accounts at the beginning of the credentialing process before the intended prescriber obtains an NIH account. This required synchronizing the Credentialing Database with the CRIS Training Database with the CIT External Account Process.

2. Development of a process to assign users to a prescriber account and a patient in the training environment so that no two users would have the same account and patient.

3. Creation of a process to refresh the training environment to reconstitute user accounts and patient records for prescribers that have completed training while minimally affecting users currently performing training.

4. Creating a process to preserve the pedagogical integrity of the existing Prescriber Online Training Environment by providing Exercises to be graded and by logging the grade in the CRIS Training Database.

Over the last 7 months, these challenges were identified, diagnosed and factored into the overall design, resulting in a very good end product for our users.

There were a lot of individuals who made significant contributions to this project, and whose efforts were critical to its success. Without such a wonderful team we would not have been able to deliver a successful product. Thus I want to say, "Thank you" to all the team members for their dedication, commitment, and hard work, including:

Susy Postal, CC DCRI: Project leader, coordinator, counselor and therapist.

Joe Hendery, CC Credential Services who worked with the team since the beginning to ensure that this process would work within the Credentialing Process.

Valerie Wampler, CIT who worked diligently with our team to develop a process to create accounts for non-NIH users to access the training environment.

The Rest of the Team: Steve Bergstrom, Claudia Briguglio, Doug Butters, Seth Carlson, Rubi Defensor, Richard Farina, Lincoln Farnum, John Kocher, Boniface Lansiquot, Myoung Lee, Philip Lightfoot, Tim Maloney, Jon McKeeby, Mark Miller, Todd Myrick, Patty Sengstack and Doug Sur.

Pharmacy Go-Live

The long-awaited Go-Live for the Pharmacy's Information system, Sunrise Medication Manager (SMM), is scheduled for Saturday May 31st. This system will be used for inpatient, clinic, and Day Hospital orders. Many months of work have gone into this very important project and the value it will add to the Clinical Center will be significant. An Inpatient Pharmacy System will allow us to improve several processes that will lead to improvements in the quality and safety of medication delivery to our patients. *Take Home medications are not affected by these changes, and will continue to work as they currently do within CRIS.*

Complete activation of SMM will be in several phases**:**
Saturday, May 17th – CRIS downtime from approximately 11 AM until Midnight. This downtime is needed to prepare CRIS for SMM. Standard down-time procedures will be used. We have spoken to our ancillary system partners (Laboratory Medicine, Transfusion Medicine, Department of Radiology) and the Nursing Department. Downtime policies have been updated and distributed.

Saturday, May 31st – CRIS downtime from approximately 5 AM to 11 AM. SMM will be activated for items dispensed from the Unit Dose Area (orals, direct injections, topicals, eye drops, etc). When SMM is operational, prescribers should notice very little difference in CRIS order forms; although some order entry enhancements will have been made.

- Current inpatient, clinic, and Day Hospital medication orders for these items will need to be discontinued and re-entered so they can cross into the new Pharmacy system. The proposed plan, subject to approval by the MEC on May 6th, is to use pharmacists for this process with quality assurance checks by other pharmacists, nurses, and prescribers. Cosignature by prescribers for these orders will be required.
- Future Outpt/Pre-Admit orders - Orders entered prior to 5/31 for use after 5/31 will not work when released. DCRI will identify any such "Future" orders in CRIS and work with prescribers to re-enter orders as needed. If possible, please wait until after May, 31 to enter Future Outpt/Pre-Admit orders.

Saturday, July 12th – CRIS downtime details will follow in a subsequent CIO Newsletter. SMM will be activated for items dispensed from the Intravenous Admixture Unit Area (piggybacks, drips, PCAs, etc). This will complete SMM activation. Similar to the May 31st downtime, IV orders will need to be re-entered.

