Blood Product Transfusion & Safe Practices Final Progress Report

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STRUCTURED ABSTRACT

Purpose

Reduce the risk of adverse events throughout the entire transfusion process.

Scope

The specific aim of project was to use wireless mobile devices, barcode technology, and a new online data-capture-response tool to prevent patient identification errors that occur in the blood transfusion process when healthcare workers collect blood samples for type and cross match, the blood bank evaluates blood samples, the blood bank dispenses blood products, and staff members administer blood products.

Methods

We developed and implemented a computerized, barcode-based tracking system for blood transfusions. A data network, wireless devices, and barcoded labels were pilot tested over 8 months before the entire hospital converted to this system in February 2005. The system recorded all transactions, thereby facilitating the assessment of the system. Errors and incident reports occurring before and after implementation were analyzed.

Results

Voluntary incident reports dropped from 41.5 reports/month in the 6 months before implementation to 7.2 reports/month following implementation. The blood sample rejection rate decreased from 1.82% in 2003 to 0.17% following implementation. The comprehensive barcode-based computerized tracking system was accepted by staff, reduced blood sample rejections, and reduced delays in transfusion.

Key Words

Blood product transfusions; Safe practices implementation; Wireless mobile devices; Barcode technology; Patient identification errors

PURPOSE

The specific aim of the Blood Product Transfusions and Safe Practices Implementation project was to 1) increase patient safety through the use of barcode technology for patient identification and 2) reduce errors in blood transfusion process using point-of-care wireless specimen and product tracking. The process uses wireless mobile devices, barcode technology, and a new online data-capture-response tool to prevent patient identification errors that occur in the blood transfusion process when healthcare workers collect blood samples for type and cross match, the blood bank evaluates blood samples, the blood bank dispenses blood products, and staff members administer blood products. Following an 8-month staged pilot test on five units, the remaining units implemented the system on 02/07/2005.

SCOPE

The project was created to replace the existing manual blood product transfusion process housewide with a point-of-care, computerized scanning process, addressing the following specific risk areas:

- Identifying the patient correctly;
- Matching the requisition, patient, and specimen sample properly;
- Encountering the blood specimen for type and cross match in the blood bank;
- Dispensing the blood product from the blood bank; and
- Administering the blood product.

METHODS

A work group that included nurses, physicians, and staff members from pathology, the blood center, and information systems met continually over the course of the project. This group developed detailed diagrams describing the workflow for the paper-based system and the proposed barcoded system, programmed and tested new computer applications, rewrote policies and procedures, developed a rollout plan and a downtime plan, and reported activity to the Grant Oversight Team. Members also reported progress to their respective departments. The work group identified a number of requisite preliminary steps that had to be completed before the new process could be pilot tested, including instituting a new barcoded ID band, installing a wireless network, and selecting wireless devices.

The previous embossed hospital ID band was replaced with the new barcoded ID band before the pilot test. This step alone required multiple steps and decisions: testing and selecting new bands and labels; purchasing and placing nearly 200 label printers, including ethernet lines; and inservicing staff about how to create and use the new labels and bands. In addition to supporting the patient-specific barcode, the new band and label are latex free, impermeable to liquid, comfortable, multipurpose, and inexpensive.

The existing network infrastructure was augmented housewide with a wireless network to support the use of point-of-care wireless devises. The UIHC utilized the expertise of Cisco System Inc.'s technical resources and contracted with Communications Engineering Company (CEC) Professional Services engineering group to conduct a facility survey and to design, configure, install, and test the wireless data network. Major system components of the

802.11B/G installation include Cisco Access Points (Aironet 1200) and antennae and Cisco Wireless LAN Solution products. We estimated how many access points we would need to achieve four access points per 20K square foot.

The project team evaluated and tested an array of wireless devices to assess reliability, ease of use, functionality, and total cost. The project team held a cart fair to allow clinicians to test all devices under consideration and to give input through a formal evaluation process. Phlebotomists and nurses ultimately selected different mobile carts, based on their different work processes. Personnel in some outpatient clinics selected handheld devices rather than carts based on space constraints or workflow needs. All devices were provided with tethered Symbol Bar Code Laser Readers, because the pilot tests demonstrated that wireless, non-laser scanners had a much lower first-time read rate than the tethered scanners.

Once preliminary steps were completed, the project team turned its attention to designing the new process and the online system so that the latter would capture and track activity at each step of the four step process:

1. Sample Collection. The barcode label on the patient's wristband is scanned first. The barcode labels on the requisition and on the blood sample are then scanned. If the barcodes on all three do not match, the sample must be redrawn.

