Medication Safety

Improving **Medication Safety** in Health Systems through Innovations in **Automation Technology**

Proceedings of educational symposia and educational sessions during the 39th ASHP Midyear Clinical Meeting, December 5–9, 2004, in Orlando, Florida

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Learning Objectives

After studying this article, the reader should be able to:

1. Describe how automation technology has been implemented and used to improve medication safety by reducing the risk of error associated with steps in the medication-use process.
2. Characterize the features of infusion pumps with intelligence that promote patient safety.
3. List strategies in selecting and implementing bar-code technology that have been shown to avoid problems that can compromise the safeguards of that technology.
4. Define benefits of current computerized physician order entry (CPOE) technology and identify features in the next generation of CPOE systems that will further enhance patient safety.
5. Describe benefits and potential pitfalls in the use of automation technologies and the role of the pharmacist in addressing these.

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Technology

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The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The program provides 3 hours (0.3 CEUs) of continuing education credit (program number 204-000-05-406-H04). This program is provided free of charge. Pharmacists who complete the program may complete the CE test and print their CE statements at the ASHP Advantage CE Testing Center (www.ashp.org/advantage/ce). The release date of this program is 4/23/05 and the expiration date is 4/23/08.

Overview of Automation Technology and Safety in the Medication-Use Process

At the 39th ASHP Midyear Clinical Meeting held December 5–9, 2004, in Orlando, Florida, many educational sessions addressed the impact of various technologies on the medication-use process and patient safety. **Mark Neuenschwander,** President, The Neuenschwander Company, Bellevue, Washington, a consultant with expertise in pharmacy dispensing automation and bar-code, point-of-administration systems provided an overview of improvements in the safety of medication-use achieved through automation technology.

The medication-use process involves ordering a medication based on patient assessment, transcribing the order, reviewing and approving the order or consulting with the prescriber about the order, dispensing or distributing the medication, administering the medication (after verifying the order), and documenting medication administration and effect (Figure 1). The process is circular, not linear, because prescribers often make decisions about whether to continue or modify drug therapy based in part on documentation of medication administration. Each step in the medication-use process involves observing, evaluating, and decision making by one or more members of the health-care team. Therefore, an integrated approach involving physicians, pharmacists, nurses, and others is needed to automate the medication-use process. Pharmacists should play a key role in overseeing this process and assume responsibility for it.

In automating the medication-use process, the automated system should be at least as safe and efficient as the system it is replacing. Efficiency sometimes is sacrificed for safety (e.g., unit-dose drug distribution systems are less efficient, but they improve safety).

An examination of institution-specific factors will determine the technologies that will provide the greatest impact on patient safety at the individual facility or health system. For all institutions, it is helpful to begin with a review of the safety of the medication-use process. The various steps of the process are associated with different medication error rates: ordering (39%), transcribing (12%), dispensing (11%), and administering (38%).[1] Approximately half of ordering errors and one third of transcription and dispensing errors are caught before the drug reaches the patient, but only 2% of errors involving medication administration are detected before the patient receives the drug.[1]

Of the many automation technologies that have been applied to the medication-use process, pharmacy information systems have had the largest impact on patient safety. These ubiquitous and relatively inexpensive systems ensure the review of medication orders by a pharmacist, which facilitates the detection of errors in the ordering step of the medication-use process. These systems also provide the foundation for automation of other aspects of the medication-use process. Although pharmacy information systems have vast capabilities, they are grossly underutilized.

Automated dispensing machines may be centralized or decentralized. Centralized machines have been used to package and label solid oral dosage forms and injectable products and to provide hands-free robotic storage and retrieval of medications in the pharmacy. These machines are more efficient and accurate than humans in selecting medications from stock. Unit-dose carts filled in the pharmacy with the assistance of automated dispensing machines have a high degree of integrity when they leave the pharmacy, but that integrity and patient safety can be compromised if staff borrow a medication from the supply intended for one patient to give it to another patient.

Decentralized machines (e.g., unit-based cabinets) were developed to improve security and accountability for medications in patient-care areas. The safety of early unit-based cabinets was questionable because staff using the machines had access to a wide variety of medications, in addition to medications ordered for a specific patient. Newer decentralized machines limit access to medications on the basis of a patient medication profile. However, safety concerns persist because of excessive use of the capability to override restrictions to medication access. In addition, these machines are not always filled with the same accuracy as unit-dose carts filled in a central pharmacy. Errors can result when staff retrieving and administering the medication assume incorrectly that the medication dispensed is the medication ordered.

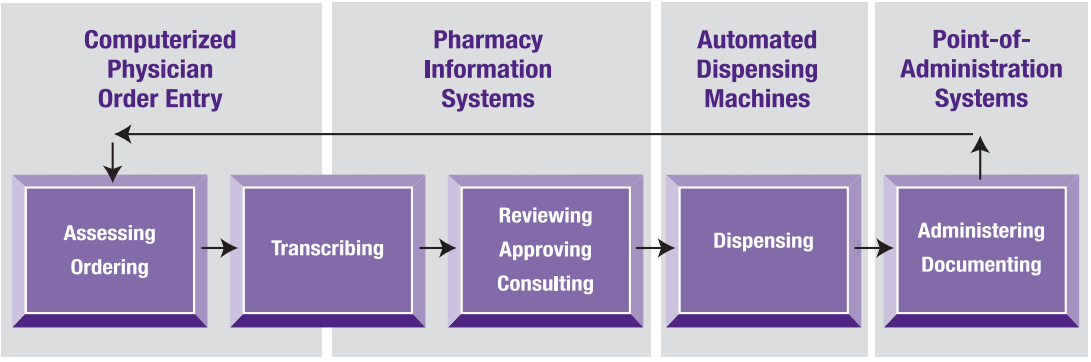

Figure 1. The Medication-Use Process and Applications of Automation Technology

Automated dispensing machines have had the least impact on patient safety among the automation technologies applied to the medication-use process, partly because dispensing is one of the least error-prone steps in the process. Despite their minimal impact, these machines require a much greater investment of financial resources than other available technologies that can provide greater impact (e.g., pharmacy information systems).

Computerized physician order entry (CPOE) systems were developed to prevent errors caused by difficult-to-read handwriting, eliminate transcription errors, and ensure that medication orders are complete. The systems are designed so that orders are not accepted unless an entry is made in every field on the order screen. Other benefits of CPOE include prescriber access to current patient information (e.g., laboratory test results in facilities where the clinical laboratory computer system is linked with the CPOE system) and the potential to save pharmacist time.

The form that a CPOE system takes may vary, with a computer at each nursing unit, a computer at each bedside, or a personal digital assistant (an electronic handheld information device commonly known as a PDA) carried in every prescriber's pocket. Speech recognition devices and tablet personal computers (electronic devices the size of a sheet of paper on which a stylus is used to handwrite orders) also have been used in conjunction with CPOE, but these technologies can result in errors similar to those found in non-automated systems (e.g., misinterpretation of speech and illegible handwriting, respectively).

Potential problems with CPOE systems include lack of integration with the pharmacy information system, inadequate clinical decision-support systems, the tendency of some physicians to override system safeguards excessively, ordering errors due to careless order entry, and physician reluctance to accept the CPOE system. Of the automation technologies applied to the medication-use process, CPOE systems are the most expensive and the most challenging to implement. Although approximately half of ordering errors are detected before the drug reaches the patient, CPOE systems have a great potential for improving patient safety.[1] However, the underutilization of pharmacy information systems raises questions about the extent to which CPOE systems will be used to their full potential.

Point-of-administration (POA) systems were developed to improve patient safety by ensuring that the right dose of the right drug is administered by the right route at the right time to the right patient. Verification of the identity of a patient and a medication is achieved by scanning a bar code on the wrist band worn by the patient and a bar code on the medication label. These systems also provide a detailed schedule for drug administration and allow for real-time documentation and creation of an electronic medication administration record (eMAR). eMARs and their integration with other technologies will be described in greater detail in the bar-code technology section. In general, eMARs include the same information as their written counterparts (e.g., drug name and dose, scheduled and actual administration times, identification of the clinician administrating the dose, etc.) but they have the added benefit of being documented in real time with information that is available to all staff involved in the overall patient care process.

As with CPOE, POA systems assume a variety of forms that may involve the use of PDA devices, tablet personal computers (PCs), desktop PCs, computers on wheels (known as COWs), or thin client servers at the bedside (an electronic device with a screen the size of a television or computer monitor that is used to provide entertainment for the patient and access to the POA system for the clinician). Smaller devices the size of a cellular phone have been introduced in recent years. Considerations in selecting among the available hardware for POA systems include capabilities, readability of information displays, portability, durability, affordability, and ergonomics (i.e., human factors in the design and operation of the devices).

Infusion devices with decision-support software (i.e., intelligent pumps) were developed to address serious medication errors caused by the intravenous (i.v.) infusion of medications.[2] Intelligent pumps can be programmed with standardized concentrations and limited infusion rates and durations so that caregivers are alerted when settings are outside these limits. Newer devices are increasingly communicative with POA and pharmacy information systems. The use of an intelligent pump alone can ensure that the right infusion rate and duration are used, but the drug might be wrong for the patient. The use of a POA system without an intelligent pump helps ensure that the right patient receives the right drug at the right time, but the infusion rate and duration might be wrong. Use of an intelligent pump in conjunction with a POA system ensures that the right drug is infused at the right rate for the right duration in the right patient. This combination of technologies also can save nursing time. POA systems with what is referred to as "i.v. automated programming" have this communication capability.

POA systems are easier and much less costly to implement than CPOE systems. They have greater potential to reduce error than CPOE systems and user acceptance is easier to obtain.

Automation of the medication-use process in an institution requires careful evaluation of the advantages and disadvantages of the various available options. Decisions to adopt new automation technologies should be based on a vision for how the technology will improve patient safety.

The preceding was based on Mr. Neuenschwander's presentation "Impact of Automation Technology on the Medication Use Process" as part of the ASHP Midyear Clinical Meeting Exhibitors' Theater entitled "Improving Medication Safety in Medication Administration: Advances in Medication Management" held on Monday, December 6, 2004.

Decision-Support Infusion Technology

Overview of Intelligent Infusion Pumps

Doris Nessim, R.Ph., M.A., a healthcare management consultant with expertise in clinical and management information systems from Mississauga, Ontario, Canada, discussed the features of infusion pumps with intelligence that are intended to promote patient safety. She emphasized that safety must be a top priority for institutions because patient safety has now become a priority of federal and state governments, accrediting bodies (e.g., the Joint Commission on Accreditation of Healthcare Organizations [JCAHO] and the National Committee for Quality Assurance), various private groups (e.g., the Institute for Safe Medication Practices [ISMP]), and other organizations.

Medication errors may result from human factors (e.g., lapses in memory or concentration or inadequate knowledge), system factors (e.g., defective equipment), and organizational factors (e.g., excessive reliance on temporary employees who are unfamiliar with the institution's policies and procedures). Medication errors can result in serious adverse drug events, especially when the i.v. route of administration is involved.[2,3]

Heparin, opioid analgesics, and insulin are among the most commonly reported i.v. medications involved in preventable adverse drug events.[4] These agents are also among the high-alert medications designated by ISMP and JCAHO as requiring special safeguards to reduce the risk of error.[5,6] Consistent hospital-wide use of these safeguards is needed.

Conventional infusion technologies depend on accurate programming of the device and double checking of the settings by another person. Errors are likely to go undetected because of human factors (e.g., lack of knowledge about dose limits), system factors (e.g., lack of a system providing for double checks), or organizational factors (e.g., multiple handoffs of responsibility without proper communication) or a combination of these factors.

Decision-support infusion technology aims to overcome these factors. Infusion pumps with intelligence have software that triggers a warning when a drug dose or infusion rate is outside the user-defined allowable limits, as listed in the drug library or profile for a patient care area or therapeutic classification. The warning prompts the clinician to reprogram the pump or override the warning.

