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July 12, 2002

Ms. Mary Gross  
Office of Drug Safety  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane, Room 15B-32  
Rockville, MD 20857

Dear Ms. Gross:

Premier, Inc., a strategic alliance of leading not-for-profit hospitals and health systems nationwide, is appreciative of this opportunity to offer our perspective on the Food and Drug Administration's promulgation of a rule to require bar code labels on institutionally administered drugs, biologicals, and medical devices. We look forward to discussing our position in person, at the FDA's July 26 public meeting on this subject.

Premier is in a position to offer the FDA a unique perspective on industry adoption of the bar code. For the not-for-profit hospitals and health systems allied in Premier, cost-effective quality improvement of care is not only a priority—it's our mission. Bar coding is a critical component of a larger, broad-based strategy to assist our hospitals achieve the highest quartile in quality and lowest quartile in costs.

Research conducted at the Colmery-O'Neil Veterans' Administration (VA) facility in Topeka, KS, is demonstrative of the potential of bar code implementation to improve safety and quality and reduce costs. The Colmery-O'Neil study, conducted between 1993 and 1999, revealed that bar code labeling of drugs reduced medication error rates by 64 percent overall. This experience compelled the VA to implement bar code technology in all of its 172 medical facilities.

Premier believes that patients across the healthcare delivery system are deserving of a comparable level of medication safety, which the issuance of a comprehensive regulation would do much to ensure. Attached, please find a short summary of our position, per the June 18 *Federal Register* notice, along with the Veterans' Administration study referenced above. Again, thank you for the opportunity to offer our perspective on this important quality and cost management issue. We look forward to working with you to achieve the patient safety improvements in that bar code implementation would facilitate.

Sincerely,

Bert Patterson, R. Ph.  
Vice President for Contracting and Contract Services  
Premier

Attachments

02N-0204

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## **ON FDA PROMULGATION OF BAR CODE LABELING REQUIREMENTS**

A summary of Premier's position, per questions posed in the June 18 *Federal Register* notice.

### *General Questions Relating to Drugs and Biologics*

1. Premier believes that all hospital-administered drugs and biologics ought to feature bar code labels—with the Universal Product Number (UPN), including the National Drug Code (NDC), as the standard industry identifier—at every level of packing, especially that of the unit-dose.
2. Premier agrees with recommendations issued by the National Council for Coordinating Medical Error Reporting and Prevention (NCC-MERP) with respect to the information bar code labels ought to contain. We are cognizant of the concerns of some of our vendor business partners, with regard to the feasibility of meeting these requirements in the near term. Therefore, we believe the regulation issued in November ought to require the NDC code, while stipulating a reasonable timeframe in which the applicable labels would contain the NCC-MERP-recommended data.
3. Premier believes that the industry ought to move toward the implementation of the more advanced two-dimensional bar codes. Current scanning technology is compatible with both the Health Industry Business Communications Council's health bar code labeler identification code (HIBC-LIC) and the Uniform Code Council / European Article Numbering's (UCC/EAN) universal product code (UPC). Therefore, we consider either symbology acceptable as the industry moves toward two-dimensional bar codes.

Another feature critical to the success of any bar code labeling initiative is the readability of the data so contained. This would safeguard against the challenges clinicians and practitioners would encounter if problems with the requisite scanning technology were to arise.

In addition, regardless of the symbology or symbologies the FDA might propose, Premier would respectfully request that they be compatible with current scanning technologies. We would urge the FDA not to adopt standards that would require hospitals to purchase optic scanning technology. We believe such a burden would delay the patient safety improvements that bar coding would foster and facilitate.

4. Premier is primarily interested in ensuring that health professionals can easily and successfully scan the bar code at the bedside. Once that consideration has been achieved, we would comfortably defer to others to make such a determination.
5. It is our understanding that a small number of hospitals currently utilize bar coding in their facilities. It is important to note, however, that these bar codes are not of the UPN format. Further, most of the items are not coded at the level of patient dispensation. Therefore, hospitals currently utilizing bar coding must repackage virtually every item for which they desire the technology to apply. In addition, a somewhat larger, but still relatively limited, number of hospitals are using bar code technology for laboratories, blood products, and inventory control.