2. Sample Arrival in Blood Bank. Blood bank personnel scan the label on the requisition followed by the label on the blood sample. If the scans do not match, the sample is rejected and must be recollected.

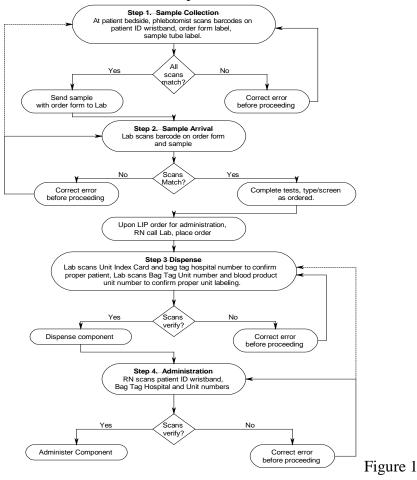
3. Product Dispense. An order card with a barcode label is sent from the patient care area. The order card is scanned followed by the barcode label on the blood product bag tag to confirm a general blood product-recipient match. Subsequently, the unit number on the blood product bag tag and the unit number on the blood product itself are scanned to confirm that the correct unit is being released. All the steps must be completed in succession without error before the "dispense" transaction is completed.

4. Product Administration. The transfusionist must scan the barcode on the patient's wristband, the barcode label on the bag tag, and the unit number on the bag tag in succession before the product can be administered. If any of the scans do not match, the product must be returned to the blood bank. (See Figure 1.)

Information Systems (IS) staff programmed an online history function that automatically tracks all activity associated with the four steps of the transfusion process (1-4, above). This function tracks Error Flag, PID, Sample ID, Requisition ID, Order Card ID, date/time, Error Message, Operator, Collector (used for downtime), and Product Type. Mis-scans are displayed in the history in red type, and key-entered data are highlighted in yellow to make these entries easy to spot for follow-up.

After the programming was completed, staff in one outpatient clinic pilot tested the system. The initial pilot utilized a dual process, requiring staff to first perform the new barcoded process for all steps and then perform the old manual process. On the basis of feedback from this unit, both the programming and the process were refined, and the pilot was extended, one unit at a

time, to an adult in-patient unit, a pediatric in-patient unit, an intensive care unit, and an adult transplant unit. Data from these units were aggregated and analyzed by the research team. Data were discussed with leadership staff.



Because patients are often transferred from one unit to another (e.g., from the emergency room to the operating room, and then to an intensive care unit) and because some units were testing the new process and others were not, staff members who were pilot testing the new method had to follow the manual process until all units were using the new system. Thus, the hospital leadership determined that all remaining units would start using the new process on one day ('big bang' rollout model). This decision had ramifications for educating staff, preparing security access, ensuring that the wireless network was functional throughout the hospital, testing the configuration of the mobile devices, and planning for 24/7 user support, all of which had to be accomplished housewide before the new system was implemented on all units. Nursing, Information Systems, and Pathology staff worked together to provide either user or superuser training to 2,000 nurses, phlebotomists, anesthesiologists, perfusionists, and personnel from the blood bank and critical care laboratory. All trained staff were given computer access to the online function based on requirements of their particular job. IS staff configured, tested, and dispensed 97 mobile and handheld devices and connected a tested scanner to each. Testing included ensuring network connectivity in each patient care room. Information Systems hired

and trained additional desk top support staff to support wireless network and hardware issues around the clock. Following the 8-month staged pilot on five units, the rest of the hospitals and clinics implemented the system on 02/07/2005.

When instituting any new computer-based process, information technology staff and the clinicians who collaborate with them must address potential concerns at the outset. The project's success depends at least in part on the project team's ability to anticipate and obviate potential workflow issues and to respond rapidly to unanticipated problems so that the system doesn't break down and the users do not give up on the process or develop workarounds. When implementing our transfusion system we addressed the following unanticipated challenges:

1) Patients' barcoded wristbands were often inaccessible to staff in the operating room because the patients' arms were covered with sterile drapes. IS staff created a specific online function (available only to staff in the operating room [OR]), called "OR proxy," to address this problem. Anesthesiologists scan the patient's wristband and a barcoded label on the anesthesiology record in the operating room before the start of the procedure. If the labels match, the anesthesiology record can be used as patient identification throughout the case.

