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## Positive Patient and Sample Identification for Blood Radiolabeling Procedures with a Bar Code System

Sean D. Waite and Joseph C. Hung

Nuclear Medicine, Department of Diagnostic Radiology, Mayo Clinic, Rochester, Minnesota and Innovative Software Systems, Oswego, Illinois

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**Objective:** Three patients have been reported to have received blood or a blood product from another patient infected with the human immunodeficiency virus (HIV) while undergoing nuclear medicine procedures. We have developed a personal computer-based bar code verification system for accurately identifying blood samples used during the leukocyte radiolabeling process.

**Methods:** The system involves production of a bar code label for each syringe and tube used in the cell labeling process. At the time of blood withdrawal, the patient is issued a wristband containing a bar code label. During the radiolabeling procedure, the labels on the tubes are scanned to match the label on the blood-withdrawal syringe. Upon the patient's return for reinjection, the bar codes are again scanned to verify the patient on the syringe and wristband match. Patient identification is also confirmed verbally and by comparing signatures obtained from the patient.

**Results:** It was anticipated that this verification procedure would be very time consuming and laborious. The patients have voiced their appreciation for the efforts we have taken to ensure their safety. The positive response from our patients has resulted in greater acceptance by the technologists working with the new system. The true value of this system is measured by the accuracy of patient identification and by the confidence that patients have in our work.

**Conclusion:** The implementation of a bar code verification system has enabled us to minimize the risk of patients receiving the wrong labeled cells without involving more personnel to perform identification procedures.

**Key Words:** misadministration; bar code verification system; positive patient identification; positive sample identification

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Many nuclear medicine procedures involve the withdrawal and reinjection of blood or blood products with the potential for transmission of blood-borne pathogens. Procedures involving

the use of blood products pose an infection control problem due to the potential for cross-contamination and misadministration of radiolabeled blood products.

An article published in the August 7, 1992, issue of *Morbidity and Mortality Weekly Report* (1) disclosed that three patients received blood or a blood product from another patient infected with the human immunodeficiency virus (HIV) while undergoing nuclear medicine procedures (2-6). The reported incidence of misadministration of blood products has prompted the Centers for Disease Control and Prevention (CDC) to issue recommendations to be followed by nuclear medicine departments performing procedures involving the use of radiolabeled blood and blood products (1). The CDC states that the risk for patient or health-care worker exposure to the bloodborne pathogens during radiolabeling blood procedures may be minimized if one carefully adheres to the CDC's eight-point recommendations (1).

Specific recommendations pertaining to verification of dose and patient identification during the blood radiolabeling procedure (1) include:

1. All doses and syringes should be examined for identification and radioassay (i.e., radiation level checked) before injection.
2. All syringes should be labeled with appropriate identifying information, including the patient's name and the name of the radiopharmaceutical; a unique identification number should also be used.
3. Consideration should be given to implementing a system to be used when administering biological products (i.e., labeled cells) that is similar to the system used for administering blood. Such a system requires cross-checking by two persons of all labeling of products to be injected, the prescription and the patient identification.
4. All procedures should be documented. Ideally, the name or identifying information of the person administering the dose and the exact time of administration should be recorded either in the patient or departmental record.

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For correspondence and reprints contact: Joseph C. Hung, PhD, BCNP, FASHP, Mayo Clinic, 200 First Street SW, Rochester, MN 55905.



**FIGURE 1.** The personal computer system with two interconnected bar code readers.

The system we developed used bar code technology to positively identify all blood samples during blood radiolabeling procedures in order to address the CDC recommendations (*1*).

## MATERIALS AND METHODS

### System Configuration

The Blood Verification System™ (Innovative Software Systems, Oswego, IL, distributed by Mayo Clinic, Rochester, MN) was designed to function with an IBM, or compatible, personal computer (PC) using a Microsoft C compiler (Microsoft Corporation, Redmond, WA). The user interface was developed using a programming library from Liant Software Corporation, C-Scape 3.2 (Liant Software Corporation, Framingham, MA). The database library used was the Raima Data Manager™ (Raima Corporation, Bellevue, WA).