Reports about the percentage of healthcare items that currently contain bar codes are inconsistent. Consensus exists, however, over the fact that the *least* amount of bar coding occurs at the unit-dose level of product packaging. Unfortunately, unit-dose products are where the greatest promise for patient safety improvement lies.

### *Medical Device Questions*

1. Premier believes that all medical devices employed in the hospital setting ought to feature bar code labels with the Universal Product Number (UPN) as the standard industry identifier. We believe the information contained in the bar code ought to meet the HIBC-LIC and/or UCC/EAN standards.
2. Premier believes that the medical devices for which bar code labels ought to be required are those with the strongest implications for patient safety and efficacy. Therefore, requiring that tongue depressors or crutches, for instance, feature bar code labels, is not Premier's primary concern. We would note, however, that in most cases, items such as bed pans, etc., sold in retail outlets do, in fact, feature bar codes. The arguments offered by the medical device industry against bar codes in the institutional setting ring somewhat hollow when such labeling is relatively prevalent in the retail setting.
3. Premier believes that those medical devices with the greatest potential impact on patient safety ought to contain bar code labels. Bar code standards pertaining to medical devices ought to be consistently applied, whether such devices are "original," or reprocessed, repackaged, refurbished, or multiple-use.
4. The public health and patient safety implications of bar code labeling are far-reaching. Should a medical device be recalled, either voluntarily or by the FDA, bar code implementation and appropriate technology would facilitate identification and protect against subsequent use and/or re-use. A bronchoscope recall, issued earlier this year by FDA, provides a telling example. Some hospitals received notice of the recall, while others, apparently, did not. Bar code labeling would provide an extra level of security to help ensure that the use of recalled devices is halted.

The bar coding of syringes and other products in the medication delivery arena harbor great promise for patient safety improvement. Oftentimes, the syringe utilized plays a critical role in the success of medication administration. Bar coding would help ensure that clinicians utilize the appropriate syringe in each case of drug administration. In addition, bar code technology would enhance the ability of clinicians to conduct research on medical devices for maximum efficacy, with respect to patient care, thereby facilitating quality improvement.

### *General Questions and Economic Impact Questions*

1. Premier will institute a bar code labeling requirement on all pharmaceutical product contracts signed after July 1, 2003.
2. Premier has requested that the NDC code be used initially, with respect to drugs and biologics, in the context of a gradual transition toward inclusion of lot number and expiration date in the code. For medical devices, Premier believes HIBC-LIC or UCC/EAN are acceptable standards.
3. Not applicable to Premier.
4. Not applicable to Premier.
5. Not applicable to Premier.

6. Premier believes that the successful implementation and integration of bar code technology is directly related to the embrace of standards. We are extremely pleased that FDA subscribes to the goal that we and many of our business partners share—that of improving patient safety. However, without an agreed upon industry standard, investment in the infrastructure necessary to utilize bar coding to its full capacity will not yield the desired optimal result.

Premier also believes that the implementation of bar code technology will generate efficiencies in the supply chain. A 1998 study conducted by Ernst & Young for the Efficient Healthcare Consumer Responsc Group (American Hospital Association, Health Industry Business Communications Council, Health Industry Distributors Association, National Wholesale Druggists' Association, and Uniform Code Council) identified the potential for \$11 billion in savings by “redesigning the healthcare supply chain” through efficient product movement, order management, and information sharing.

Premier is cognizant of the considerable effort that would be required of hospitals in preparing to integrate and utilize the requisite bar code technology following implementation of the FDA rule. We are committed to assisting our hospitals in that effort. Premier has actively championed legislation introduced in the 107<sup>th</sup> Congress that would provide grants and other assistance to hospitals for the implementation of the bar code and other patient safety technologies.

7. Premier believes that the effective date for the proposed rule ought to allow affected companies ample time to comply. However, we also believe that innovative and forward-thinking manufacturers who have already addressed and/or engaged in bar code labeling ought not be penalized by an implementation date that is, in effect, too far-removed. Premier will, in fact, require bar codes on all pharmaceutical products for which contracts are signed, effective July 1, 2003.