Ergonomic design is an important consideration for safeguarding against the human factors that contribute to error. While infusion devices with intelligence have aimed to incorporate ergonomic design, a device's compliance with the Consensus Standards on Human Factors Design for Medical Devices, as well as clinician ease of use with a particular device (such as determined through simulation exercises or pilot programs) should be considered. For a list of human factors standards, refer to Food and Drug Administration (FDA), Center for Devices and Radiological Health, "Human Factors Design Process for Medical Devices" at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=6196. Training of staff in the proper use of these pumps and standardization of i.v. solutions, drug concentrations, doses, and administration times and procedures are essential to patient safety.

Intelligent infusion pumps perform a test of "reasonableness" using clinical decision-support software to ensure that pump settings are within the institution's defined upper and lower limits for the drug's dosage, concentration, and infusion rate before drug administration begins. These variables are customized for a "drug library" of selected medications at an institution based on evidence-based literature and local practices. Additional information on drug libraries and minimum and maximum dose limits is provided in the next section of this monograph.

The various commercially available intelligent infusion pumps differ in their display and alarm features, the i.v. product line that they support (e.g., large- and small-volume parenteral products, syringes, cassettes for patient-controlled analgesia), and the extent of communication capability with eMARs, POA systems, and pharmacy information systems and integration with the patient's electronic health record. A bar-code reader may be built into or tethered to the infusion device to allow a nurse to scan the label on an i.v. medication to verify the identity and concentration of the drug. Some newer devices also use bar-code technology to verify the identity of the patient and clinician (using a bar-coded employee identification badge) and the diluent used for the i.v. medication.

Design considerations in selecting intelligent infusion pumps include work flow for the nursing staff. An inconvenient location of the bar-code scanner and a large number of items that must be scanned are examples of factors that can present barriers to the efficient use of the device by nurses. Manufacturers of intelligent infusion pumps will assist clinicians and administrators with selecting pump features and programming options that enhance staff work flow and patient safety. Pilot programs and simulations can be conducted to determine if policies and procedures should be adapted to optimize the use of a particular device.

Intelligent infusion pumps allow for improved communication of information to care providers (e.g., uploading updates to drug libraries based on new dosing guidelines, providing clinician notification when the next dose is due, and producing quality improvement reports). Technical support services provided by pump manufacturers can assist institutions by developing customized quality improvement reports that provide more valuable feedback (e.g., the frequency with which specific alerts are overridden, which might signal a problem with a particular drug).

Newer, increasingly intelligent infusion pumps offer real-time, two-way communication with the POA system and eMAR. Wireless communication has been used in some settings and will likely become more common as an increasing number of devices with this feature are made available.

Intelligent infusion pumps are considered medical devices by the FDA, so the devices undergo FDA review prior to marketing. Therefore, obtaining information from manufacturers about features under development may be limited while the manufacturer is waiting for what is known as 510k clearance.

Financial considerations in implementing decision-support infusion technology include the capital costs of the equipment (e.g., the device itself and i.v. poles) and operating costs (e.g., i.v. administration sets and pump maintenance costs). The life expectancy of intelligent infusion pumps is approximately 5 to 7 years. Therefore, institutions should secure a contract that provides for upgrading hardware and software during the course of the agreement. This is especially important because these devices are rapidly increasing in sophistication (e.g., two-way, wireless communication capabilities).

The use of decision-support infusion technology should be part of an institution's broader information technology initiative to improve patient safety. Implementation of this technology should take into consideration its integration with other technologies (e.g., medication management and clinical information systems) that can impact its effectiveness in enhancing patient safety. The implementation process can be complex and time consuming. Therefore, a successful implementation strategy requires a team approach, involving executive support through active engagement with staff with clinical, technical, risk management, and financial expertise. Ongoing monitoring, education, and training of clinicians is essential to ensure that intelligent infusion devices realize their full potential to promote patient safety. Pharmacists play a key role in all aspects of the selection, implementation, and ongoing quality improvement processes by working closely with physicians, nurses, biomedical engineers, information systems staff, risk managers, and others. Working in partnership with device manufacturers can also streamline each of these processes. Although nothing can replace sound clinical decision making by the clinician at the patient's bedside, implementing strategies with clinical decision-support software, such as that found in intelligent infusion devices, will make it harder for the clinician to introduce errors into the medication-use process.

The preceding was based on Ms. Nessim's presentation "Improving Medication Safety with Decision-Support Technology" as part of the ASHP Midyear Clinical Meeting Exhibitors' Theater entitled "Improving Medication Safety in Medication Administration: Advances in Medication Management" held on Monday, December 6, 2004.

Implementation and Outcomes of Intelligent Infusion Pumps: One Facility's Experience

Angela Cassano, Pharm.D., BCPS, Manager, Quality Assurance and Drug Safety at Crozer Keystone Health System (CKHS), Upland, Pennsylvania, discussed in detail the steps in implementing decision-support infusion technology based on her experience at CKHS. CKHS is an 800-bed health system with five hospitals, including one community teaching hospital, located in the suburbs of Philadelphia. CKHS has three pharmacy and therapeutics (P&T) committees with some differences in the formulary established for each site. A total of 686 intelligent infusion pumps are used throughout the health system and the same drug library containing information for ten clinical care areas is used for all pumps.

The steps in implementing decision-support infusion technology are listed in Table 1. Stakeholders in this process might include hospital administrators, nurses, pharmacists, biomedical engineers, and physicians. Administrators may delegate the responsibility for implementation to others after a financial commitment is made, but they should be kept informed of progress. It is essential to obtain the support of nursing staff from the outset of the implementation process because nurses are the end-user of the technology. Clinical and staff pharmacists are as valuable as pharmacy managers during the implementation process because of their more direct involvement with nurses and patient care. Biomedical engineers are particularly vital in loading the drug library and in downloading alerts and overrides from the pumps. Physician involvement will vary at each institution and is dependant on whether current P&T committee policies reflect standardized prescribing practices or protocols. Even when these protocols exist, key members of the medical staff should be kept informed about the capabilities of the infusion technology and the status of the implementation process. It also may be advisable to report progress to certain committees (e.g., patient safety and quality improvement).

Evaluating infusion software capabilities should take into consideration the maximum number of characters allowed in each data entry field, the units of measurement and precision for flow rates (e.g., mL/hr versus mcg/kg/min and 0.1 mL/hr versus 0.01 mL/hr), the maximum number of unique patient care areas and drug entries that can be included, the frequency and ease with which the software can be updated, and the overall data storage capacity of the software program. This evaluation is the least time-consuming step in the implementation process. Most of the information required for this step can be found in the user manual for the pump.

Evaluating current institutional practices and making decisions about systems, policies, and procedures related to use of the intelligent infusion pumps are the most time-consuming steps because they involve extensive research and collaboration among representatives from a variety of departments. When evaluating current practices, the most

TABLE 1

Steps in Implementing Decision-Support Infusion Technology

- Identifying stakeholders
- Evaluating the capabilities of the infusion software
- Evaluating current health-system practices
- Making decisions about systems pertaining to the technology and institutional policies and procedures for its use
- Writing drug libraries
- Preparing for the "go live" start date
- Pilot testing (optional)

commonly used i.v. medications should be determined using both computerized and anecdotal reports. Procedures for the use of high-alert medications warrant special attention. Dosage forms, packaging, and drug-delivery requirements (e.g., i.v. bags versus syringes) should be part of the analysis. Drug therapy protocols, standardized drug concentrations, and i.v. drug infusion guidelines approved by the P&T committee also should be taken into consideration during the evaluation.

Decisions about infusion technology systems, policies, and procedures include determining which patient-care areas will employ the technology, the specific medications for which it will be used, and the infusion parameters for each medication. Collectively, this information will form the basis for developing the drug library. A drug library contains information about a customized group of drugs that may be specific to a patient-care area or apply to the full institution. For each medication, it provides the drug name, dose or concentration and units of measure, diluent (if any), and therapeutic or pharmacologic class. This information should also reflect the findings from the steps in which health-system practices were evaluated and decisions about systems, policies, and procedures were made.

In addition to the standard dose or concentration, minimum and maximum recommended administration parameters are defined, either as dosing units per measure of time (e.g., milliliters per hour) or dose per unit of time based on patient weight (e.g., micrograms per kilogram per minute). The dosing units and limits can be defined to correspond with the patient age, weight, condition, or care unit (e.g., higher infusion rates may be allowed in critical care areas where additional monitoring equipment is available). These limits are determined by clinical personnel in the hospital and verified by literature or current practice. The limits are then programmed as "soft stops" or "hard stops." Based on this information, the software will alert the clinician if a programmed dose is outside the minimum or maximum dose range. A clinician can override a soft limit warning, while a hard limit warning does not allow the clinician to continue. The use of hard stops should be judicious because excessive use can lead to frustration and "work arounds" (i.e., short cuts), which circumvent the safeguards that hard stops are designed to provide. Infusion pump configurations that provide users with convenient access to settings for the most commonly used drugs and concentrations, and make effective use of hard and soft stops can improve the user friendliness of the technology.

Other decisions that should be made during the implementation process are identification of individuals with the authority to modify the drug library, determination of the frequency of drug library updates, and whether approval of the P&T committee will be required for these changes. Completion of this background work must be thorough to ensure that the next step of writing the drug library goes smoothly.

Writing the drug library involves entering this information into the software program and this data-entry step should be relatively quick. All entries should be triple checked for accuracy before they are finalized.

Education of nursing, pharmacy, and biomedical engineering staff is vital when preparing to "go live" with the new technology. Both written and oral formats should be used for education. Conducting a test or pilot study in certain patient-care units using an abbreviated drug library is an optional step before facility-wide implementation.

Medication errors involving i.v. medications (e.g., total parenteral nutrient admixtures and fat emulsions, heparin, and morphine) were identified at CKHS prior to the implementation of decision-support infusion technology. These problems were evaluated and addressed during the implementation process. Errors in which total parenteral nutrient admixtures were administered at the rate recommended for fat emulsions and vice versa were identified, so a hard stop was established for infusions of fat emulsion. Two months after implementation, an analysis of data from 58% of infusion pumps and 8471 infusions revealed a 46% rate of compliance with drug libraries. This figure served as a baseline and underscored the need for further education and modification of the drug library.

An institution-wide analysis of infusion activity by time of day revealed decreased compliance in using the drug library during shift changes. Analysis of activity by the type of patient-care unit revealed that use of intelligent infusion pumps was greatest in the obstetrics–gynecology and neonatal care units. The relatively small number of i.v. medications used in these areas likely contributed to nursing compliance with use of the pumps. Another possible reason for increased compliance in these areas is because these care units are small and have specially trained staff who do not work elsewhere in the

institution. Therefore, the nurses may be more familiar and comfortable with the new equipment and procedures.

Maintenance i.v. fluids were the most common medications administered via the intelligent infusion pumps, likely because most patients receive maintenance i.v. fluids. Oxytocin, heparin, total parenteral nutrient admixtures, and fat emulsions also were among the common medications administered using decision-support infusion technology. No attempt has yet been made to compare the number of doses of a particular i.v. medication dispensed by the pharmacy with the number of infusions of that drug administered using decision-support infusion technology. However, such an analysis might be useful for identifying compliance rates.

Analysis of 226 alerts and subsequent overrides of soft stops found 25 programming changes were made by nurses and 10 of these (40%) represented a "critical catch." A critical catch is defined as any programming change that results in the infusion being delivered at a rate different from the initial value that was programmed. These critical catches involved several instances in which morphine would have been infused too rapidly and two instances in which the infusion rates for the total parenteral nutrient admixture and the fat emulsion were switched.

These data were presented to the nursing department and additional training sessions for nurses were planned. Additional refinements to the drug library were made to improve the ease of using these devices.