The system is equipped with a bar code reader (American Microsystems Model 2002, Metrologic Instruments, Inc., Blackwood, NJ) (Fig. 1) and two printers: the first printer (Zebra Technology Corporation, Vernon Hills, IL) is an ASCII-based printer employed to produce bar code labels, and the second printer (Microline 320, Okidata Corporate Office, Mt. Laurel, NJ), is used to print a daily summary of all radiolabeling procedure activities (Fig. 2).

The overall system was designed to allow the user to enter new patient information consisting of patient name, patient



**FIGURE 2.** The two printers that generate the bar code labels (left) and the daily report (right).

identification number, type of blood radiolabeling procedure and the initials of the technologist performing the radiolabeling procedure. The user is also able to edit patient information and cancel patient records. Bar code labels and daily reports can be generated by the user (Fig. 2). Proper patient identification of all syringes and tubes is verified using the bar code reader to read the system generated labels. The user is notified of any nonmatching tubes or syringes and must interact at the keyboard in order to continue processing. Scanning the labels enables the system to store the time of verification for the generation of a summary report.

### Patient Information

When a patient is scheduled for a blood radiolabeling procedure, the patient's demographic information is entered into the computer system. The user enters the patient information and the type of blood radiolabeling procedure (Fig. 3). Entering the type of radiolabeling procedure will define tube labels



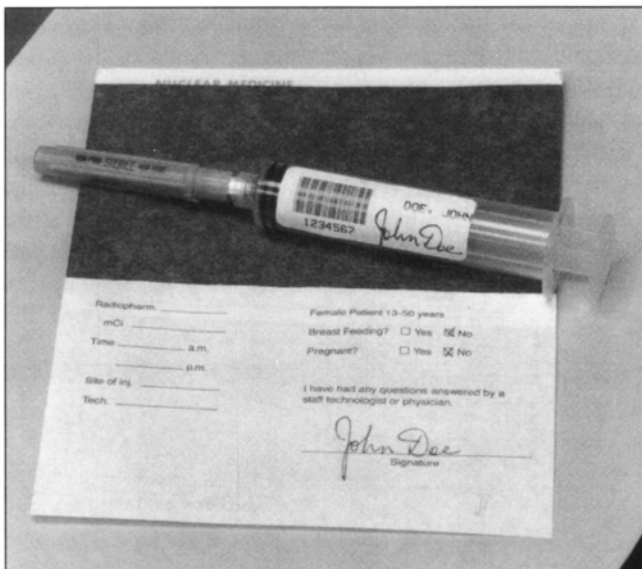
**FIGURE 3.** Entry of patient information (i.e., name and identification number) and the type of radiolabeling procedure (i.e., regular sedimentation or Ficoll-Hypaque separation method).



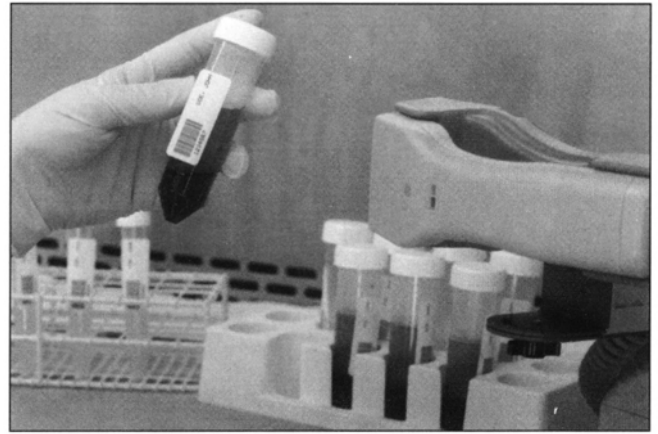
**FIGURE 4.** Bar code labels for syringes and tubes. A small aliquot of the final radiolabeled product is transferred to the small tube in the lead container for the complete blood count. This small sample tube is also bar coded.

for each step of the blood radiolabeling procedure. Prior to beginning the radiolabeling process, bar code labels are produced for each syringe and tube used in the procedure. The labels include the patient's name and unique identification number in addition to the bar code. The technologist places the labels on the blood withdrawal syringe, vials, and tubes used for the labeling procedure (Fig. 4).