# VETERANS AFFAIRS: ELIMINATING MEDICATION ERRORS THROUGH POINT-OF-CARE DEVICES

Technical Paper for 2000 Annual HIMSS Conference  
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## INTRODUCTION

Medication administration errors have long been recognized as a significant cause of morbidity and mortality in hospitalized patients. According to a recent report from the Institute of Medicine, an arm of the National Academy of Sciences, as many as 98,000 Americans die each year due to medical mistakes made by physicians, pharmacists, and other health care professionals. Of these deaths, most are due to medication errors.<sup>1</sup> To address this serious issue and attempt to reduce medication errors, the Colmery-O'Neil Veterans Affairs Medical Center (VAMC) developed a prototype automated system that uses wireless, point-of-care technology with an integrated bar code scanner. Nurses scan bar codes on patient wristbands and medications. The system validates and documents the transaction. Since the system was deployed, Colmery-O'Neil has administered 5.7 million doses, and results to date demonstrate that no medication errors occurred when the technology was used as designed. In fact, an electronic Averted Error Trap demonstrates that the system has prevented over 378,000 errors since its inception.

The success of the prototype prompted the Veterans Health Administration (VHA) to create a system that could be used nationwide. Based on the Colmery-O'Neil prototype, a new project called Bar Code Medication Administration (BCMA) was established. The goal of this new project was to design and implement software that would electronically validate medications for inpatients and document medication administration. The computerized system ensures that the patient receives the correct medication, in the correct dose, at the correct time, and visually alerts staff when the proper parameters are not met. The software reduces reliance on memory with a system of reports that remind clinical staff when medications need to be administered or the effectiveness of doses administered should be assessed. It also alerts staff to potential allergies and adverse reactions for the patient.

## THE PROBLEM

### Pharmacy Issues

The delivery of medications to hospital patients is a complex process involving the coordination of numerous disciplines, the implementation of system checks and balances, and the standardization of delivery and administration procedures from the time the order is written until the patient receives the medication as prescribed. A breakdown in any one system—from physician ordering to transcription and verification, dispensing and delivery, and administration of medications—can lead to adverse drug events. The prevention of these events is multifaceted, involving numerous handoffs and systems checks to help ensure that the physician's order is carried out as written. However, when handoffs and checks are manual and rely on short-term memory, they create an environment that promotes error within our health care systems.

Manual systems create adverse drug events due to 1) incomplete order handoffs between the various hospital disciplines involved in the process, 2) order misinterpretation, 3) incomplete or improper transcription, 4) communication breakdowns, 5) faulty drug identity checking, 6) rule violations, 6) faulty dose checking, 7) drug

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<sup>1</sup> Weiss, R. "Thousands of Deaths Linked to Medical Errors," The Washington Post, November 30, 1999: A1.

stocking and delivery problems, 8) slips and memory lapses, and 9) lack of standardization of terms and procedures. Many of these directly effect Pharmacy's role in medication administration. For example, in a manual environment, if a dose of medication is not available for administration, the nurse must stop administering medications, find a phone, and call the Pharmacy. This interrupts the workflow in Pharmacy while the pharmacist answers the phone; records the drug, patient, and date/time needed; verifies the request; and delivers the medication. This process creates several opportunities for error and is disruptive for both services.

As reported in medical literature, most medication administration errors are the result of multiple system failures that are due to faulty system design.<sup>2</sup> Better systems should promote fewer errors and include effective mechanisms for catching those that do occur. Newly developed computerized systems that rely on real-time, electronic technology are addressing the problem of adverse drug events by transforming manual systems into automated systems that medical professionals use at the patient point of care.

#### Nursing Issues

In a manual system, one paper document is used for many processes of medication administration—to communicate to the nurse any medications that are due and/or have been administered and to communicate changes in medication orders. This reliance on a single paper document creates numerous challenges to accurate medication administration. The paper document, known as the Medication Administration Record (MAR), shows all medications for 24 hours, so that the nurse must review the entire MAR to select which medications are to be administered at the current time. The paper document is changed as each new medication order is addressed, runs for many pages, and mixes active and inactive orders. Checking the document is a time-consuming process, and medications can be overlooked or administered at the incorrect time. In addition, multiple clinical staff need to view the same MAR to determine appropriate care and treatment for the patient. When the paper document is being used by others, the nurse's workflow is disrupted.