Barriers to implementation encountered at CKHS include the time investment and attention to detail required, software limitations (e.g., inadequate drug library capacity), and human limitations (e.g., lack of training and resistance to change). Decision-support infusion technology encouraged staff at CKHS to examine their medication-use processes and make improvements to ensure that i.v. medication use is appropriate and consistent throughout the institution. It also represented an exciting opportunity for staff who embrace change. The primary benefit of decision-support infusion technology was the potential to improve patient safety by reducing the risk for medication error.

The preceding was based on Dr. Cassano's presentation "Benefits, Barriers, and Results: Implementation of Decision-Support Infusion Technology" as part of the ASHP Midyear Clinical Meeting Exhibitors' Theater entitled "Improving Medication Safety in Medication Administration: Advances in Medication Management" held on Monday, December 6, 2004.

The Impact of Intelligent Infusion Pumps on Patient Safety

Jim Eskew, R.Ph. M.B.A., Director of Pharmacy at Clarian Health Partners, Indianapolis, Indiana, a 1400-bed, multihospital system, identified the five top concerns of pharmacy directors in 2004—medication safety, rising drug costs, maximizing the use of automation technology, expanding clinical pharmacy programs, and promoting rational drug use. He explained how intelligent infusion pumps, which were introduced in 2001, can be used to address these concerns.

Conventional infusion pumps were developed to provide accurate infusion flow rates for patients ranging in weight from 600 grams (i.e., neonates) to 150 kilograms (i.e., obese adults). However, conventional pumps had no provisions to test at the time of infusion for the reasonableness of the infusion rate or dose and serious errors were associated with the use of these devices. Intelligent infusion pumps use software that can be customized with upper and lower infusion rates and dose limits for a variety of patient populations (e.g., neonates, children, and adults). Clinical alerts (e.g., warnings about the risk of red-man syndrome from rapid infusion of vancomycin) can be incorporated for display to the nurse at the point of administration. The software also enables the pump to serve as a "black box" analogous to that on an airliner that records all setting changes made to the pump.

In justifying the adoption of intelligent infusion pumps to hospital administrators when financial resources are limited, it is important to stress that these pumps facilitate the use of best practices and prevent the most serious medication errors (e.g., administration errors involving insulin, heparin, and dopamine). They also address pharmacy directors' concerns about promoting rational drug use.

When compared to other technologies, adoption of decision-support infusion technology requires less time and minimal agreement among clinicians in different patient-care areas because the software is flexible enough to meet the specific needs of each area. Although intelligent infusion pumps can communicate with other information systems, interfaces are not required and the pumps can stand alone if desired.

Upgrading the software for intelligent infusion pumps can be labor intensive. However, the use of this technology provides potentially life-saving, knowledge-driven care on a "24/7" basis in all locations in the institution (e.g., emergency department) and at times when a pharmacist cannot be available. Intelligent infusion pumps also have been used in conjunction with pharmacy information systems to reduce wastage and improve the timeliness of i.v. medication delivery to the patient-care area, thereby addressing pharmacy directors' concerns about rising drug costs.

Following implementation of this new technology, an analysis was conducted of 12 months of data involving 2.8 million intelligent infusion pump "start-ups" at Clarian Health. (Start-ups were defined as the number of times the start key on the programming devices was pressed. Therefore, the number of start-ups represents all programming events, including initiation of an infusion and all dose alterations [e.g., titrations]). The analysis revealed 1748 reprogramming events, including those in response to 101 alerts for dosages exceeding 10 times the defined upper limit for the drug. Thus, the use of this technology had a measurable impact on patient safety by preventing potentially serious errors in i.v. drug administration.

The preceding was based on Mr. Eskew's presentation "Introduction to Smart Infusion Pump Technology" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Preventing Harm with High-Risk Medications: The Role of New Infusion Technology" held on Wednesday, December 8, 2004.

The Analysis of Pump Event Data and Its Role in Risk Prevention

Sharon K. Steingass, R.N., MSN, AOCN, Professional Practice Leader, City of Hope National Medical Center, Duarte, California, discussed the rationale for examining all medication event data (not just error data) that are available through decision-support infusion technology. She also described the use of these data to uncover systems, educational, and cultural issues that may affect i.v. medication administration from a nursing perspective.

Health-care organizations typically rely on nurses to report medication errors because nurses usually are involved from the time a medication order is written until the medication is administered. Medication errors that are detected and prevented usually go unreported, but they are of concern to clinicians and administrators because they may reflect systems problems that need to be addressed. Failure to report medication events with the potential for patient harm may be the result of a cumbersome reporting system, failure to recognize such events, or fear of the consequences.

A major benefit of decision-support infusion technology is that it allows the identification of all medication event data, including actual and potential errors. Because all data are collected, analysis is not limited to a convenience sample obtained at a time of day or week that may not reflect the times when problems occur.

The individuals responsible for analyzing the data, the frequency of data analysis, and procedures for reporting results of the analysis to staff should be determined during the process of implementing decision-support infusion technology. It is important to remember that event rates do not necessarily reflect error rates because event data include prevented errors (i.e., near misses and critical catches). Analysis of event data often presents opportunities for risk prevention. Therefore, a multidisciplinary team that includes physicians, pharmacists, nurses, risk managers, and others should review the data.

The event data generated by intelligent infusion pumps can be overwhelming, and considerable time is required to analyze the information and put it into a useful framework. The event data should be used in a constructive, non-punitive manner to identify systems, educational, and cultural issues that should be addressed to improve patient safety. Possible systems issues include the need to modify the drug library to improve clarity (e.g., resolve inconsistencies in units of measure) or accommodate accepted practices and the need to adjust staffing levels, schedules, and budgets to accommodate

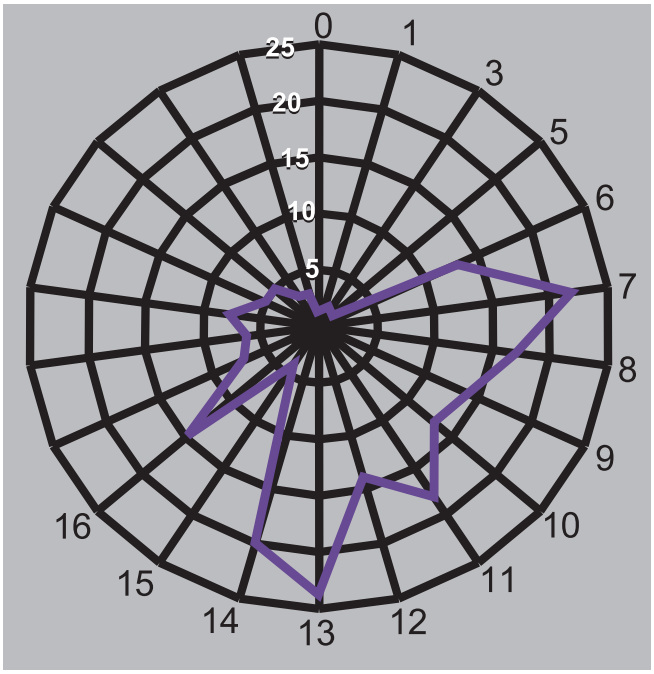

Figure 2. Sample Chronogram with Potassium Event Rate by Time of Day

workload fluctuations. Educational issues might include knowledge deficits, failure to follow policies and procedures, and inappropriate or excessive reliance on temporary staff. Cultural issues relate to staff attitudes and often manifest as habits or practices, such as work arounds. These may be more common at certain times of the day or week and therefore, also be related to systems issues.

It is important to establish priorities for evaluating event data. Events might be analyzed by the type of drug (e.g., high-alert medications or those with hard stops). Other possible priorities for analysis include the extent to which the programmed dose or infusion rate exceeded the soft or hard stop, the action taken by the nurse (e.g., reprogramming the pump or overriding the soft stop), the location within the institution or the time of day or week when the event occurred, or another variable. A chronogram can be used to provide a graphic display of changes in the event rate over the course of a specific period and identify the most problematic times (Figure 2).

A review of event data for high-alert medications at City of Hope National Medical Center identified a large number of events in which the intelligent infusion pump was programmed to exceed the maximum dose for potassium replacement solutions. Further analysis revealed several systems, educational, and cultural issues. Events often occurred during nursing shift changes and distractions while programming infusion pumps likely contributed to events. Potassium orders also were not always consistent with hospital policy and many nurses were not accustomed to programming pumps to deliver a concentration (mEq/mL) per unit of time

rather than a volume (mL) per unit of time. Identification of these issues enabled staff to take corrective steps to reduce the risk of error.

At City of Hope National Medical Center, decision-support infusion technology served as a powerful tool to explore i.v. medication administration practices. Analysis of event data from these pumps fostered collaboration between nursing and pharmacy. Involvement of staff in the analysis helped identify the causes of events and various systems, educational, and cultural changes that were necessary to improve patient safety.

The preceding was based on Ms. Steingass' presentation "Nursing Impact of Smart Pump Technology: Uncovering Hidden Issues in IV Drug Administration" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Preventing Harm with High-Risk Medications: The Role of New Infusion Technology" held on Wednesday, December 8, 2004.

Applying Event Data to Continuous Quality Improvement

Ray R. Maddox, Pharm.D., Director, Clinical Pharmacy and Research, St. Joseph's/Candler (SJ/C) Health System, Savannah, Georgia, described a specific application of decision-support infusion technology for continuous quality improvement in the administration of i.v. propofol for sedation in patients requiring mechanical ventilation in the intensive care unit. Intelligent infusion pumps were first used at SJ/C Health System in 2002 and event data from 525 pumps over a nine-month period in 2002 and 2003 were analyzed. There were 8294 events, including 598 events (7%) that resulted in reprogramming of the pump or cancellation of the pump settings, suggesting that the events represented errors that were prevented. The majority of events (57%) involved a dose or infusion rate that exceeded the maximum defined by the drug library, and 31% of events involved propofol or oxytocin. Modification of the maximum oxytocin dose defined by the drug library corrected the problem with events related to that medication, but propofol-related events were further investigated.

At the time the event data were collected, there were no guidelines for using propofol at SJ/C Health System, and orders for propofol were written in a vague manner, despite the availability of published authoritative clinical practice guidelines for sustained used of sedatives and analgesics in the critically ill adult.[7] These guidelines call for establishing a therapeutic endpoint, the use of a validated sedation assessment scale, titration of therapy to the endpoint, tapering off or daily interruption in therapy and repeated titration to avoid excessive sedation, and use of a treatment protocol, algorithm, or guideline.[7]

Propofol is highly lipophilic and widely distributed in tissues.[8] The drug has a rapid onset of action. Plasma concentrations decline in a triphasic manner, with short initial distribution (α) and redistribution (β) phases and a long terminal (γ) elimination phase lasting up to 31 hours.[8] Propofol is included in the ISMP list of high-alert medications because it is associated with systemic toxicity (e.g., cardiac arrhythmias, myocardial infarction, seizures, and abnormal movements).[5,8] Propofol is an expensive drug that is dosed by body weight. Tachyphylaxis (i.e., a progressive reduction in therapeutic response after repeated administration) can develop.

The average propofol dosage used at SJ/C Health System during the nine-month data collection period was 25% higher than the maximum dosage recommended in the published guidelines. An analysis of the number of alerts associated with overrides for propofol infusion rates and creation of a chronogram with time-of-day event data revealed that nursing staff were following physician orders for dosage titration, although the orders were not consistent with the published guidelines. Some alerts involved an infusion at a high rate that reflected bolus infusion of the drug over a short period of time.

An action plan was developed to establish a protocol for use of propofol in a manner consistent with the published authoritative guidelines.[7] Prescribers were required to use a preprinted sedation order sheet that specifies a sedation goal based on a validated sedation assessment scale. A research project is under way to compare the patient outcomes (e.g., length of stay in the intensive care unit, incidence of toxicity, and number of days of mechanical ventilation), number of events, and the amount and cost of propofol used before and after implementation of the propofol protocol at SJ/C Health System.