Prior to the patient arriving in the nuclear medicine area, the nuclear medicine technologist ensures that there are no empty, used or loaded syringes in the venipuncture room other than those to be used for the patient. The patient is then asked to state her full name and is also asked to sign her name on the label of the final dose syringe and on the report form (Fig. 5). The label with the patient's signature is immediately placed on the syringe that will contain the final dose for reinjection (Fig. 5).



**FIGURE 5.** Patient's signature on the bar code label of the reinjection syringe and on the report form. The patient's signature provides another verification to ensure positive patient identification.



**FIGURE 6.** The transfer tube that contains blood products is scanned with a hands-free scanner.

Prior to starting the labeling procedure, the vertical laminar flow hoods are checked to make sure there are no used syringes or tubes present other than the ones to be used in the radiolabeling procedure. The blood is then taken to the nuclear pharmacy, and the labeling process is begun. Only one patient's blood can be transported at a time to eliminate any chance of mixing up blood samples from different patients. The nuclear medicine technologist is allowed to perform only one radiolabeling procedure on one patient's blood at any one time.

### Radiolabeling Procedure

At the start of the procedure, the technologist activates the appropriate patient data files and enters his initials into the system. The software records the date and time of the radiolabeling procedure. Database files are now prepared for sample verification during the radiolabeling procedure.

The labeling process is performed according to the appropriate labeling procedure (i.e., regular or Ficoll-Hypaque method). The system requires that the bar coded withdrawal syringe be checked against each of the bar coded tubes used during the labeling process (Fig. 6). Each time a transfer is to be made the withdrawal syringe (master tube) is scanned, as is the transfer tube (Figs. 6, 7). Upon a successful match, a message is displayed (Fig. 8), a tone is emitted and the time at which the tube was scanned is saved in the system database. The labeling process continues according to protocol.

If an unsuccessful match is encountered during the labeling process, the system alerts the technologist with an audible tone and a visual message (Fig. 9), and the information is recorded in the patient data files. The system requires the technologist to enter his initials to confirm the message and exit the message screen. If an unsuccessful match is encountered, the system assumes that wrong blood product exists in the radiolabeling area. Therefore, the entire blood radiolabeling procedure must be canceled and no blood products can be reused. The system updates the patient record and prevents the labeling process from continuing in the computer system.



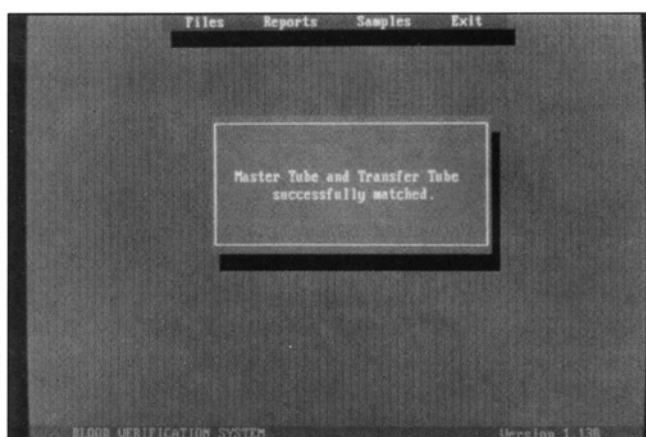
**FIGURE 7.** Each time the blood product is transferred to a new tube, the bar code on the master tube (i.e., the syringe used to draw the patient's blood) is scanned and compared with the bar code on the transfer tube.