Add to these problems other factors, such as inevitable time delays in communicating order changes and the potential for error and misinterpretation because the MAR is modified manually.

**Impact.** It is easy to see that the potential for errors in a manual system and the ability to manipulate the manual system can affect patient safety and patient therapy. Errors can lead to prolonged hospital stays, physical injuries, disabilities, and death. The impact goes beyond physical measures of the patient and the nurse. The psychological results can be devastating for the patient and nurse, as well as for family members, co-workers, and the institution of health care.

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<sup>2</sup> Leape LL, Bates DW, Cullen DJ, et al. Systems Analysis of Adverse Drug Events. *Journal of the American Medical Association.* 1995;274:35-43.

## THE SOLUTION

### Overview

**Defining System Considerations.** The BCMA system required the software to be developed and supported by a nationwide team of practitioners and technical experts. The system also had to integrate with the existing VA hospital Pharmacy and Nursing software programs. Other system requirements included limiting variation that required staff to learn several different procedures; using protocols; and reducing reliance on memory, making it difficult to make an error by forcing functions. Making the right thing the easiest thing to do and identifying potential errors prior to administration were also essential requirements.

**System Features.** The process of identifying software requirements resulted in the development of a system that records One-Time, On-Call, Stat, and Now orders in addition to the regularly scheduled medications. The system is also flexible enough to allow the nurse to record refused medications, document the refusal reason, request missing doses electronically from the Pharmacy, and record early or late medications which were approved for administration by a physician outside the regular administration window.

The software offers a comprehensive package of management and accountability tools, including the following:

- Automated DUE list, generated by the nurse, which lists immediately prior to each administration time the medications to be administered
- PRN effectiveness list that alerts the nurse to record the effectiveness of *pro re nata* (PRN) or "as needed" doses after they have been given
- Paperless Medication Administration History (MAH), which electronically records the nurse's initials and the exact time the medication was scanned as given in a conventional MAR format
- Patient Medication Log that is used by all clinical staff and can be accessed throughout the medical center to review patient medication needs. With this report, clinicians may review the number of doses or times a drug has been recorded as given for a user-specified date range.
- Missing Dose Requests that automatically print on a designated printer in the Pharmacy alerting Pharmacy personnel when a dose should be reissued. The missing dose software also captures the nurse ID, the drug requested, the time requested, and the reason the dose was missing. These functions are carried out at the time the nurse is administering medication, thereby reducing the reliance on memory, minimizing user-required keystrokes, and minimizing workflow disruption.

See Figure 1, Software Features, for a complete listing.

During the medication administration process, visual alerts signal the nurse when the software detects a wrong patient, wrong time, wrong medication, wrong dose, or no active medication order. These alerts require a nurse to review and correct the reason for the alert before actually administering the drug. The data are captured in an Averted Error Trap file, creating a tool for management to review the number of avoided errors against the total number of doses dispensed. A review of this file concludes that 5.68 percent of all doses created an alert for the

nurse administering medications, thereby avoiding a medication error. The Averted Error Trap file captures the nurse ID, ward, time, drug, and averted error type.

### System Requirements

**System Architecture.** The BCMA mandate was to create a software application that performed the required functions, was cost effective, and easy to use. The team determined that the best solution for meeting these requirements was a Graphical User Interface (GUI) application built on standard MS Windows-based equipment. This architecture was chosen because the GUI aspect would be more familiar to users of computer systems than any proprietary systems, and the Windows-based computer hardware could be re-used for other purposes. Combined, this overall solution created an ideal architecture for development of the BCMA product.

**Network Connectivity.** Because nurses administering medications move from patient to patient and ward to ward, automated systems must be mobile. (However, in areas of the hospital that do not require clinician mobility, wired networking can be used.) BCMA uses Wireless Local Area Network (WLAN) technology to place real-time information in the hands of the clinical staff and thereby decrease the possibility of medication errors. To achieve this real-time ability, the software requires a continuous Ethernet connection to the VA hospital information system database. Nurses use battery-powered laptop computers and handheld bar code scanners that can be moved from patient to patient or ward to ward.