2) Staff in the operating room often need to give multiple units of blood in a very short period of time. In those situations, staff do not have time to scan the patient's wristband multiple times. Thus, IS staff developed another on online function to save time during rapid transfusions. The "multiple blood product" function is available during the dispensing and administration steps in the transfusion process. The order card, patient wristband, or anesthesiology record is scanned only one time. Blood bank personnel or transfusionists in the operating room can then complete the scans for each product without having to repeat the initial step.

3) Perfusionists could not use the anesthesiologists' scanning equipment, because perfusionists must stay by their equipment. Thus, perfusionists were provided with their own scanning equipment, which was mounted in a site convenient to their work.

4) Staff pilot tested the new application, a new process, numerous types of new equipment, equipment configurations, and a new wireless network simultaneously. Because the whole system was new, some staff who had problems with a computer would conclude that the entire application didn't work rather than asking whether the trial wireless workstation had lost reception or whether the new wireless network was not functioning. In the future, we would test the parts separately, if possible.

5) To ensure that the process did not increase the risk of errors, staff had to use both the new and the old process until the entire implementation was complete. This increased the amount of work staff had to do, which in turn increased the possibility of errors.

6) The workflow in the Same Day Surgery Clinic requires that staff print labels the day before the patient's procedure, resulting in a 'wrong date' on the printed label. IS staff had to solve this problem so that the hospital could comply with national standards for blood banks.

Project Time Line

ID	0	Task Name	Start	Finish	2nd Qua 3rd Qua	4th Qua	1st Qua	2nd Qua	3rd Qua	4th Qua	1st Qu
1	\checkmark	BarCode Patient ID Labels	M on 6/23/03	Fri 2/20/04			-				
2	\checkmark	Develop	M on 6/23/0	Fri 7/25/03							
3	\checkmark	Logistics – printers, labels, bracelets, other	Fri 8/1/00	Mon 9/22/0							
4	\checkmark	Phased Implementation Roll-Out	M on 10/6/0	Fri 2/20/04							
5	\checkmark	Auto Print upon CheckIn	Tue 12/9/0	Fri 12/12/0:		I					
6	\checkmark	Design	M on 6/2/03	Fri 8/29/03							
7	\checkmark	Development	M on 9/1/03	Fri 2/20/04	· · · · · · · · · · · · · · · · · · ·						
8	\checkmark	Online Tracking and History Functions	M on 9/1/0	Wed 10/22/03							
9	\checkmark	Test and Demo	M on 11/3/0	Fri 1/30/04							
10	\checkmark	Wireless Lab	Thu 1/1/04	Fri 2/20/04							
11	\checkmark	SelectWireless Devices/Order/Setup	Fri 2/20/04	Thu 9/16/04			-				
12	\checkmark	Order and Trial Carts, PC's, and Laptops	Fri 2/20/04	Thu 9/16/0 [,]							
13	\checkmark	Install equipment for phlebotomy and CCC	Wed 3/24/04	Mon 3/29/0			1				
14	\checkmark	Pre-pilot Observations	M on 2/23/04	Fri 3/26/04							
15	\checkmark	Web Survey	Fri 2/20/04	Fri 2/20/04			1				
16	\checkmark	Pilot	Tue 4/20/04	Fri 12/31/04				, 			,
17	\checkmark	Outpatient CCC	Tue 4/20/0	Fri 12/31/04							
18	\checkmark	Pilot Survey	Thu 4/29/0	Thu 4/29/0							
19	\checkmark	Adult Inpatient - 4JPE	Tue 5/25/0	Fri 12/31/04							
20	\checkmark	Pediatric Inpatient - 3JCP	Wed 7/7/04	Fri 12/31/04							
21	\checkmark	Intensive Care - M ICU	Tue 8/10/0	Fri 12/31/0							
22	\checkmark	Bum Unit - 7RCW	Tue 11/2/0	Fri 12/31/0							
23	\checkmark	Pilot Observation and Evaluation	Tue 4/20/0	Fri 12/31/04							
24	\checkmark	Enhance Fx/ProductLabel based on Feedback from Pilots & OR	M on 6/7/04	Fri 1/21/05							
25	\checkmark	Implementation	M on 1/3/05	M on 2/14/05						ų	
26	\checkmark	Gander Support for Dropping Duel Process	M on 1/3/0	Fri 1/21/05							B -1
27	\checkmark	Deploy COWS House-wide	M on 1/17/0	Fri 2/4/08							
28	\checkmark	Train 1800 Users	M on 1/10/0	Fri 2/4/05							
29	\checkmark	House-wide Implementation	M on 2/7/0	M on 2/7/0							
30	\checkmark	Drop Duel Manual Process	M on 2/14/0	Mon 2/14/0							¥
31		Ev al uate Data	M on 2/7/0!	Fri 9/30/05							