### Dose Reinjection

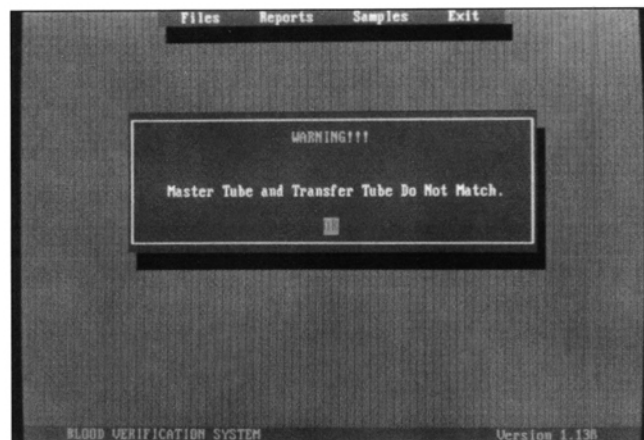
Once the final dose syringe is verified, the dose is radioassayed and the information recorded in the pharmacy computer system (Nuclear Pharmacy Manager®, Du Pont Merck Pharmaceutical Company, Billerica, MA). A label containing the patient's name, the name of the radiopharmaceutical and a unique study number is generated and applied to the final dose syringe. The final dose syringe has two labels on it: the bar code label with the patient's signature and the label from the pharmacy computer system (Fig. 10).

Before bringing the dose syringe into the venipuncture room, the nuclear medicine technologist must check the room to assure that there are no used or loaded syringes in the area. The dose is then taken to the patient for reinjection.

Upon the patient's return, the nuclear medicine technologist asks the patient to state her full name and also requests the patient to sign her name on the report form (Fig. 11). This signature is then used for comparison with the other two signatures obtained from the patient (Fig. 11). The appropriate radiolabeled blood product is then reinjected into the patient.



**FIGURE 8.** This message is displayed on the computer monitor when the bar codes on the master tube and transfer tube are matched.



**FIGURE 9.** A warning message is displayed when the bar codes on the master and transfer tubes do not match.

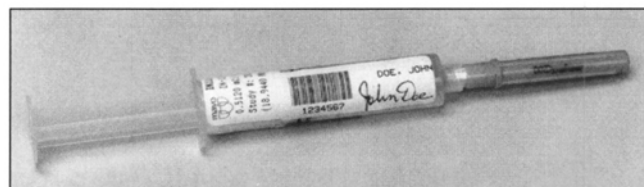
### Record

To complete the patient record, a final summary record (Fig. 12) is printed for all successful labeling procedures. A labeling procedure which was halted at any point during the process also produces a permanent record for the patient's chart.

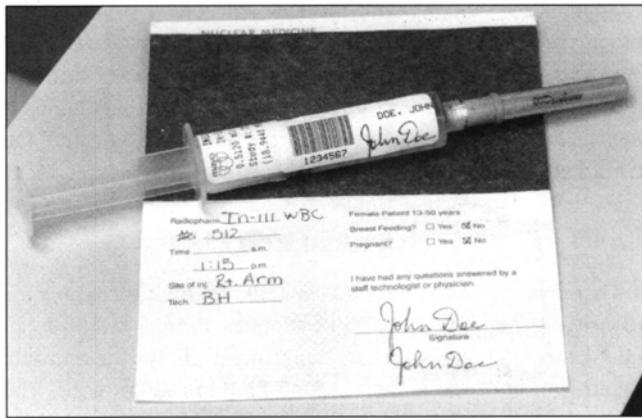
### Commercial Nuclear Pharmacy Services

For nuclear medicine laboratories that use commercial nuclear pharmacies for blood radiolabeling services, the patient verification with signature comparison and verbal name confirmation could be performed by the nuclear medicine technologists prior to the blood withdrawal and the dose reinjection. The syringes that contain the patient's blood must be properly labeled with patient identification information including the type of blood radiolabeling procedure, whereas a label with the patient's signature is placed on the final dose syringe before sending it to the central nuclear pharmacy for radiolabeling. The commercial nuclear pharmacy could then use our system to enter patient identification information and the type of blood labeling procedure according to the information stated on the syringe label. During the radiolabeling procedure, the blood sample verification process could be accomplished by following the same steps described.