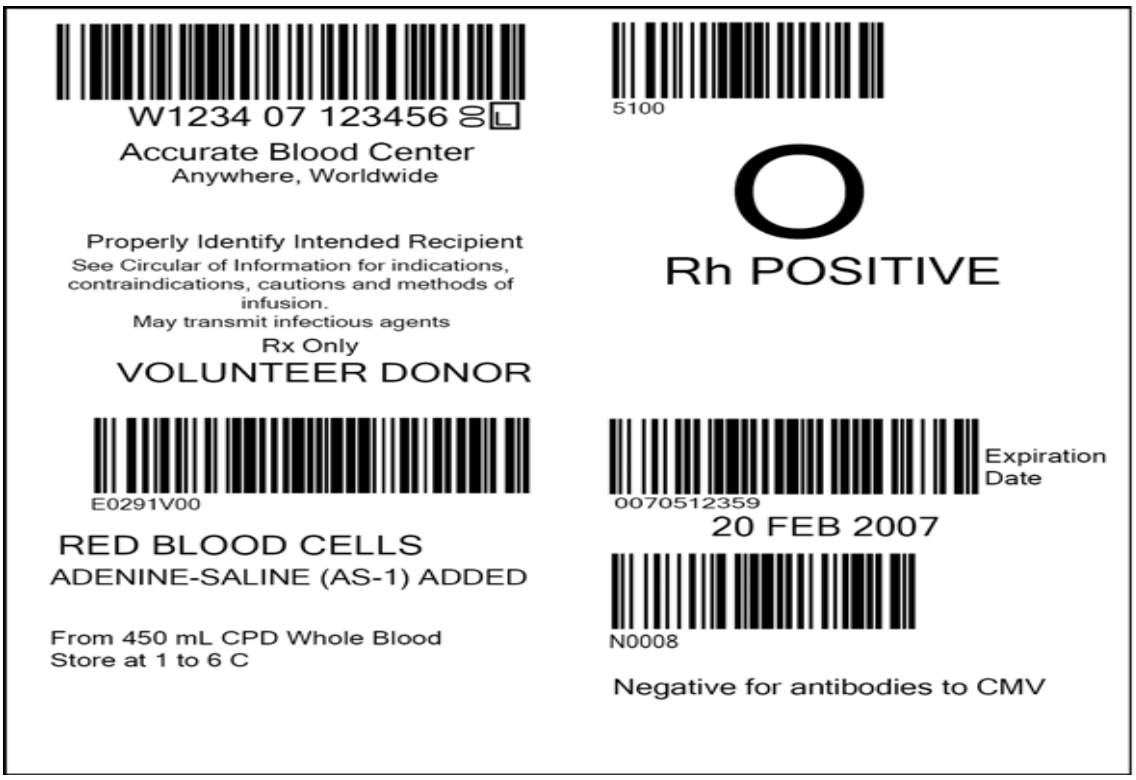
New Progress Note to Document Protocol Consent

On April 14th, a new generic progress note, Progress Note – Documentation of Consent, was added to the Document Browse under Prescribers → Generic. This note allows investigators to document when a research subject has given consent to participate in a protocol. Completed notes will appear on the Documents tab under Prescribers → Progress Notes → Generic. As always, medical staff members entering CRIS progress notes print out and file a hardcopy of their progress note into the inpatient charts while outpatient reports print in the Medical Record Department for filing in the medical record.

New DTM Blood Products Labeling

The Department of Transfusion Medicine began implementing a new labeling format for blood components on April 28, 2008. The change utilizes a bar code symbology called *ISBT 128* and is mandated by the AABB to be implemented on or before May 1, 2008 by all association members. The labeling format was designed by the International Society for Blood Transfusion (ISBT) and is maintained by the International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA). Its purpose is to provide a global standard for the identification, labeling and information processing of human blood, tissue and organ products across international borders and disparate health care systems. *ISBT 128* provides for unique identification of any donation worldwide. It does this by using a 13 character identifier built up from three elements, the first identifying the collection facility, the second the year, and the third a sequence number for the donation. The appearance of the blood label will change to an all black and white format laid out in quadrants each displayed in both bar code and eye readable formats. The quadrants display the unique donation number, ABO Rh group and type, product code and expiration date. Look for more information in the April edition of CC Nursing Quick Updates. For additional information please contact Sherry Sheldon (301) 451-8654 or Karen Byrne (301) 451-8645.

Following is a generic example of the new ISBT 128 label.



Privacy Officer

In 1974, Congress enacted legislation creating the Privacy Act, which was the first major legislation enacted to protect the privacy/confidentiality rights of U.S. Citizens. The Act established a constitutional right to privacy and affected the collection, maintenance, use and dissemination of all personally identifiable information collected by Federal Agencies.

Specifically, the Act limits collection of personal information, prohibits establishment of secret Government records systems and prohibits the secret use of records the Government does establish. In addition, the Act specifies that each individual has the right to see and correct one's own records and further stipulated that the Government must have safeguards in place to assure the security and accuracy of the records it creates. The Act also establishes, both, civil and criminal penalties for violations.

Here at the NIH, the Act limits the collection of information to that which is necessary to carry out the Agency's official function to conduct biomedical research. Of course, this function requires the NIH to establish many different systems of records, including medical and research records on individuals who agree to participate in research. Obviously, these kinds of records often contain very sensitive personal information that patients expect to be maintained in a secure and confidential manner. It is not farfetched to presume that without such an expectation of confidentially many, if not most, patients might not continue to participate in research or come to the NIH in the first place.

NIH has established an administrative structure to address privacy across the various levels of the organization which is comprised of the NIH Senior Privacy Official, the IC Privacy Officers/Coordinators, Record System Managers, Records Management Officers, Forms Management Officers, Contract Officers and Information Systems Security Officers.