RESULTS

We calculated the relative risk of detecting an identification error during the pilot test and during the same time periods in 2002 and in 2003. The relative risk of detecting a misidentification before blood was administered (95% CI) was:

2004 (Study Year) vs. 2003: 9.98 (1.28, 78.0)

2004 (Study Year) vs. 2002: **3.33** (0.92, 12.1)

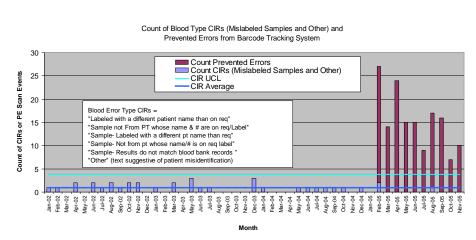
Thus, the pilot test suggested that the barcode system caught identification errors approximately three to 10 times more frequently than did the manual system. Among the misidentifications caught by the system, all but one was caught at the step when the misidentification occurred.

Identification Errors 4/21/04 – 2/07/05 (Pilot Period)					
Prevented	Step/	Step/	Туре		
Errors	Occurred	Discovered			
Count					
2	Collection	Collection	Mismatch: Label/Patient		
1	Collection	Arrival	Wrong barcode on requisition		

Identification Errors 4/21/04 – 2/07/05 (Pilot Period)					
12	Dispense	Dispense	Mismatch: Order card/Blood product in blood bank		
1	Dispense	Dispense	Wrong order card sent by unit		

After the first few months (2/7/05-4/21/05) of using the barcoded process housewide, we again estimated the relative risk of identifying a misidentification with the new system compared with the old system (2/7 to 4/21 in 2003 and 2004). We found about a 10-fold increase in detection for the new system at sample processing (RR = **9.98**; 95% CI = 2.9, 34.5; total activity = 6,953 transactions) and a 30-fold increase at any step of the process (RR = **30.6**; 95% CI = 9.5, 98.4; total activity = 22,569 transactions). Thus, we estimate that we are 30 times more likely to catch an identification error using the barcode system than with the manual system.

Figure 2

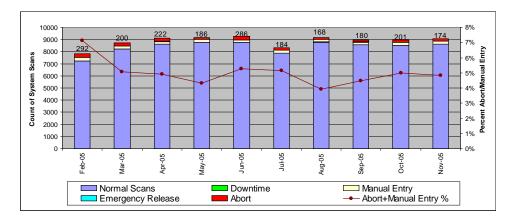


Detecting and Preventing Patient Misidentification

The data retrieved from the "Transfusion: Blood Product History" function was used to sort recorded errors into four major categories. Mis-scans were identified as errors on scanning when the user self-corrected and completely resolved the discrepancy before the next transaction, such as scanning the unit number on the bag tag instead of the barcode label. Skipped steps were errors discovered on the subsequent step, such as attempting to administer a unit when the dispense transaction had not been completed correctly. Wrong steps occurred when the user simply chose the incorrect transaction within the "Transfusion: Blood Product Tracking" online function. Prevented errors were defined as mismatches between barcode labels on the patient's wristband, blood sample, requisition, order card, blood product, or anesthesiology record at any step in the process.

The total number of system entries including normal scans, aborted scans, manual keyed entries, and downtime entries during the first 11 months post-implementation are shown in Figures 3-5. Greater than 90% of scans were successfully completed normal scans. The percentage of aborted/ manually entered scans accounted for approximately 3-7% of the total system scans over this 11- month period. Aborted barcode scans ranged from 168 to 292 per month. The aborted scans were sorted into mis-scans, skipped steps, wrong steps, and prevented errors using the aforementioned definitions. Mis-scans and skipped steps accounted for the preponderance of aborted barcode scans, with prevented errors ranging from 9 to 25 per month.