The findings related to propofol use at SJ/C Health System raise questions about what other drug therapy-related problems have gone undetected in critically ill patients. The use of intelligent infusion pump event data as part of continuous quality improvement efforts has the potential to help uncover iatrogenic problems so that strategies can be devised to improve patient care.

The preceding was based on Dr. Maddox's presentation "Smart Pump Data: A Road for Process Improvement" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Preventing Harm with High-Risk Medications: The Role of New Infusion Technology" held on Wednesday, December 8, 2004.

Bar-Code and eMAR Technology

Applying Bar-Code Technology to the Medication-Use Process

Bill Churchill, M.S., R.Ph., Director of Pharmacy Services, Brigham and Women's Hospital (BWH), Boston, Massachusetts, described his experience implementing bar-code technology at that facility. The plan at BWH was to develop a new web-based pharmacy information system that

would be linked electronically with the eMAR and would utilize machine-readable bar-code scanning technology. An on-site drug-repackaging center was established to ensure that 100% of medications were bar-code labeled. Bar-code scanning was planned for all aspects of dispensing in the pharmacy, delivery to the patient care unit, and drug administration at the bedside. BWH is also planning to implement a real-time interface between the eMAR and intelligent infusion pumps.

The bar code was developed in 1974 and it was used initially in the food industry. The first bar code appeared on a medication package in 1991. In 2004, the FDA issued a final rule requiring bar codes on most prescription and nonprescription drug products commonly used in hospitals to reduce the risk of medication errors.[9] This requirement must be met within two years after the regulation is implemented (i.e., by mid 2006).[10] All new drug products must bear a bar code within 60 days after marketing.

The use of bar-code technology as part of an ideal medication administration system, with CPOE, a pharmacy information system, and eMAR, provides a fail-safe automated system for medication identification and feedback in real time. As discussed previously, it can help ensure that the right dose of the right drug is administered by the right route at the right time to the right patient. Bar-code technology will allow nurses to focus more time on direct patient care, promote the efficient use of pharmacy technicians, and likely will help to free up pharmacists from drug distribution responsibilities for patient care-related activities.

Considerations in Implementation

Table 2 lists factors to consider in implementing bar-code technology. FDA regulation requires that manufacturer bar codes must include at a minimum the National Drug Code (NDC), which represents the manufacturer, drug, dosage form, strength, and package size and type (e.g., ampul or bag).[11] However, it is important to note that there is no FDA requirement for manufacturers to provide unit-dose packaging for specific drug products. There is growing concern among pharmacists that some pharmaceutical manufacturers will eliminate unit-dose packaged drugs from their product lines rather than incur the retooling expense required to add bar codes to these packages.[11] Feedback provided from drug wholesalers indicates that the availability of unit-dose products has decreased significantly since 2000, which substantiates this concern.

Availability of Bar-Coded Drug Packages

At BWH where more than six million doses are dispensed annually, approximately 50% of drug products did not have bar codes, and repackaging was required for 3.2 million doses. The decision was made at BWH that all products that are repackaged must bear a bar code with the lot number, expiration date, and NDC number.

Selecting the smallest packaging was critical for BWH because automated dispensing machines have a limited amount of storage space and unit-dose medications provided by commercial medication repackaging companies typically require significantly more storage space when compared with the smaller unit-dose medications supplied by pharmaceutical manufacturers. Therefore, flexibility in bar-code label sizes, packaging and formats is required to accommodate various dosage forms (e.g., individual tablets, oral liquids, vials, syringes, and rectal suppositories). Early bar codes (e.g., the Uniform Product Code and what are known as code 128 and code 39) are a linear series of vertical bars and spaces. The linear bar codes work well for meeting FDA requirements for including the NDC number, but their use on small unit-dose packages that also include lot numbers and expiration dates is problematic because adding additional information increases the horizontal length of the bar code.

Staff at BWH opted to use a two-dimensional bar code because this format can accommodate greater data density for small packages.[11] Examples of two-dimensional bar-code formats include the stacked Reduced Space Symbology (RSS) composite (a portable data file [PDF] code stacked on top of an RSS) and the Data Matrix bar code (Figure 3). The latter was chosen as the standard bar-code format at BWH because Data Matrix bar codes are 30 times smaller and have greater scanning accuracy than linear code 39 bar codes. Data Matrix bar codes can be easily printed using a standard printer and read accurately, even when they are damaged. However, Data Matrix bar

Figure 3. Data Matrix bar code

TABLE 2

Considerations in Implementing Bar-Code Technology

- FDA regulations and institutional requirements
- Availability of unit-of-use products with bar codes
- Bar-code formats
- Bar-code readers
- Repackaging of drug products (in house versus outsourced)
- Patient ID bracelets
- Employee ID badges
- System platform
- RFID technology
- Barriers to implementation
  - drug database issues
  - scanning issues
  - hardware issues
  - human factors

FDA = Food and Drug Administration, ID = identification, RFID = radio frequency identification

codes currently are not widely used on commercially-available drug products.

It is extremely important to select bar-code readers that can decode multiple bar-code formats because multiple formats are currently being used by pharmaceutical manufacturers. Data Matrix bar codes can only be read using a two-dimensional bar-code reader or a specially programmed imager. Two-dimensional readers and imagers can read both linear and two-dimensional bar-code formats, but they are more costly than linear bar-code readers because of their two-dimensional bar-code scanning capability. They may be wireless or tethered to a laptop computer or desktop PC. Wireless bar-code readers are advantageous in many health-care settings (e.g., intensive care units) because staff may find them easier and more convenient to use than tethered scanners. Wireless Bluetooth® technology may be used, although careful evaluation of potential compatibility problems with other medical equipment must be done before a decision to use this technology is reached.

Repacking of Drug Products

Because the pharmaceutical industry has until 2006 to comply with FDA bar-coding requirements, a limited number of bar-coded products are commercially available at this time. BWH needed to decide whether to repackage medications in house or outsource repackaging. Commercial drug repackaging companies were unable to meet the needs of BWH for reasons of volume, turnaround time, package size, and costs. However, the staff at BWH lacked experience in repackaging medications. Therefore, the decision was made to establish an in-house repackaging center at BWH by working in conjunction with their prime vendor.

Requirements for a hospital pharmacy-based drug repackaging center include a high degree of automation, the capacity to handle a large volume, staff who are able to accurately perform multiple tasks simultaneously, redundant back-up systems in case of mechanical failure, and a fail-safe verification process to minimize error. At BWH, pharmacy technicians conduct redundant checks of the data entered (i.e., settings for labeling equipment) before starting the repackaging process and pharmacists visually verify the data entered, product selected, and final packaged product. Products are segregated during each phase of the setup, repackaging, and verification processes. Pharmacists conduct a final visual and electronic verification of the repackaged product by scanning the bar code on the source product and comparing it with a reference database. Full documentation of all repackaging is maintained.

Infrastructure requirements include sufficient work and storage space, sinks, computer and telephone lines, electric power (including back-up emergency power), water, and compressed air supplies. The drug repackaging center at BWH required 350 square feet of space. Computer-support requirements included a central computer database and network for all repackaging operations, with the ability to track lot numbers, expiration dates, repackaging dates, and the identity of the technician and pharmacist involved in each repacking process. Labor requirements included two full-time equivalent (FTE) certified pharmacy technicians and 0.5 FTE pharmacist to operate two shifts five days a week. Extensive staff training and back-up support for vacations and illness also were arranged.

Repackaging operations increased over a period of several months at BWH, with 1.2 million doses repackaged during the first year. Nearly half of these doses were oral tablets. Following implementation, the staff at BWH wanted to verify the effectiveness of the fail-safe verification process. A study conducted over a period of 10 weeks involving more than 260,000 doses revealed a preliminary error rate of 2.4%. Study results indicated that two thirds of the errors occurred during data entry when an incorrect lot number or expiration date was entered into the computer system (i.e., errors not likely to result in patient harm). All of these errors were detected during the fail-safe verification process and validated that no incorrect medications left the repackaging center. This study confirmed that fail-safe redundant checking processes are required to ensure an accurate bar-code labeling process.

Identification of Patients and Care Providers

Selection of patient identification (ID) bracelets and employee ID badges are important infrastructure considerations in implementing bar-code scanning technology. At BWH, the desired features of patient ID bracelets include low cost, durability, and the ability to accommodate all patients (e.g., premature neonates and children and adults) and multiple bar-code formats. The Data Matrix bar-code format was chosen for patient ID bracelets at BWH because they are easy to scan (the bracelet need not be flat and it can be scanned from either side and upside down as well as right-side up). As at many other institutions, several patient ID bracelets are produced at the time of patient admission to BWH. This practice can present a potential work around problem if staff circumvent the safeguards built into the system by scanning one of the extra bracelets instead of the one that the patient is wearing. However, the eMAR software used at BWH does not permit this work around because only one patient ID bracelet is active at a time. The importance of maintaining the integrity of the safeguards provided by bar-code scanning of patient ID bracelets was underscored by data that suggest that 4% or more of medication errors are categorized as drug administration to the wrong patient.

The ability to photocopy bar codes on employee ID badges and circumvent system safeguards is also a consideration in choosing a bar-code format for this application. A PDF bar code was selected for use on employee ID badges at BWH because it is more difficult to copy this format than one-dimensional linear bar codes. The cost of converting to a new employee ID badge system with bar codes must be considered. At BWH, over 3,000 staff were issued new bar-coded ID badges at an approximate cost of $24,000. A contingency plan was devised for employees who arrive at work without their badge

whereby the employee manually enters a user ID and password to access the computer system. The decision was made to not make available temporary badges because of the difficulty in controlling access and ensuring that the badges would be promptly returned and deactivated. As an additional safeguard, employee ID badges at BWH require daily activation by the user and the badge is automatically deactivated after 13 hours (nursing shifts typically last 12 hours). These system design elements help prevent work arounds and maintain system integrity.

Bar Coding I.V. Products

Several system choices needed to be made in implementing bar-code technology and automating the i.v. drug delivery platform at BWH. These choices included the information to include in the bar codes, whether the bar codes would be used to automatically program infusion pumps, and whether bar codes on i.v. drug products should be scanned into the i.v. pump, the eMAR, or both. The goals of automating the i.v. drug delivery process at BWH were to reduce i.v. pump programming errors, standardize the drug-administration process, improve communication among caregivers, and provide continuity of care. An intuitive and user-friendly system that prevented work arounds and offered real-time tracking and reporting of changes in infusion rates and near misses was sought. The system was designed with interfaces that provided for two-way communication between order entry, the eMAR system, and the pharmacy information system. Feedback will allow the pharmacy department to provide timely delivery of i.v. medications to the patient care area. The BWH eMAR–pharmacy system prioritizes medication orders for pharmacists and nurses and allows staff to track orders from the time the order is placed, through drug delivery to the unit, and until the drug is administered to the patient.

Currently BWH includes the following information in the bar code on a patient-specific i.v. admixture: the patient name, medical record number, and order number. In the near future, BWH will also include the drug name, NDC, and concentration. This enhancement will provide the necessary platform within the bar code to automate the programming of infusion pumps.

Radio frequency identification (RFID) technology, a method of identifying unique items using radio waves, is an alternative to bar coding that has many potential applications in health-care institutions, including automating i.v. pump programming. This wireless technology can be used to provide real-time information about patients, staff, or assets (e.g., infusion pumps and other equipment). An RFID tag programmed with specific information can be used instead of a bar code. However, the cost of the technology is a consideration because RFID tags are much more expensive than bar-code labels. In the future, it may be possible to print i.v. labels with RFID tags for use with infusion pumps that have RFID readers. The RFID tag on the i.v. label would be passively scanned by the reader when a nurse brings the medication near the infusion pump. This passive scanning is a major difference between RFID technology and bar-code technology, which requires active scanning of bar codes.