Wireless LAN technology creates a network that operates much like a wired Ethernet network, but without the wire. WLAN devices communicate network traffic via radio frequency (RF) transmissions. The personal computers (PCs) connected by WLAN technology can communicate using Telnet Communication Protocol/Internet Protocol (TCP/IP) anywhere in the RF coverage area. These devices avoid interference with other RF devices by using spread spectrum technology. Interference is greatly reduced by spreading the transmissions out over a wide band of frequencies. This technology, combined with data encryption, creates a secure network infrastructure for many applications.

Implementation of WLAN technology requires planning and input from many departments. When selecting a WLAN system, the planners must consider the coverage areas, supported applications, point-of-care devices, infrastructure, and interference with other RF devices in the hospital. A site survey by experienced technical personnel is recommended to avert problems in these areas before implementation.

### Pharmacy Changes

Changes in technology often demand changes in procedures and policies and standardization of terms and processes. Historically, Pharmacy and Nursing have not worked cohesively to address issues related to drug delivery and administration. Lack of communication, ineffective standardization protocols, and a lack of understanding of the complete process have created barriers to patient safety. An important step in implementing BCMA was the

development of a multidisciplinary team to address these issues and foster understanding in the complete process. This created an environment for change that benefits patient care, reduces hand-offs, and improves communication.

Order interpretation guidelines created through this multidisciplinary approach ensure that Nursing, Pharmacy, and providers interpret the medication order the same way. Physicians can know when their order will be carried out regardless of the ward where a patient is assigned. And Pharmacy is able to coordinate drug delivery processes with Nursing expectations.

Standardization offers many benefits to both patient care and Pharmacy-Nursing communication. The electronic transcription process allows both Pharmacy and Nursing to use the same electronic document for dispensing and administering medications. This ensures that Pharmacy and Nursing are verifying the same electronic order. Because Nursing and Pharmacy share the transcription process, any discrepancies in transcription are identified during the verification process and corrected before a transcription error causes patient harm.

Development of a missing dose delivery procedure ensures that electronic requests for missing doses are processed and delivered to the nurse within defined time limits. The system also creates a missing dose file that can be downloaded and reviewed by a quality improvement team consisting of both nurses and pharmacists. Colmery-O'Neil VAMC has reduced the numbers of missing doses by 68 percent through the analysis of this data, and identified drug storage and delivery problems, unit-dose drug cart filling concerns, and package identification concerns. Correcting these issues has reduced workflow interruption that could lead to compromised patient safety.

Standardization of labeling procedures eliminates the need for hand written labels that may not be legible. Pharmacy bar codes all medications that leave the Pharmacy for inpatient use. The barcode labeling software contains fields for patient name, ward location, instructions, filled by, checked by, drug name, and dosage ordered. The bar code label prints the internal control numbers for the Pharmacy Drug File in a bar code format that is used as a unique drug identifier during the scanning process. In addition, Pharmacy may use manufacturers bar coded National Drug Codes (NDC) or Universal Product Codes (UPC).

#### Nursing Changes

Computerization allows multiple users to access medication administration information in real-time. This decreases the interruptions to the medication nurse and decreases the potential for missing medications to be administered. It also helps prevent administering medications outside the medication administration window, because the information is presented to the medication nurse even if another individual is accessing the patient's medication administration information.

The Virtual Due List (VDL)—which replaces the paper MAR—allows the nurse to view medications that are due to be administered for a selectable time frame and offers additional features not possible with manual systems. If

nurses attempt to administer a medication outside of the schedule for that medication, the system provides them with appropriate information. The YDL provides visual information as to the status of the administration of the medication to reduce the occurrence of omissions. Because the computer only displays active orders, the potential for administering a discontinued or expired order is eliminated.

A computerized system offers many advantages to nurses. Because the computerized system does not rely on communication between individual nurses, order changes are communicated instantaneously and in real-time. Time delays are avoided. Users can configure the format to suit their individual preferences, so that, unlike with a paper system, there is no need to re-write information. In addition, the user does not have to spend time sifting through paper documents. The nurse can request a missing dose electronically in a process that takes approximately 3 seconds, and the information is communicated directly to Pharmacy for immediate action. The nurse can continue with the medication administration process without leaving the computerized system, thereby decreasing workflow interruptions and minimizing medication administration errors. The electronic record displays the actual time the medication was scanned as administered, which promotes accurate administration information and enhances decision making by clinicians in developing patient therapies and treatments.