Figure 3

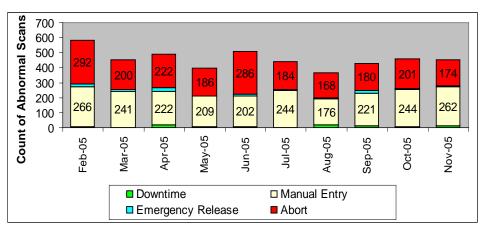


Sample Collection Through Product Administration: Barcode System Scans

Four Steps in Barcode Scan Process

Sample Collection – sample collected/scanned at patients side Sample Arrival in Lab - sample scanned into the blood bank Dispensed from Lab – blood product dispensed/scanned out of the blood bank Product Administration – product is given/scanned at the patients side

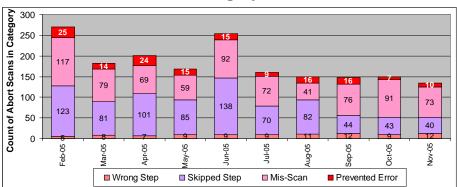




Sample Collection Through Blood Administration: Abnormal Scan Counts

4 Steps in Barcode Scan Process Sample Collection – sample collected/scanned at patients side Sample Arrival in Lab - sample scanned into the blood bank Dispensed from Lab – blood product dispensed/scanned out of the blood bank Product Administration – product is given/scanned at the patients side

Figure 5



Sample Collection Through Blood Administration: Abort Category Counts

Prevented Error = Mismatch between two different, valid Patient IDs

Skipped Step = An upstream scan was not completed correctly

Mis-scan = Invalid PID scans don't match on same step, or invalid barcode scanned

Wrong Step = An incorrect step was performed, followed quickly by the correct step for that user.

Most errors discovered during sample collection in the first 10 months of implementation were skipped steps (Figure 6). Skipped steps occurred when the nurse or phlebotomist failed to scan

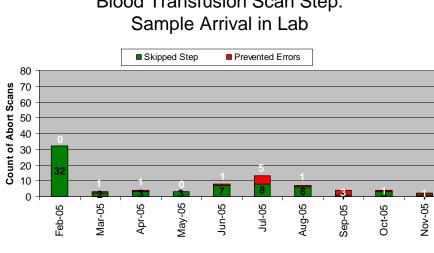
the patient's barcoded wristband, requisition, and blood sample in succession. Prevented errors, a mismatch between the barcoded labels, represented a small proportion of the errors during sample collection. The blood sample rejection rate during 2003 at our hospital was 1.82%, predominantly due to errors such as illegible handwriting, transposed medical record numbers, incorrect spelling of the patient's name, and missing signatures. The sample rejection rate fell to 0.17% following hospitalwide implementation (2/7/05-4/21/05) of the barcode-based system. Skipped steps also represented most errors during sample arrival, when blood bank personnel failed to scan both the requisition and blood sample (Figure 7).

Blood Transfusion Scan Step: Sample Collect Skipped Step Prevented Errors 80 70 **Count of Abort Scans** 60 50 5 6 40 30 20 10 0 Jun-05 Jul-05 Vov-05 May-05 Aug-05 Feb-05 Mar-05 Apr-05 Sep-05 Oct-05

Figure 6

Prevented Error = Mismatch between a Patient ID band and barcode labels on Requisition and Sample.

Skipped Step = Sample Collect Scan not performed completely.



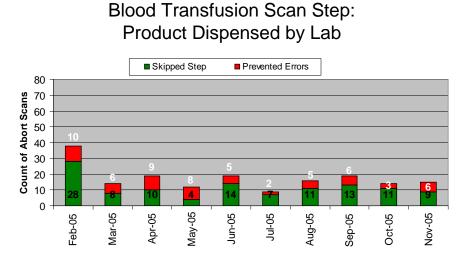
Blood Transfusion Scan Step:

Prevented Error = Mismatch between a Patient ID band and barcode labels on Requisition and Sample.

Skipped Step = Sample Arrival Scan not performed completely.

The preponderance of skipped steps and prevented errors over the first 10 months of implementation occurred when blood products were dispensed (Figure 8). The primary reason for these dispensing errors was the inherent complexity of distributing multiple blood products to more than one patient in a timely manner using a new system. Skipped steps represented failure to complete all the necessary scans before blood products could be dispensed. Blood products may be dispensed at our hospital via the main blood bank or through a satellite Critical Care Laboratory. Blood products are distributed to the satellite laboratory from the main blood bank. Skipped steps often occurred because personnel within the Critical Care Laboratory failed to complete the dispense step following distribution from the main blood bank. Prevented errors during the dispensing step were any mismatches between the barcode label on the order card and barcode label on the blood product bag tag (Figure 9).