It should be emphasized that the nuclear medicine technologist must ensure that no empty, used or loaded syringes are present in the venipuncture room with the exception of the syringe to be used for the patient. In addition, the nuclear pharmacist must make sure that there are no used syringes or



**FIGURE 10.** The final syringe for reinjection has two labels affixed to it. The top label is the syringe label which is required by NRC regulation, and the bottom label is the bar coded sticker with the patient's name, identification number and signature.



**FIGURE 11.** Before reinjecting the final radiolabeled blood product, the patient's signature on the report form and on the bar code label of the final syringe must be verified by the technologist. On the report form, the top signature is signed by the patient prior to withdrawal of the blood for the radiolabeling procedure and the bottom signature is signed by the patient before the re-injection.

tubes in the laminar flow hood prior to the radiolabeling procedure. Commercial nuclear pharmacies should allow only one nuclear pharmacist to perform one blood radiolabeling procedure on one patient's blood at any one time to avoid any possible cross contamination.

### DISCUSSION

Nuclear medicine procedures such as white blood cell labeling, platelet labeling, gastrointestinal bleeding studies, splenic imaging and cardiac blood pool studies require the withdrawal of blood from the patient followed by the reinjection of the radiolabeled blood components. Within the past few years, there have been three documented cases in which a patient undergoing a nuclear medicine study inadvertently received an intravenous injection of a blood product that was infected with HIV (2-6). In an effort to reduce the risk to patients, the CDC has published a set of recommendations for nuclear medicine departments to follow when performing blood labeling procedures (1). The recommendations focus on areas of education, patient identification, syringe identification, disposal of contaminated syringes and proper documentation (1). Implementation of such a system, as mentioned in the CDC recommendations, may require additional staffing to allow for the cross-checking procedures which requires two persons (1). In the current environment, the need for additional staffing may not be accommodated easily. In addition, human error is still possible even with the cross-checking system by two persons (1).

Walsh, et al. developed a color-coded system in order to prevent cross-contamination and misadministration involving radiolabeled blood products (7). Although this color-coding system is relatively simple to perform and inexpensive to implement, the entire verification system still relies upon a human operator and therefore may lend itself to human error. In fact, the syringe involved in the third HIV-misadministration incident was properly labeled with a color-coded (yellow)

DOE, JOHN		1234567	
LABEL TYPE: Regular		TECHNOLOGIST: BH	
TRANSFER TUBE	VERIFIED		9:41
TRANSFER TUBE	VERIFIED		9:41
TRANSFER TUBE	VERIFIED		9:45
TRANSFER TUBE	VERIFIED		9:45
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TRANSFER TUBE	VERIFIED		10:57
TRANSFER TUBE	VERIFIED		11:0
TRANSFER TUBE	VERIFIED		11:8
TRANSFER TUBE	VERIFIED		11:8
TRANSFER TUBE	VERIFIED		11:8
TRANSFER TUBE	VERIFIED		11:8
TRANSFER TUBE	VERIFIED		11:11
TRANSFER TUBE	VERIFIED		11:17
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TRANSFER TUBE	VERIFIED		11:41
TRANSFER TUBE	VERIFIED		11:41
FINAL SYRINGE	VERIFIED		11:42