#### Impact

Among preventable events that occur under manual systems, 56 percent of errors occurred in the ordering stage, 6 percent occurred in transcription, 4 percent in the dispensing stage, and 34 percent at the point of administration, the second highest incidence of error. Errors are much more likely to be caught and intercepted if they occur early in the process, which means that most medication administration errors are not caught in manual systems. One study of manual systems indicates that 48 percent of ordering errors were intercepted, 23 percent of transcription were intercepted, 37 percent of dispensing were intercepted, but 0 percent of administration errors were intercepted.<sup>3</sup> The purpose of a computerized med admin system is to intercept and prevent errors due to medication administration mistakes.

### REAL LIFE

#### Personnel

The institution of any new system affects the people using it. Old systems are modified or discarded and new methods must be learned. Some BCMA users, as well as the professional unions, are concerned that, with the enhanced tracking and reporting tools offered by the system, nurses may be punished for medication errors. However, management can take care to assure staff that inaccurate medication administration should be considered the end result of a chain of events possibly set in motion by poorly designed processes, procedures, or medication delivery mechanisms, and not the result of one individual's action. Reporting of inaccurate medication administration must be in a positive, non-punitive review process that includes the trending of root cause and end result. The intent of BCMA software is to provide the nurse with an additional check and balance system that

augmentations, but does not replace, clinical judgement. The software communicates important clinical information to the nurses, which improves their ability to safely administer medications.

The professional unions have also expressed concerns regarding the time required to pass medications with a computerized system. BCMA is a tool to improve patient safety, efficiency of documentation, and promote clinical decision-making. There are many variables that affect the amount of time required to administer medications regardless of the system used. It is anticipated that an electronic system saves time by reducing the interruptions to view the medication administration record, speeding the request and delivery of missing doses, and eliminating the need for nurses to review pages and pages of a paper document to determine how medications are to be administered.

Training is another issue that affects personnel and must include software, hardware, processes, and procedures related to the electronic record versus the paper record in the medication administration process. Hands-on training with printed materials that provide a quick resource to needed information is essential in the development of the user's comfort with the system. Allowing nurses to use the system in their particular setting in a non-threatening environment and at their own pace has proven beneficial.

#### Implementation

Implementing an electronic system is a complex endeavor, which involves the training and integration of several hospital disciplines and the establishment of policies and procedures that consider the needs of the users as well as the needs of the system.

**Nursing.** In some locations, Nursing staff are unfamiliar or uncomfortable with using computers. To help ensure that staff have basic MS Windows-based skills, the VA training office purchased, and provided to all facilities, disk-based training for Word 97, Excel 97, PowerPoint 97, and MS Windows NT 4.0 Introduction. In addition, an Intranet site devoted to the project contains training and user materials. All of the training materials try to anticipate basic facility needs and provide supplemental support for on-the-job training.

Administration of medications should be completed within a specific time frame determined by each facility. A medication administration time window should be established based upon Nursing workload. The window may be defined, for example, as 1 hour before through 1 hour after the scheduled administration time. The challenge of determining policies and procedures of this kind fall to the multidisciplinary group established at each facility.

**Pharmacy.** Pharmacy is responsible for bar coding medications. Most Pharmacies will use a combination of different bar codes to identify drug products at the point of administration. During national train-the-trainer sessions,

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<sup>3</sup> Bates DW, Cullen DJ, Laird N, et al. Incidence of Adverse Drug Events and Potential Adverse Drug Events; JAMA. July 5, 1995, Vol 274: 29-34.

various bar coding methods were thoroughly discussed and demonstrated. It is suggested that in each facility, Pharmacy designate someone responsible for bar code labeling requirements.