Coordination of Bar Code Technology with Information Systems

Several drug database issues arose during the bar-code implementation process at BWH. A generic sequence number (GSN) was used instead of the NDC to overcome difficulties in linking similar products with different NDCs in the database. For example, each brand of acetaminophen 325-mg, unit-dose tablet has a unique NDC number. However, all brands of acetaminophen have the same GSN number. This solves a potential problem by providing a link so that no matter which brand of acetaminophen is dispensed, the system will recognize that these products are generically equivalent and will allow the drug to be administered without an error message.

The need to generate bar codes for investigational drugs, total parenteral nutrient admixtures, and other compounded i.v. products was also identified. Ongoing efforts are needed to maintain the database and resolve database discrepancies and other problems.

Post-Implementation Challenges and Improvements

Problems with scanning arose initially at BWH because of the use of multiple bar-code formats, sizes, and locations on drug products, which created confusion for staff who lacked scanning experience. The quality of the reader has a large impact on the success of scanning. Some bar codes are affixed to drug products in a manner that precludes scanning or makes it difficult (e.g., bar-code labels that wrap around small vials). Other issues that were considered during the equipment selection process were durability of bar-code scanners, battery life of scanners and laptops, and ergonomics. The quality of printers was also a major deciding factor because printers that produce poor quality bar codes are associated with scanning errors and work arounds.

Human factors can pose a barrier to the successful implementation of bar-code technology. Many staff resist change and fear the consequences of error tracking. They are likely to find the use of new electronic equipment time consuming and challenging initially, although the technology has the potential to improve efficiency in the long term. Work arounds (e.g., photocopying bar codes or scanning after drug dispensing or administration instead of at the time of the event) may become a problem.

A prospective study was conducted at BWH to compare the rate of error in pharmacy dispensing before and after bar-code implementation. The analysis included more than 140,000 doses dispensed over a 30-day period before implementation of bar-code scanning and a similar number of doses following implementation. Study results demonstrated a 75% reduction in dispensing errors after bar-code implementation. The majority (96%) of those errors involved an incorrect quantity rather than an incorrect medication. While a 75% reduction is a significant improvement, there is still

opportunity to further reduce the incidence of medication errors. Eliminating work arounds is an important strategy that is expected to help achieve the goal of zero dispensing and administration errors.

In summary, implementation of bar-code technology is a complex process involving many considerations. Human factors play a large role in the success of implementation because changes in staff behavior and avoidance of the tendency to use work arounds are required.

The preceding was based on Mr. Churchill's presentation as part of the ASHP Midyear Clinical Meeting Exhibitors' Theater entitled "Practical Strategies for Implementing Bar Code Technology in the Institutional Setting" held on Tuesday, December 7, 2004.

Bar-Code Technology: One Year Following Implementation

Charles H. Elliot, Pharm.D., a clinical pharmacist at Sutter Roseville Medical Center (SRMC), Roseville, California, provided an overview of his experience one year after implementing bar-code technology at the rapidly-growing, 190-bed facility. Pharmacy services at SRMC are provided on a 24-hour basis, using a profile-driven system, cart-less drug distribution, and decentralized clinical pharmacists.

Bar-code technology was implemented 30 days after a new pharmacy information system was installed, which complicated the implementation process. Bar coding was phased in throughout most of the hospital over a three-month period.

The major focus initially was to ensure that bar coding was used on 100% of drug products. Although this goal was initially daunting, it was achieved relatively easily and quickly. Three things were needed to achieve the goal: a labeling mechanism for small packages, additional pharmacist and technician staff, and an automated drug repackaging system. Non-formulary medications presented a challenge because of the need to create a unit-of-use package with a readable bar code for each unique drug product.

The current rate of bar-code scanning at SRMC is 93%. Barriers to achieving a high rate of bar-code scanning include legibility problems (e.g., blurred bar codes provided by pharmaceutical manufacturers and poor printer resolution), the use of temporary nursing staff who are unfamiliar with the bar-coding system, and extemporaneous compounding by nurses that resulted in i.v. admixtures without bar codes. The system's software also permitted users to circumvent bar-code scanning by using a mouse to make selections from a menu of items, and this user-friendly feature reduced the bar-code scanning rate.

The time required for pharmacy order entry increased by 25 to 30% after bar-code implementation because of the need to schedule administration of medications given on a scheduled and as-needed basis (e.g., saline flushes and inhaled respiratory medications). The software provides nurses with a chronological list or queue of medications to be administered and it differentiates between doses that are overdue, those that are currently due, and those that are due in the future. During implementation, there was resistance among some nurses, who perceived that bar-code scanning prolonged the medication administration process. However, most nurses eventually found that bar-code technology did not add substantially to the time required for medication administration. Another concern is the potential use of the queue to schedule non-drug events, such as sterile dressing changes. This practice was discouraged at SRMC because it tended to distract from medication administration.

Bar-code implementation caused a dramatic increase in the reported medication error rate at SRMC because of a large increase in the detection of late doses and missed respiratory treatments. In most cases, the late doses were not clinically significant, but the missed respiratory treatments remain a concern. The rate of potentially serious errors decreased significantly as a result of bar-code implementation.

Weaknesses of the current system at SRMC include the opportunity to "borrow" doses scheduled for the future and the tendency to fail to check the accuracy and completeness of orders entered by pharmacy staff because of a "technology bias" (i.e., the authoritative appearance of information once it is entered into the system). Nurses were also unlikely to detect the absence of an order that inadvertently was not entered by the pharmacy staff. Failure of the software to provide special safeguards for high-alert medications is another shortcoming.

Unexpected benefits of bar-code implementation at SRMC include online access to the eMAR, which allows pharmacists to schedule drug administration and has resulted in less rescheduling of doses and fewer problems with drug interactions. The time to administration of the first dose, which can be particularly important for antibiotic therapy, also has decreased. Greatly improved reporting capabilities are another unexpected benefit.

A continuous quality improvement approach was used after bar-code implementation at SRMC. A multidisciplinary committee of staff from pharmacy, nursing, respiratory therapy, and information technology departments met on a weekly basis to identify problems. The need for repeat training of the nursing staff was identified as a method to ensure that nurses retained all information provided during initial training. Pharmacy order entry review (i.e., double checking of order entry by pharmacy staff) was implemented as a safeguard in the event that nursing staff might overlook inaccurate or incomplete order entry by the pharmacy staff. Staff at SRMC discovered the need to plan for computer down time and mechanical failure, and contingency plans were made. Now that one year has elapsed since implementation of bar-code technology at SRMC, feedback from staff is favorable and complaints are rare.

The preceding was based on Dr. Elliot's presentation "Bar Coding to the Bedside: One Year Later—Insights and Unexpected

Benefits" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Management Case Studies—Session G" held on Wednesday, December 8, 2004.

Assessing the Impact of Bar-Code Technology: Advantages, Disadvantages and Reality

Advantages and disadvantages of an eMAR and bar-coding system implemented in 2002 were discussed by **Jean M. Caba, Pharm.D.,** Pharmacy Clinical Manager and **Michael J. Sovie, Pharm.D., M.B.A.,** Director of Pharmacy, St. Lucie Medical Center (SLMC), Port St. Lucie, Florida. SLMC is a 196-bed facility with 24-hour pharmacy services. The pharmacy uses a cart-fill distribution system and laptop computers are stationed on medication carts in the patient care area. A nurse consults the laptop computer, obtains a medication from the cart for a specific patient, and scans the bar codes on the patient ID bracelet and the medication label before administering the drug. This process helps ensure that the right drug and right dose are given by the right route at the right time to the right patient.

Before the availability of eMARs, a paper MAR was created manually based on a series of medication orders for a patient. This process was subject to error because of difficulties in reading handwriting, misinterpretation of orders, and human error in the transcription process.

The use of the eMAR provides real-time communication between pharmacy and nursing staffs at SLMC. A requirement for nurse verification of orders entered by the pharmacy staff provides a safeguard against errors in order interpretation and entry. The eMAR system can be programmed with extra safeguards for specific medications (e.g., electronic prompts to remind nurses to check heart rate or level of sedation before giving digoxin or opioid analgesics, respectively). The eMAR system also provides access to notes and reports in the patient medical record (e.g., laboratory test results, vital sign data, and history and physical examination notes). The use of the eMAR also improves the efficiency of patient care activities by providing pharmacists with convenient and real-time access to patient data (e.g., documentation and availability of pharmacokinetic and total parenteral nutrient consultations).

Disadvantages of the use of bar coding in conjunction with the eMAR system at SLMC include an increase in pharmacy staff time requirements for drug repackaging and quality control procedures (i.e., checking repackaged drugs). Equipment and software problems also consume extra staff time. Although bar-code technology is designed to eliminate human factors that contribute to error, use of the technology requires human intervention to generate bar codes for drug products and maintain hardware. The potential for errors in repackaging operations related to the wrong label, wrong bar code, or wrong drug product remain, although quality-control measures increase the likelihood of detecting these errors.

Pharmacy staff often are called on by nursing and even information technology staff to trouble shoot problems with the eMAR system. The pharmacy staff at SLMC have become an information technology resource for the nursing staff because information technology staff typically are available for shorter hours than pharmacy staff, who are available 24 hours a day.

Increased order entry time requirements for pharmacy staff is a disadvantage of the eMAR system at SLMC. Nurses often request that pharmacy staff make minor changes to drug administration times on the eMAR. For example, a nurse might ask the pharmacist to modify the scheduled administration time for a dose if a patient was away from the care unit for a procedure at the scheduled dosing time. Although the delayed administration would not be clinically significant, it would otherwise result in a late-dose report. Nurses also find it convenient to incorporate non-drug reminders (e.g., blood glucose checks) into the eMAR and this additional order entry adds to the pharmacy workload.

Although the use of eMAR and bar-code technology has the potential to improve patient safety, staff at SLMC have found that shortcomings in the technology are a reality. Pharmacy staff are frequently interrupted to address scanning problems and other unresolved issues. A variety of different bar-code formats are in development and reading the newer formats will require updated scanning equipment. Decisions also were made about scanning procedures for certain products (e.g., bulk items, such as topical medications and inhalers and floor stock items, such as heparin flushes). In addition, education is necessary because nurses often do not recognize that floor stock is a medication, the administration of which needs to be documented. Errors in order entry have also gone undetected for a period of time when the order was not double checked against the patient medical record before administration of the medication. Finding a workable way to enter orders for titrated i.v. medications also posed a problem at SLMC because multiple rate changes are involved and nurses make these changes as ordered, in accordance with therapeutic endpoints. However, the pharmacy staff were reluctant to allow the nurses to modify these orders in the eMAR because of the potential to inappropriately use this authority to modify orders for other medications and patients.

The eMAR and bar-coding system currently are not used in the emergency department or operating room at SLMC. This poses challenges in continuity of care because documentation for a patient is maintained in two different places (i.e., paper and eMAR systems) if the patient is then transferred to a patient care area that uses eMAR and bar-code technology.

The impact on the pharmacy department at SLMC following implementation of the eMAR and bar-coding systems was substantial and the learning curve for new staff to become efficient in using the system was steep. Additional pharmacist and technician staff were required, primarily for repackaging operations and hardware maintenance.

These difficulties were offset by improvements in medication administration and patient safety that resulted from use of eMAR and bar-code technology at SLMC. A wrong drug, wrong dose, or wrong patient was involved in 876, 768, and 26 alerts, respectively, and the drug was not given in any of these cases. These near misses represent potentially serious medication errors. The reduction in liability associated with improved patient safety helped justify the expense of implementing bar-code technology at SLMC.

In conclusion, the use of eMAR in conjunction with bar-code technology provides health-care providers the opportunity to improve the safety of the medication use process, but only to the extent that users understand the limitations of these systems and create a culture that eliminates the use of work arounds.

The preceding was based on Dr. Caba's and Dr. Sovie's presentation "Electronic Medication Administration Record (eMAR) and Bar Coding: The Good, The Bad, and the Reality" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Management Case Studies—Session G" held on Wednesday, December 8, 2004.