Each IC has a Privacy Officer/Coordinator who is the front line person responsible for all Privacy Act matters within their IC. They serve as expert advisor to their IC on privacy matters, they conduct privacy audits and prepare reports of their findings, they draft required systems notices, they consult with the NIH Office of General Counsel and they coordinate with all the other members of the privacy structure, as well as the NIH Senior Official for Privacy.

Jerry King has been the CC Privacy Officer for over 25 years and has participated in the creation of most of the CC official records systems during that time. Currently the CC has over 40 individual records systems, both large and small, that contain confidential information. As such, Mr. King must review each record system annually and submit a Privacy Impact Assessment for each. In addition, Mr. King works closely with the Information Systems Security Officer to be sure that digital information is safeguarded as required by the Privacy Act. As most of you are aware, in this digital age we all must be particularly careful not to create unauthorized records systems and to protect the data we use from authorized systems. Too often lately, we open the paper to read about another stolen laptop or hacked database. The CC Privacy Officer is here to answer your questions and assist you in meeting the requirements of the Privacy Act while maintaining access to the information you need to do your job.

If you have any questions or concerns about the Act or other privacy/confidentiality matters at the CC, please contact Mr. King. He may be reached at (301) 451-4954 or via e-mail at JKing@nih.gov.

Information Systems Security Section

The Information Systems Security Section of DCRI is responsible for the coordination, implementation, and enforcement of Government-required information security policies that affect the CC. John Franco, the Information Systems Security Officer and Boniface Lansiquot, the Associate Information Systems Security Officer lead the section. Some of their responsibilities include, but are not limited to:

1. Evaluate new or existing systems to assure compliance with applicable laws and regulations.
2. Provide guidance to CC employees on compute security issues related to the acquisition, utilization, and disposal of computer hardware and software.
3. Create and/or distribute written computer security policies sand procedures that enable the CC to achieve its mission.
4. Ensure that all CC employees are exposed to computer security awareness and training.
5. Receive, monitor and investigate allegations of improper/illegal activities by employees who may have violated privacy/confidentiality, security policies, regulations or other requirements this jeopardizing the security of CC computer systems.

The ISSOs are available to answer questions or recommend solutions to computer related security issues. John Franco has been as CC employee for over 20 years. He can be

reached at (301) 285-9412 or via e-mail at JFranco@cc.nih.gov and Boniface Lansiquot can be reached at (301) 435-7924 or via e-mail at BLansiquot@cc.nih.gov

Security Requirements

Please be aware that because we are now in a new fiscal year, the required Security Awareness Training (http://irtsectraining.nih.gov/) has been updated to include the FY '08 Refresher component. You may check your status when viewing your student record. As with previous years, those taking the initial full security awareness course after October 1, 2007, will automatically receive credit for the FY08 Refresher (i.e., if they previously took the course, and just repeated it, they do NOT receive credit for the Refresher---it's just the first time). All NIH employees and contractors are required to complete the refresher by June 30, 2008. Remember – you'll have to review and acknowledge that you have read the NIH Rules of Behavior as part of this annual training.

User Training: CRIS Prescriber Training: Online Availability

As shared in the March CIO Newsletter and Special Edition Online CRIS Prescriber Training CIO Newsletter, the Department of Clinical Research Informatics (DCRI) proudly unveils a new era of CRIS Prescriber training: online availability which began April 25, 2008.

A roll out plan for this online CRIS training process for new Prescribers is currently being implemented. For the first three months, DCRI will offer instructor led CRIS Prescriber training classes; however, we highly encourage new Prescribers to use the online training process. DCRI has met with Program Coordinators and key stakeholders who are planning for CRIS training needs of new medical staff to help answer any questions or concerns. We are excited about this new training format and hope that you will be pleased with it as well.

If you have any questions regarding Online CRIS training or how to register for an instructor led class, please call CRIS Support at (301) 496-8400 during normal business hours (Monday – Friday, 7:00 am– 5:00 pm).

CRIS Support

Please come visit our CRIS Booth and meet some of the CRIS Support staff on May 19, 2008 outside the second floor cafeteria 8:00 am -9:30 am and again from 11:30 am-1:00 pm. . We will review creating personal filters for viewing information in CRIS and demonstrate the new online CRIS Prescriber training process.

Please stop by as we look forward to meeting you and addressing your concerns and questions about CRIS. Resource material is available at the booth to take with you and share with your colleagues. You can also find resource materials at the CRIS website training material section http://cris.cc.nih.gov/cristraining/training_materials.html

Have a CRIS Question? Give CRIS Support a call (301) 496-8400. From 7:00 am to 5:00 pm Monday through Friday, an analyst is on site and assigned to answer your calls. At other times, support calls are answered by the DCRI Operations staff who have responsibility for continual monitoring/troubleshooting of clinical systems and access to additional resources to assist you. Occasionally they may be performing their duties away from the phone when you call for assistance. If you reach voicemail when contacting CRIS Support, please leave a message with your full name and a contact number. Someone will call you as soon as possible.