Nursing and Pharmacy. The use of bar coding and scanning hardware presents additional challenges in implementing a computerized system. Nursing and Pharmacy staffs need to know how to use the particular bar code scanning devices and other hardware purchased for use at their site. Training should include all aspects of the software module as well as the effective use of PCs and the safe operation of a laser scanner. Within the VA, each facility was asked to send appropriate representatives from Nursing and Pharmacy to be trained. They would then be responsible for conducting local training at their own facilities.

Communication is key to the successful implementation of any new software. Each facility was encouraged to establish a focus group and a mail group to discuss system-related concerns, such as when medications do not scan properly due to equipment failure, policy deviation, or order entry procedure failure.

#### CONCLUSION - THE COLMERY-O'NEIL EXPERIENCE

In the years that the Colmery-O'Neill VAMC has been using the electronic prototype, medication errors have been reduced dramatically. Of the 1,885,651 inpatient doses dispensed in 1993 and 409 reported medication errors, the reported error rate was 0.0217 percent or 21.7 incident reports for each 100,000 units. The error rate so far for 1999 is 0.00775 percent or 7.7 incidents per 100,000 units, with 825,305 units dispensed and 64 reported errors. This is a 64.5 percent improvement in the reported error rate for 1999 over that of 1993, as shown in Figure 2, Reported Error Rate as a Percent of Total Doses Dispensed.

No medication errors have occurred as a result of the scanning software. However, errors continue to occur when the device or software is not used in accordance with the practice standard. Additional system failures make up the remainder of the reported errors. These include physician's orders, transcription, verification, dispensing, delivery, and monitoring errors.

Table 1, Reported Error Rate per Total Doses Dispensed, compares the types of reported medication errors between 1993 and 1999. In each category of error, fewer errors occurred while the electronic prototype system was in use, as is demonstrated by the following:

- 73.8 percent improvement in errors caused by the wrong medication being administered to a patient
- 56.6 percent improvement in errors caused by the incorrect doses being administered
- 91.3 percent improvement in wrong patient errors
- 91.6 percent improvement in wrong time errors
- 69.9 percent improvement in errors caused when medications scheduled for administration were not given

Colmery-O'Neil investigates reported errors as system problems in an attempt to simplify the system that may have created the occurrence. Medication errors in all facilities are under-reported due to several factors, and analysis of reported medication errors has inherent limitations based upon the voluntary nature of the reporting system. It is impossible for all medication errors to be reported when individuals are unaware that an error has occurred. Therefore, these results should be considered qualitative rather than quantitative. Colmery-O'Neil contributes the profound reduction in reported medication errors directly to the computerized medication administration software developed at the facility.

A medication administration error file was designed into the point-of-care medication administration system to catch deviations in drug, dose, frequency, or administration time prior to the drug being administered to the patient. These errors are considered averted errors because an intervention occurs prior to administration. The automated system creates an alert whenever the nurse scans medication that deviates from the order. A visual message is displayed for the nurse on the PC at the patient's bedside. The error is then reviewed and corrected prior to administration, and the error is considered avoided. This data is captured in the error file.

Table 2, Automated Error Alerts as a Percent of Total Inpatient Doses Dispensed, shows the number of error alerts generated per total inpatient doses dispensed from 1996 to 1999 using the bar code scanning software. These doses included oral drugs, topical drugs, injectable drugs, intravenous admixtures, and intravenous piggybacks. Overall, there was a decrease in error alerts. The system's error trap captured 98,605 events in 1996, for an averted error rate for the period of 5.88 percent. Similarly, in 1997, 5.44 percent of doses administered could have been given in error if the alert warning had not been generated. Data analysis for 1998 reflects a 5.76 percent alert rate and a 5.37 percent rate so far for 1999.

Further review of the avoided errors allows examination of the percentage breakdown by the five error types shown in Table 3, Automated Error Alert Distribution by Error Type. A medication administration window was designed around each administration time. The allowable tolerance requires the nurse to administer the medication within 1 hour before or after the administration time indicated on the electronic VDL. Late dose alerts comprise 54.8 percent of the error trap entries for the total period shown in Table 3, while early alerts are generated in 9.3 percent of cases. Errors in drug, dose, or patient selection are the next most frequent entries in the error log file, and average 31.5 percent of 288,485 incidents captured.