Using Failure Mode and Effects Analysis to Improve the Use of Technology at a Small Rural Hospital

Tonya Smith, Pharm.D., Director of Pharmacy, Jefferson Memorial Hospital (JMH), Ranson, West Virginia, described her experience optimizing the use of eMARs at a small, community hospital in a rural area. The average daily census at JMH is approximately 40 patients. The local population is comprised of many elderly individuals, including nursing home residents, and younger residents who commute to the metropolitan Washington, D.C. area, which is not far away. The hospital serves as a family practice residency site for West Virginia University.

The pharmacy department at JMH is open 12 hours on weekdays (from 7 am until 7 pm) and six hours on weekends and holidays (from 8 am until 2 pm). A pharmacist is on call when the pharmacy is closed. The pharmacy staff consists of a director, 1.8 FTE staff pharmacists, and 2.5 FTE pharmacy technicians.

Dr. Smith arrived at JMH about six months after the eMAR system was established, so she was not part of the system implementation process and she identified areas for improvement in the system she inherited. Implementing an eMAR system in a facility without 24-hour pharmacy services had been a challenge. A profile-driven system was used for automated dispensing, and this system was implemented after the eMAR system.

The pharmacy conducted a failure mode and effects analysis (FMEA) of the entire medication-use process from the time a medication order was written until the drug was administered. A multidisciplinary team (primarily pharmacists and nurses) was involved in the FMEA process. The eMAR system had been in place for approximately 12 months when the FMEA was conducted, and through this analysis, opportunities to improve the use of eMARs were identified.

During the hours when the pharmacy is open, medication orders are faxed to the pharmacy by a unit clerk, reviewed and entered into the computer system by a pharmacist, and double checked by a nurse. When the pharmacy is closed, a unit clerk enters a temporary order into the computer and faxes the order to the pharmacy, and a nurse verifies the entry of the temporary order. Once the pharmacy reopens, a pharmacist reviews the temporary order and approves it or consults with the prescriber to modify the order.

Two key steps in this process that represented opportunities for improvement were identified in the FMEA: (1) errors in medication order entry by non-pharmacists after hours, and (2) appearance of these orders on automated dispensing machine patient profiles. Non-pharmacist medication order entry was associated with an increased rate of error because of the deficit of medication and drug therapy knowledge in the staff performing the function. Correcting the resulting errors in order entry was time consuming for pharmacists. The FMEA also revealed that any clinical monitoring alerts in the system that were bypassed by the unit clerk during order entry were then not available to the nurse.

To rectify the situation, mandatory education on medication order entry was provided to unit clerks at the time of hiring and annually thereafter. Standard drug administration times and appropriate computer screen use for order entry were emphasized to ensure that labels would print appropriately for batch medication compounding. Reference guides with information on converting brand names to generic names and other helpful information were developed and provided to unit clerks. Competency assessments also were conducted.

A new policy was established that required the unit clerk to notify a nurse if he or she received a clinical monitoring alert (i.e., overriding the alert was no longer permitted). The nurse was required to contact the on-call pharmacist about the alert before administering the drug.

Appearance of temporary orders on the automated dispensing machine patient profiles resulted from transmittal of this information at the interface between the eMAR and the automated dispensing machine patient profile. This was an unintended consequence of implementing the profile-driven automated dispensing system after implementation of the eMAR system and without considering the implications of the interface on temporary medication orders. Once the problem was discovered, changes were made to ensure that temporary orders in the eMAR were blocked from appearing on the automated dispensing machine patient profile until a pharmacist approved the order. A policy and mechanism were devised to allow nurses to override the safeguard and gain access to necessary doses at times when the pharmacy was closed. Use of this override mechanism required a second nurse as a witness to verify the need for access to the medication.

Following these changes, there was a substantial reduction in the time required for pharmacists to correct errors in medication order entry. Reports of overrides are reviewed by pharmacists on a daily basis to ensure that medications are used appropriately after hours.

Experience at JMH demonstrates that the use of an eMAR system can have unanticipated consequences, with implications for staff efficiency, compliance, and patient safety. Medication-use processes must be continuously evaluated to identify opportunities for improvement in the use of eMAR systems. CPOE may provide a good solution to some of the challenges at JMH, but like many smaller institutions, the cost of implementing this technology is prohibitive at this time.

The preceding was based on Dr. Smith's presentation "Optimizing the Use of Electronic Administration Records (eMAR) in a Rural Hospital" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Management Case Studies—Session G" held on Wednesday, December 8, 2004.

Computerized Physician Order Entry

Implementing CPOE at a Large Health System

James D. Carpenter, R.Ph., M.S., Decision Support Pharmacist, Regional Information Services, Providence Health Systems, Tigard, Oregon, described his experience in implementing and maintaining a CPOE system at a large, multifacility health-care organization. Providence Health System is an 18-hospital health-care organization located on the west coast, with more than 5000 acute and long-term-care beds. The organization is headquartered in Portland, Oregon, which is where Providence Portland Medical Center (PPMC), the "go live" hospital for CPOE is located. The goal for implementing CPOE at Providence Health System is to facilitate order creation and communication in a knowledge-rich environment. Implementation is a work in progress at Providence Health System, with plans to gradually phase in and conduct pilot studies of CPOE in various parts of PPMC in the coming months.

Implementing CPOE is challenging because of the complexities of medication orders and the clinical decision support that is required. Every possible type of order must be accommodated. Order communication channels are complex and communication is not necessarily linear. Professional knowledge and information are not discrete bits of data that can be stored and retrieved at will and they do not map in a simple manner onto other schemata.[12]

According to Carpenter, the introduction and flow of electronic information has the potential to disrupt what he refers to as the "magic glue" that holds together conventional paper information systems, which he believes have functioned efficiently despite the inherent flaws of these systems. Converting to an electronic system requires redesign of the work flow associated with the creation and communication of orders. Therefore, a decision was made to use a hybrid of a conventional paper order system and the new electronic order system at PPMC to ease the transition.

A wide variety of staff from Providence Health System and PPMC are involved in the CPOE implementation process, including the regional pharmacy director, regional pharmacy clinical coordinator, clinical specialists, information technology coordinator, chief medical information officer, director of nursing informatics, and CPOE analysts (pharmacists, nurses, laboratory staff, and others dedicated to CPOE). There are plans to involve frontline staff pharmacists in "test driving" sessions during the CPOE system build process. Even though finding time for these staff to participate may be difficult because of their work commitments, this step is critical to successful implementation. Physician staff and hospital administration are heavily involved in the CPOE implementation process at the P&T committee and executive committee level.

Mr. Carpenter noted that pharmacist participation is essential in CPOE project committees (e.g., the project steering committee and clinical decision support committee), system design and testing, content management, and communication. Pharmacists' experience with order entry and their understanding of the pitfalls of clinical decision-support software is invaluable for system design. Testing of interfaces between the CPOE system and the pharmacy information system is also needed. At PPMC, this is a challenge because a new pharmacy information system currently is under development and it will be implemented at approximately the same time as the CPOE system.

Pharmacists' activities in CPOE system content management include compiling medication order sets, validating information in treatment guidelines and protocols, and accommodating formulary considerations (e.g., orders for non-formulary or investigational drugs). Provisions must be made for automatically screening for drug allergies and drug interactions and providing warnings about high-alert medications. These content management activities are time consuming and ongoing.

According to Carpenter, pharmacists are key members of the CPOE implementation team because they can effectively communicate process goals and status updates using the channels and rapport that they already have established with the physician and nursing staffs. Mr. Carpenter also noted that CPOE will not diminish the need for cognitive input in medication ordering. In fact, pharmacists' cognitive role in medication management will increase after CPOE implementation.

Several issues have been raised in CPOE work-flow mapping sessions at PPMC. How to provide for order verification and co-signatures, and whether non-physicians will be allowed to enter orders are issues that still need resolution.

Mr. Carpenter anticipates that pharmacist involvement in CPOE design and maintenance will help ensure successful

system implementation. Collaboration with physicians, nurses, information technologists, and others will contribute to this success.

The preceding was based on Mr. Carpenter's presentation "Preparing for the CPOE Environment" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "CPOE 2005 and Beyond: Is Your Pharmacy Prepared?" held on Tuesday, December 7, 2004.

Using the CPOE System for Guideline and Formulary Management

Mark J. Sinnett, Pharm.D., FASHP, Director, Clinical and Educational Services, Montefiore Medical Center (MMC), Bronx, New York, described his experience with a fully-implemented CPOE system at that institution. MMC is a multi-faceted health system with two hospitals, two long-term-care facilities, and numerous clinics and ambulatory care sites. More than four million orders were generated over the past 12 months and more than one third of those orders were for medications. The CPOE system was implemented gradually throughout MMC, beginning in certain patient care units and eventually adding in others. The conversion from a paper-based system to an electronic one was executed quickly in each patient care area, without prolonged use of a back-up paper system. Medication error rates decreased by approximately 50% after conversion.

The total annual drug budget for acute care at MMC rose to nearly $20 million in 2002. The cost of biotechnology drug products and new drugs for treating cancer and cardiovascular disease nearly doubled between 1998 and 2004. However, overall drug expenditures at MMC have remained relatively constant since 1999, a fact that has been attributed to drug-use guidelines and controls facilitated through CPOE.

Doug D. Cusick, Senior Consultant and Service Line Practice Lead, Healthlink, Inc, London, England, and former employee with the vendor of the CPOE system used at MMC, described his participation in the CPOE implementation project at MMC. Demonstration of return on investment was an essential part of the project. A pilot study was conducted to compare order processing efficiency over a 10-day period before and after CPOE implementation on an inpatient family medicine unit. The average amount of time between order creation and order receipt by the pharmacy decreased by about two hours following CPOE implementation. Significant time savings for unit clerks and nursing and pharmacy staff were realized that could translate into cost savings if the time was reallocated to other duties.

Dr. Sinnett then described the use of CPOE for formulary management at MMC. When CPOE was first implemented, there were concerns about physician acceptance of the system. Therefore, orders for non-formulary drugs were accepted much as they were with the former paper-based system. Subsequently, the CPOE system developed a process that allowed non-formulary drug order entry only after the prescriber contacted a pharmacist to discuss the rationale for use of that product. Non-formulary drug orders decreased substantially after that change was implemented, largely because the "hassle factor" associated with contacting a pharmacist served as a deterrent to ordering non-formulary drugs that were not medically necessary. Negative feedback from prescribers has been minimal. The financial impact has not yet been quantified.

Therapeutic interchange had been established at MMC long before CPOE implementation to control drug-therapy costs without compromising safety or efficacy. However, prescribers often were not aware of the interchange and nurses often were confused about substitutions. These are factors that can increase the risk of medication error. Incorporation of the therapeutic interchange function into the CPOE system helped resolve these problems. Computer screens direct the prescriber to the preferred formulary alternative, although there is a mechanism for overriding the preferred agent and ordering a non-preferred medication. A cost savings of more than $200,000 has been realized from the therapeutic interchange program for low molecular weight heparin at MMC. Therapeutic interchange is also used at MMC for other drug classes.

The CPOE system at MMC accommodates a protocol devised for automatic conversion from i.v. to oral therapy for six drugs if the patient is eating and does not complain of nausea or is taking other medications orally. The physician is automatically notified of this conversion. Cost savings are associated with the use of the oral route of administration instead of the i.v. route, although the savings associated with use of this protocol have not been quantified at MMC.

The CPOE system at MMC has resulted in a reduction in the medication error rate, improved order turn-around time, and demonstrated an annual cost savings of more than 1 million dollars. It also has increased the clinical focus of pharmacy practitioners. Thus, the benefits of CPOE extend beyond improvements in medication safety.

The preceding was based on Dr. Sinnett's and Mr. Cusick's presentation "Pharmacy Services in a Fully Implemented CPOE Organization" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "CPOE 2005 and Beyond: Is Your Pharmacy Prepared?" held on Tuesday, December 7, 2004.