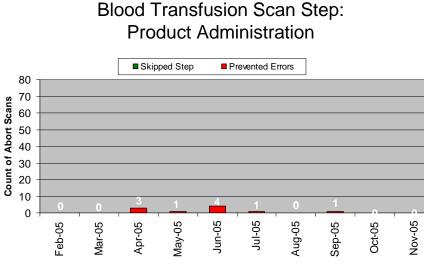
Figure 8



Prevented Error = Mismatch between a Blood Bag barcode label and the barcode label on the Request Index Card.

Skipped Step = Sample Dispense scan event not performed completely.

Skipped steps during administration occurred when the transfusionist failed to complete all three scans in succession: the patient's barcoded wristband, the barcode label on the bag tag, and the unit number on the bag tag. Prevented errors during the administration step were due to a mismatch between the patient's barcoded wristband and the barcode label on the blood product bag tag (Figure 9).



Prevented Error = Mismatch between a Blood Bag barcode label and the Patient ID barcode – corrected at scan.

So far, we have identified only one incident in which healthcare workers may have circumvented the process. This occurred at night in an intensive care unit shortly after the system was activated. The staff members were using the barcode system for the first time. Since then, there have been no other incidents detected.

We conducted a survey of users during the pilot test, and we recently repeated the survey. The rates significantly improved from survey of the pilot units to the survey of all users for all but two of the 16 items assessing how well the equipment performed and how well the users liked aspects of the system. These data suggested to us that the development team had addressed adequately most of the user concerns.

In summary, there are a number of system, workflow, and hardware and software issues that must be addressed to ensure the successful implementation of a wireless, barcoded blood products administration process. Our preliminary data from the pilot suggest the effort is worthwhile, because the new process identifies many more errors than did staff using the manual process, thereby increasing patient safety.

This project required a large, complex, academic medical center to bring together multidisciplinary teams to review and re-engineer critical workflow related to administration of blood products across a spectrum of clinical services. To deploy the new technologies, the project team had to re-engineer several information systems processes. The experiences gained while implementing the transfusion system have positioned the institution to move forward with implementation of similar technology for managing medication administration. The experiences

Skipped Step = Product Administration Scan not performed completely.

and outcomes of this project would help other healthcare institutions as they plan for similar patient safety initiatives.

LIST OF PUBLICATIONS AND PRODUCTS

Conference Proceedings

Walker KP, Carmen LT., Herwaldt LA, editors. Patient Safety and Health Information Technology: Making the Health Care System Safer through Implementation and Innovation. Agency for Healthcare Research and Quality (AHRQ) 2005 Conference. June 6-10, 2006, Washington, DC. "Improving the Accuracy of Patient Identification"

Carmen LT, Walker KP, Herwaldt LA, editors. Patient Safety and Health Information Technology: Making the Health Care System Safer through Implementation and Innovation. Agency for Healthcare Research and Quality (AHRQ) 2005 Conference. June 6-10, 2006, Washington, DC. "Patient Safety with Blood Products Administration Using Wireless and Bar-Code Technology"

Levitt JS, Dane SK, Greene DL, Vande Berg JA, Kemp JD, editors. American Association of Blood Banks (AABB) 2005 Annual Meeting. October 15-18, 2005, Seattle, Washington. "Implementation of a Barcode-Based Computerized Tracking System for Patient and Blood Product Identification in the Transfusion Process"

Porcella A, Walker KP, editors. American Medical Informatics Association (AMIA) Annual Symposium. Oct. 22-26, Washington, DC." Patient Safety with Blood Products Administration Using Wireless and Bar-Code Technology"

Porcella A, Walker KP, editors. Iowa Healthcare Collaborative 2nd Annual Conference for Quality, Patient Safely and Value. November 2, 2005, Des Moines Iowa. "Patient Safety with Blood Products Administration Using Wireless and Barcode Technology."

"University of Iowa Hospital starts using barcodes." News paper article. Iowa City Press Citizen 02/16/2005.

"UI bar codes ensure safe transfusions." News paper article. Cedar Rapids Gazette 02/20/2005.

"Method eliminates mixups." News paper article. Press Citizen 03/11/2005. http://www.bridgemedical.com/03_11_05.shtml

Askeland RW, McGrane S, Levitt JS, Dane SK, Greene DL, VandeBerg JA, Walker K, Porcella P, Herwaldt LA, Carmen LT, Kemp JD. Implementation of a Computerized Barcode-Based Tracking System: Improving Transfusion Safety at an Academic Medical Center. In preparation.