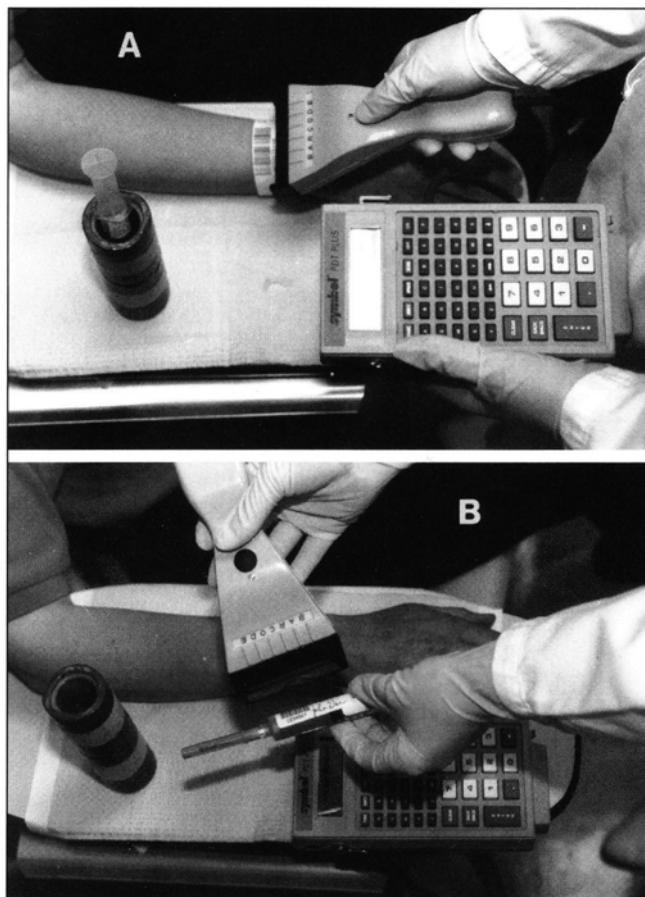
**FIGURE 12.** The final summary report record which contains the patient information, the type of radiolabeling blood procedure, the identity of the nuclear medicine technologist, and the exact time of the blood withdrawal, each radiolabeling step and exact time of the final reinjection.

sticker for <sup>99m</sup>Tc-MAA (6). The nuclear medicine technologist simply did not read the color-coded label on the syringe which was previously used on an HIV-infected patient, and injected the residual material into a second patient who was scheduled for a bone scan (6). The other risk in using the color-coding system is that it is not suitable for color-blind human operators.

Our institution has developed a blood labeling procedure which concentrates on accurate patient and syringe identification using the patient's signature, verbal verification of the patient's name and a computer-based bar code system. Our guidelines for radiolabeling blood procedures contain a number of checks which help to ensure that any mistakes can be identified prior to reinjection of the radiolabeled blood product into a patient.

The cost of the software and bar code equipment with the use of existing computer hardware is approximately \$2,000, which is much less than adding additional staff in order to comply with the CDC's cross-checking requirement. Although the cost of litigation and settlements involved with a misadministration of a blood product cannot be accurately estimated, it would undoubtedly far exceed this cost.

We continue to evaluate and improve this system so that it will enhance the effectiveness of the blood labeling procedure.



**FIGURE 13.** A portable bar code reader is used to scan the (A) patient's bar code wristband and the (B) bar code label on the final reinjection syringe.

In the future, we are planning to implement a portable bar code reader that will provide mobility for verification of patient identification. This system could be carried by the nuclear medicine technologist to the patient's room or venipuncture area and used to compare the bar code on the syringe with either the bar-coded appointment envelope or the wristband that is given to the patient at the time blood is drawn (Fig. 13).

We had anticipated that the use of the bar code system and the blood radiolabeling guidelines would make the blood labeling process more time-consuming and laborious. However, after implementing the patient and sample identification system and guidelines, we found that our patients were appreciative of the efforts that our staff had taken to ensure the accurate identification of their radiolabeled blood. The positive response from our patients reflected favorably onto the nuclear medicine technologists who have readily accepted the

change. After working with the new bar code system and the blood radiolabeling guidelines, our technologists have become comfortable with the procedure and find it to be of minimal inconvenience. The true value of the system and guidelines is measured by the accuracy of patient identification and the confidence that patients have in our work.

## CONCLUSION

Employment of the bar code system and the procedures for identifying patients and blood samples during radiolabeled blood product studies in our department allows for accurate identification of the patient and all blood products used. The implementation of this verification system has allowed us to use a blood bank-type of verification procedure to minimize the risk of cross-contamination and misadministration without the need to increase staffing or staff involvement. The bar code system should alleviate the possibility of human error present in double check systems, whether based upon a unique identification number or color coding. The expense of the bar code system implementation is far less than that of a misadministration or an increase in staffing to allow for double checking of labeling procedures. The system is able to accurately and positively identify all blood products used in the radiolabeling procedure, ensure proper patient identification and supply complete documentation.

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