The Next Generation of CPOE

Early CPOE systems sought to manage clinical information. Improvements in order legibility, completeness, timeliness, and overall accuracy; formulary management; and patient safety were byproducts of these systems. The next generation of CPOE systems will facilitate making clinical judgments. **Ron Robb, Pharm.D.,** Pharmacy Product Manager for a commercial vendor that provides CPOE systems, described the evolution of the next generation of CPOE systems.

Various organizational, financial, regulatory, technological, and societal factors have led to innovations in CPOE systems (Table 3). Health-care organizations are increasingly

TABLE 3

Factors Driving the Evolution of CPOE Systems

- Health-care organizational change
- Shrinking revenues/rising costs
- Increasingly complex regulations and requirements
- Focus on health-care delivery redesign
- Pharmacy and nursing shortages
- Increasing prevalence of chronic illness
- Growth in consumerism

under pressure to provide improved continuity of care and to meet requirements set forth by the federal government and health insurers that call for more comprehensive health-care documentation. Revenues are shrinking while costs are rising because of the availability of increasingly sophisticated and costly treatment options. At the same time, the Health Insurance Portability and Accountability Act (HIPAA) and other requirements of federal and state regulatory agencies and accrediting bodies involved with health care (e.g., the FDA, state boards of pharmacy, and JCAHO) have become increasingly complex.

Redesigning health-care delivery to improve the safety of medication use has been the focus of various groups, including ISMP, the Institute of Medicine (a nonprofit organization established by the federal government to provide independent science-based advice on health matters), and the Leapfrog Group for Patient Safety (a voluntary initiative of private companies and public organizations that purchase health care).[13,14] These groups provide impetus for CPOE system innovations. Pharmacist and nursing staff shortages also contribute to redesign initiatives. Aging of the "baby boom" generation and increases in the prevalence of chronic illness and the extent to which the general public is knowledgeable about health issues also play a role in the evolution of CPOE systems.

One benefit of new CPOE systems is that pharmacy and other departments involved in the medication-use process will no longer be islands separate from other institutional departments and services. These systems will have applications and modules that are interwoven, with boundaries that are absent or fluid.

New CPOE systems provide for the ubiquitous availability of information at the point of use in a variety of locations (e.g., a patient's home, physician's office, or patient bedside in the inpatient setting). Web technology is an enabler in this process. Data are reformatted and intelligent displays are used to accommodate each viewer's specific electronic device (e.g., cellular phone, paging device, other handheld device, or laptop and desktop PC). The systems have components designed for the patient that allow for round-the-clock continuity of care. For example, a patient with diabetes might upload data from a home blood glucose self-monitoring device for review by a nurse at another location.

Various architectural, infrastructural, and functional changes are associated with new CPOE systems. Event managers and work flow engines can now be configured to manage order-processing work flow and provide alerts to system users as needed. The sophistication of knowledge bases and rules engines has increased and these changes have improved the accuracy and efficiency of therapeutic decision making and facilitated formulary management. Interfaces with dispensing devices and intelligent infusion pumps have been built into new CPOE systems. Clinical report preparation is now more sophisticated and user friendly, with a point-and-click user interface. To address HIPAA security requirements, advances have been made in system capabilities for order authentication, auditing, and authorization of system users to enter, activate, sign, co-sign, reject, or reroute orders.

New CPOE systems also provide context to order entry. Examples of context include the patient's age, sex, and type of health insurance and the institutional department or service and the type of health-care practitioner involved. For example, role-based medication alerts can be used to display different alerts to different health-care practitioners (e.g., nurses versus physicians or cardiologists versus family practitioners) based on what information is needed by that practitioner to perform his or her duties.

Early CPOE systems were burdensome for physicians because they required selection of a specific drug product (e.g., a 30-g tube of triamcinolone 0.1% ointment for topical use). These systems also were burdensome for pharmacists because of the need to correct errors in orders entered by physicians who were unfamiliar with formulary drug products. Newer CPOE systems use multi-stage medication order entry whereby the physician selects a drug; dose, strength, or concentration; route of administration; and dosing interval (e.g., triamcinolone 0.1% for topical use two to four times daily) and leaves the decisions about dosage form (ointment) and package size (30-g tube) to a pharmacist.

The use of guideline-based treatment is cost-effective, but rates of prescriber adherence to guidelines is low.[15,16] This problem has been attributed to information overload and reliance on the unassisted human mind for recall.[17] Incorporation of guidelines into CPOE systems can provide a solution to the problem by offering targeted, relevant guidance to the prescriber at the point of care and automatically evaluating patient-specific data at critical therapeutic decision points. However, achieving these goals presents a challenge for clinical informatics staff because guidelines that are computer-interpretable are required.

New CPOE systems are also designed to resolve concerns related to a lack of continuity in patient care. In a critical analysis of patient safety practices, the Agency for Healthcare Research and Quality noted that patient safety can be compro-

mised by discontinuities in care resulting from poor information transfer or faulty communication.[18] Hospital admission is the single most disruptive event in drug therapy for an ambulatory patient because information about treatments and drug allergies often is lost or incompletely communicated. The outpatient care plan typically is overlooked or unavailable, and there usually is no access to the patient's drug therapy history. Information about therapeutic response (especially failures) can be particularly valuable.

In June 2004, a survey of health-care information technology professionals was conducted by the Healthcare Information and Management Systems Society (HIMSS) to ascertain the perceived impact on patient care of several proposed JCAHO National Patient Safety Goals for 2005.[19] Accurately and completely reconciling medications and other treatments across the continuum of care was the proposed goal with the greatest anticipated impact on patient care. This goal was adopted (among others) by JCAHO in 2005 for full implementation by January 2006.[20] It involves documenting a complete list of current medications at the time of patient admission and comparing this list with the medications provided at the institution (the latter list may include drug therapies initiated in the hospital and reflect the discontinuation or modification of drug therapies taken at home). JCAHO also requires communicating a drug therapy list that is complete and current to the next health-care provider who will provide care when the patient is transferred within or outside the organization.[20]

Models for this medication reconciliation process have been developed for use in CPOE systems. These models check for inappropriate dosages, drug allergies, and drug interactions. At the time of hospital discharge, a list of medications for use at the patient's destination (e.g., the patient's home or a nursing home) and a discharge instruction sheet for the patient with specific instructions on which medications to continue is generated.

Development of the next generation of CPOE systems is a challenging proposition that requires leadership and vision. However, the potential rewards of persistence in this endeavor are great.

The preceding was based on Dr. Robb's presentation "CPOE: The Next Generation" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "CPOE 2005 and Beyond: Is Your Pharmacy Prepared?" held on Tuesday, December 7, 2004.

The Critical Role of the Pharmacist in CPOE Implementation

Gil J. Kuperman, M.D., Ph.D., Director, Quality Informatics, New York-Presbyterian Hospital, New York, New York, echoed what was said by other presenters about the potential for improvement in medication safety through CPOE, and he provided a physician's perspective on the role of pharmacists in CPOE. Dr. Kuperman also described the experience, skills, and knowledge that make pharmacists critical to the implementation of future CPOE systems.

The favorable impact of CPOE systems that provide drug-use guidelines has been documented. In a study measuring the impact of CPOE on prescribing practices in an inpatient setting, the percentage of doses that exceeded the recommended maximum dose decreased significantly from 2.1% before CPOE implementation to 0.6% after implementation.[21] CPOE screens with "pick lists" (Figure 4) allow a prescriber to choose among several possible doses, strengths, or concentrations instead of using a free-text data entry field. This enhancement can reduce the risk of error (e.g., error associated with misplaced decimal points). In a study of 7490 patients with renal insufficiency for whom more than 97,000 orders were written for drugs that are eliminated renally or potentially nephrotoxic, the percentages of orders with appropriate doses and dosing intervals were significantly higher when CPOE was used instead of usual ordering processes.[22] A clinical laboratory interface and recommendations for dosage adjustment based on test results (e.g., serum creatinine concentration or creatinine clearance) are particularly helpful components of a CPOE system for such patients. Future CPOE systems will have these features.

In Kuperman's view, pharmacists are critical to the success of CPOE system implementation projects because approximately 40% of all orders at New York-Presbyterian Hospital are for medications. Pharmacists contribute both process and domain knowledge. Process knowledge relates to specialized work-flow patterns in the emergency department, operating rooms, and recovery areas as well as routine patterns in other areas of the hospital. This knowledge also includes information about processes involving patient transfer to and from specialized care units (e.g., intensive care units). Domain knowledge includes pharmacokinetics, drug interactions, the use of agents for which therapeutic drug monitoring is required (e.g., anticonvulsants, aminoglycosides, and heparin), and formulary considerations.

The skills and aptitudes required of pharmacists assisting in CPOE implementation include project management skills, an ability to work in a collaborative manner with other members of the implementation team, an analytical view of systems (i.e., an understanding of systems logic), and skills in data analysis. Participation in CPOE implementation may require the acquisition of these skills.

In summary, many health-care practitioners possess valuable process and domain knowledge. CPOE enables this expertise to be applied and used consistently throughout the institution to improve patient safety. With their unique process and knowledge domains, pharmacists can play an important role in the success of CPOE implementation projects.

Kevin C. Marvin, M.S., Project Manager, Fletcher Allen Healthcare, Burlington, Vermont, explained the changes in pharmacy practice that will be brought about by future CPOE systems and the skills and knowledge that will be needed to accommodate this transition. Current CPOE systems are centered on physicians and the orders that they generate.

Figure 4. Sample CPOE Screen with Dose Pick List

Administrators often focus on the percentage of orders processed by CPOE as a measure of success. However, the validity of order processing rates as an outcome measure has been questioned because of problems inherent in CPOE systems that are not reflected by these rates.

Many current CPOE systems were designed by physicians to improve order entry efficiency, but many of these individuals lacked a full understanding of the work flow involved in order processing. In many cases, current systems do not provide a mechanism for users to communicate to other members of the health-care team their reasons for overriding system safeguards. This can result in disruptive telephone calls that are required to provide clarification. Nurses often have a need to learn the status of an order and many current systems are inadequate in providing this information. In some institutions, the clinical alerts built into the system have been deactivated because they impeded physician efficiency. Thus, there is a need to improve the rule sets used in system design to make work flow efficient for all members of the health-care team and retain system safeguards.

In many institutions, pharmacists have been extensively involved in system implementation and much of their effort has been invested in creating order sets. However, these order sets often are used by prescribers in a piece-meal fashion. In some settings, it is possible for a prescriber to modify parts of standardized orders, but it is not readily apparent to the pharmacist what was changed.

In the future, CPOE systems will use a broader approach that involves the entire health-care team and takes a comprehensive view of a patient's drug therapy. Fully-integrated CPOE systems will eliminate the need for transcription and provide access to all parts of the patient medical record, including the patient's history of medication use and response. Pharmacist review of medication orders will be done in conjunction with a review of laboratory test results and other patient-specific data to obtain a complete picture of the patient's health. Pharmacists will need to be physically present in the patient-care setting to obtain patient medication histories and participate in physician rounds and other clinical activities.

Over the past 50 years, pharmacy practice has evolved from a product-oriented one in which pharmacists were concerned with medication compounding, packaging, and distribution to a practice in which pharmacists focus on medication orders and drug therapy. Future CPOE systems will decrease pharmacists' emphasis on medication orders and increase their focus on drug therapy management. These systems will require pharmacists to work closely with physicians and other health-care practitioners and the patient. Pharmacists will need skills in drug literature evaluation and an understanding of the principles of clinical research design, statistical analysis, and decision-support system logic. The transition to future CPOE systems will present pharmacists with both challenges and opportunities to have a favorable impact on patient care.

The preceding was based on Dr. Kuperman's and Mr. Marvin's presentation "Supporting CPOE Now and in the Future" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "CPOE 2005 and Beyond: Is Your Pharmacy Prepared?" held on Tuesday, December 7, 2004.

Technology Caveats

Automation technology innovations offer many benefits, most notably improvements in medication safety. However, the use of new technologies can introduce error into the medication-use process. This section will provide an overview of the potential errors related to use of these technologies and conclude with specific examples of strategies to address errors related to use of automated dispensing devices.