The overall numbers of alerts per doses dispensed may be inflated due to several factors. The legibility of manufacturer barcodes is inconsistent since all lots do not scan with the same accuracy. Approximately 5 percent of the total doses administered is given by scanning a manufacturer bar code. The readability of Pharmacy repackaged doses is much more accurate than available manufacturer barcodes. The alerts generated by error type percent are reflective of the general distribution of error alerts that are generated. Readability of manufacturer barcodes adversely affects the overall number of alerts that are generated during the medication administration process. The statistics captured through this unique method should be considered qualitative instead of quantitative.

Improvement in the specificity of alerts and expansion of the alert types generated will improve the accuracy of data collected.

Based on the experience at Colmery-O'Neil, the advantages of an automated system—increased accuracy of medication administration, availability of management tracking and reporting tools, enhanced documentation, and greater patient safety—appear to offer many more benefits than can be realized through manual systems. Detail-oriented planning, multidisciplinary communications, ongoing training, and careful implementation can help medical facilities and their staffs overcome their natural reticence to adopting computerized systems.

#### FIGURES AND TABLES

- ✓ *Automated DUE List*
- ✓ *Missed Dose List*
- ✓ *PRN Effectiveness List*
- ✓ *Paperless MAR*
- ✓ *Audible and Visual Alerts*
- ✓ *Missing Dose Requests*
- ✓ *True Point-of-Care Technology*
- ✓ *Record Now and Stat Orders*
- ✓ *Record Vital Signs*
- ✓ *Record Refused, Early, or Late Medications*
- ✓ *Automated Error Trap*

Figure 1, Software Features

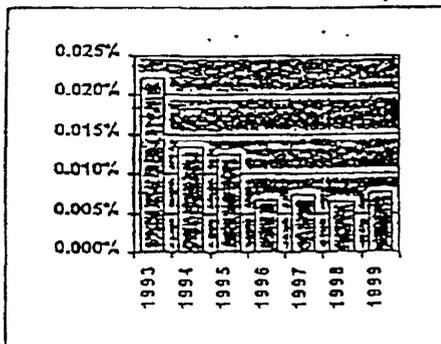


Figure 2, Reported Error Rate as a Percent of Total Doses Dispensed

Error Type	1993 (%)	1999* (%)	Improvement (%)
Wrong Medication	0.00371	0.00097	73.8
Wrong Dose	0.00334	0.00145	56.6
Wrong Patient	0.00138	0.00012	91.3
Wrong Time	0.00143	0.00012	91.6
Omission	0.00917	0.00279	69.6

Table 1, Reported Error Rate per Total Doses Dispensed

Year	Error Alerts (#)	Doses Dispensed (#)	Error Alerts (%)
1996	98,605	1,675,564	5.88
1997	70,176	1,290,569	5.44
1998	68,767	1,193,718	5.76
1999*	50,973	950,081	5.37

\* January through September

Table 2, Automated Error Alerts as a Percent of Total Inpatient Doses Dispensed

Error Alert Type	1996 (%)	1997 (%)	1998 (%)	1999* (%)
Late Doses	58,999	36,612	35,270	27,338
Wrong Med/Dose/Pt	27,428	23,257	24,351	15,798
Early Doses	6,971	7,279	6,569	6,143
Multiple Units/Dose	4,927	2,750	2,335	1,516
Wrong Day of Week	256	266	242	178
Total Alerts Generated	98,581	70,164	68,767	50,973

\* January through September

Table 3: Automated Error Alert Distribution by Error Type

## PRESENTER BIOGRAPHIES

Bill Malcom, with Electronic Data Systems, is the Technical Manager for the Bar Code Medication Administration project. He has developed health care related software for over 10 years.

Russell A. Carlson, BSN, is the Nursing Consultant for the Bar Code Medication Administration project. He is currently an Automated Data Processing Applications Coordinator for Nursing at Colmery-O'Neil VAMC.

Chris L. Tucker, RPh, Pharmacy Consultant for the Bar Code Medication Administration project, has been involved in hospital pharmacy automation programs for 13 years. He works at Colmery-O'Neil VAMC.

Candice Willette, Phase Manager for Implementation for the Bar Code Medication Administration project at the Department of Veterans Affairs, also serves as Implementation Manager for three other national projects.