Technology Implementation as a Beginning, Not an End

David W. Bates, M.D., Medical Director of Clinical and Quality Analysis, Partners Healthcare System and Chief, Division of General Medicine, Brigham and Women's Hospital (BWH), Boston, Massachusetts, described the benefits as well as potential areas of concern with automation technology by highlighting experience at BWH with CPOE, bar coding, and intelligent infusion pumps. He emphasized the ongoing need to study these technologies after they are implemented, not only to ensure that the intended goal of improved patient safety was achieved, but also to identify and correct potential problems. As he described it, the purchase of the equipment is not the end, it is the beginning.

There are several ways in which information technology has improved patient safety: (1) by preventing errors and adverse events, (2) by facilitating a rapid response following an error or adverse event that occurs and (3) by tracking and providing valuable information on such events, including those that might not otherwise be identified.[23] However, when technology is implemented, the potential for new errors is

high. Therefore, it is necessary that implementation plans provide for dedicated and ongoing resources to review the impact of new technologies and make adjustments. Most implementation plans vastly underestimate the need for and extent of resources required for this function.

Though the types of errors may vary by the technology employed, there are some common characteristics in errors introduced by new technology. Because of the systems nature of technology, errors that result can occur in large numbers. Technology errors are also a concern because individuals develop a false sense of security that the information or action suggested by the technology is correct. For example, a standard or suggested dose may be incorrect in a CPOE system, but the authoritative appearance of the information lends to it credibility that may make the error hard to detect.

As discussed earlier, CPOE is perhaps one of the most powerful interventions, especially when implemented with associated clinical decision-support systems. Even early systems, with rudimentary decision support (i.e., those that checked only for complete orders and common drug-allergy and drug-drug interactions), resulted in a 55% reduction in serious medication errors.[24] Future decision-support systems will focus on the areas with the most impact: dosage calculations based on patient-specific characteristics (e.g., age, weight, and renal or hepatic function), default dosing, and maximum dose limits.

Despite these benefits, CPOE can also introduce new errors. In addition to the potential for technology bias, CPOE does not eliminate the potential for incorrect order entry if the wrong patient profile is accessed by the prescriber. Digital picture identification of patients is one method that could decrease this source of error.

Excessive alerts generated by CPOE clinical decision-support software are of particular concern as cumbersome systems can lead to the excessive override of alerts and potential errors. For example, at BWH 7761 drug alerts were recorded from August to October 2002. These alerts were overridden 80% of the time. A review of these alerts found that only 6% were triggered by an exact match of the drug ordered and the patient allergy. The remaining alerts were cross-interactions (e.g., an allergy to a different opiate or furosemide triggering a warning for sulfa allergy). These are low-alert interactions that are unlikely to result in patient harm. This review of alerts also highlighted a lack of differentiation between low and high alerts. Ideally high alerts should present in a more prominent fashion. At BWH, the focus of ongoing CPOE efforts will include not only fine-tuning *when* to alert, but also *how* to provide high alerts to improve recognition.

Improving the user-friendliness of the CPOE system is also an ongoing effort at BWH. Studies are aimed at determining what type of information is most beneficial to specific users of the system. For example, a "snapshot" that displays the patient's diagnosis, medication history, and recent laboratory results was developed to increase the usefulness of information provided to pharmacy staff. In addition, all display screens have a function that allows the user to submit suggestions or questions related to use of the system. Responses are generally provided within 24 hours and an ongoing list of system changes is generated from this input.

As noted earlier, bar-code technology offers several potential benefits including assisting in matching drug orders to drug products, tracking drug dispensing and administration, and providing patient identification. However bar coding can raise new concerns.[25] Among these are the potential for decreased coordination and communication between nurses and physicians, discontinuation or delay of other nursing duties to reduce workload during peak drug administration times, and decreased ability of nurses to deviate from routine duties when necessary.

Intelligent infusion pumps prevent serious medication errors and record data that provide a wealth of information for quality assurance and work-flow analysis. Post-implementation, a controlled study in the surgical and cardiac care units at BWH demonstrated that the infusion of drug therapy in these areas is a complex procedure. The results of the study identified complicating factors that include the extent of patient transfers between different care areas (e.g., operating room to recovery room, recovery room to intensive care unit, and intensive care unit to general nursing floor) and the need for frequent reprogramming of pumps based on dose titration. It was determined that 90% of programming of infusion pumps was reprogramming. This is important to note because implementation training is often focused on initial programming.

A review of the data from intelligent infusion pumps also identified other areas for improvements, including the need to review the use of low-end dosage range warnings that may not be useful, increase agreement about maximal dosages, and establish procedures for the administration of bolus doses. Future goals for improvement at BWH include the use of wireless communication between the CPOE system and the intelligent infusion pumps and the integration of this infusion administration information with that recorded for oral medications through the use of bar-code technology.

In summary, new technology that is designed to prevent errors also has the potential of increasing an institution's vulnerability to new errors. Recognizing this potential and allocating resources to make appropriate mid-course corrections are key components to ensuring that technologies achieve the desired result of improving patient care.

The preceding was based on Dr. Bates' presentation "IT and Medication Safety" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Technology is Risky Business: USP Error Findings on Computer Entry, CPOE, and Automated Dispensing Devices" held on Thursday, December 9, 2004.

A Specific Example of Continuous Quality Improvement

Robert J. Weber, M.S., FASHP, Executive Director of Pharmacy, University of Pittsburgh Medical Center (UPMC), and Associate Professor and Chairman of Pharmacy and Therapeutics, School of Pharmacy, University of Pittsburgh, Pittsburgh, Pennsylvania, discussed medication errors associated with decentralized automated dispensing machines and quality improvement strategies to eliminate or reduce these errors. Decentralized automated dispensing machines (e.g., unit-based cabinets) are widely used in health-care institutions to provide nurses with efficient, controlled, point-of-care access to medications.[26] The devices were developed to reduce medication errors and improve patient safety, and they contribute to these goals. However, the use of automated dispensing devices is not without problems.

Errors associated with these devices at UPMC demonstrated a need for improved organizational oversight. Errors in repackaging have been propagated throughout the institution because mistakes in drug identity are not readily detected once a label with a bar code is attached to a drug product. Errors have occurred in filling automated dispensing machines (e.g., meperidine cartridges have been loaded into the morphine drawer of a unit-based cabinet). Other errors involve the retrieval of medications from the machines (e.g., piperacillin–tazobactam was obtained from a unit-based cabinet for a patient with an allergy to penicillin). Some errors involved overrides of system safeguards.

UPMC subscribes to MEDMARX®, a medication error reporting program and quality-improvement tool for health systems operated by the United States Pharmacopoeia (USP). The program allows subscribers to collect, track, and analyze medication errors and compare their data with those of other health systems. Using facility-specific data and information available through participation in MEDMARX®, staff at UPMC identified potential sources of error and devised a quality improvement plan to address safety concerns in the use of automated dispensing machines. This plan entailed providing staff training and competency assessment and using bar-code and visual-database technology to improve the accuracy of drug repackaging and device filling operations. Policies and practices were analyzed and end users were involved in functionality changes.

Automated dispensing machine overrides were a cause for concern because of the potential impact on patient safety. The P&T committee sought to limit the use of overrides (i.e., the types of medications to which nurses would have access without prior pharmacist review of the order, as well as the frequency of this access) to situations when it was clinically appropriate (i.e., emergent or urgent clinical situations). In making these decisions the committee acknowledged that these decisions require balancing convenience and safety. There is a trade off between these two factors, whereby providing for one factor requires a compromise in the other factor.

An expert panel was established to develop evidence-based criteria for determining which medications would not be available by override, make policy changes, and conduct staff education programs about the proper use of the override function. The panel decided to permit overrides only for medications with a clinical indication for emergent or urgent use (e.g., chewable aspirin for chest pain) and in ready-to-use, immediate-release dosage forms. Overrides were not permitted for high-alert medications. Access to medications was permitted only for nurses with proper training in safe use of the drug. Overrides for certain medications were authorized only for specific patient care areas (e.g., intensive care units). In developing the criteria, the panel evaluated each of the 240 different medications for which overrides were authorized in 2001 and reduced this number to 140 medications by 2003.

Opioid analgesics were targeted in efforts to improve the safety of override practices at UPMC because errors resulting from this drug class are commonly associated with patient harm. At UPMC, the panel's efforts to limit opioid analgesic overrides and conduct staff education programs resulted in significant reductions in opioid analgesic override rates over a six-month period.

Analysis of decentralized automated dispensing machines overrides is an ongoing process at UPMC. The appropriateness of overrides is evaluated by comparing them with medication orders. Unit-based cabinet data are used to determine the types and frequency of overrides. Override data are analyzed by practitioner, time of day or week, and patient condition. These analyses can help identify problems that impact patient care.

The preceding was based on Dr. Weber's presentation "Understanding and Responding to Errors Involving Automated Dispensing Devices" as part of the ASHP Midyear Clinical Meeting educational symposium entitled "Technology is Risky Business: USP Error Findings on Computer Entry, CPOE, and Automated Dispensing Devices" held on Thursday, December 9, 2004.

Conclusion

Innovative automation technologies improve the safety of the medication-use process and provide a variety of additional benefits. However, the limitations of these technologies must be understood, and steps should be taken to optimize use of the technology and avoid compromising system safeguards.

Pharmacists can play a vital role in implementing new technologies. The use of automation technologies will enable pharmacists to assume a larger role in drug therapy management in the future.

Self-Assessment Questions

1. **In which of the following steps in the medication-use process are errors least likely to be detected before the patient receives the drug?**
   a. Ordering
   b. Transcribing
   c. Dispensing
   d. Administering

2. **Which of the following automation technologies has had the largest impact on patient safety to date?**
   a. Computerized order entry
   b. Pharmacy information systems
   c. Automated dispensing machines
   d. Point-of-administration systems

3. **Which of the following automation technologies is the most costly to implement, but can reduce costs for drug therapy and staff time?**
   a. Computerized order entry
   b. Pharmacy information systems
   c. Automated dispensing machines
   d. Point-of-administration systems

4. **The test of "reasonableness" performed by stand-alone intelligent infusion pumps provides information about _____.**
   a. whether the pump settings are consistent with the physician's order
   b. whether the right drug is given to the right patient at the right time
   c. whether the right infusion rate and duration are used
   d. whether the medication selected is a high-alert medication

5. **Which of the following best describes the soft stops used in intelligent infusion pumps?**
   a. They provide upper limits in the dose, concentration, or infusion rate.
   b. They provide lower limits in the dose, concentration, or infusion rate.
   c. They provide absolute limits in pump settings that cannot be overridden.
   d. They provide limits in pump settings that may be overridden under certain circumstances.

6. **Information about a customized group of drugs, with the drug name, dose or concentration and units of measure, diluent (if any), hard and soft stops, and therapeutic or pharmacologic class is referred to as a _____.**
   a. drug compendium
   b. drug library
   c. formulary
   d. rule set

7. **Which of the following steps in implementing decision-support infusion technology is the most time consuming?**
   a. Identification of stakeholders
   b. Evaluation of infusion software capabilities
   c. Evaluation of current health system practices
   d. Pilot testing

8. **Which of the following is a consideration in implementing bar-code technology?**
   a. 510k clearance from FDA
   b. The bar-code format
   c. The chronogram of events
   d. The drug library

9. **Which of the following is an advantage of Data Matrix bar codes over linear bar codes?**
   a. Lower cost of scanning devices
   b. Lower data density
   c. Smaller size
   d. Wider use on commercially available drug products

10. **Which of the following features is an advantage of radio frequency identification technology over bar-code technology?**
    a. Two-way communication
    b. Wireless capability
    c. Active scanning
    d. Passive scanning

11. **Short cuts taken by staff to circumvent safeguards inherent in the use of bar-code technology in an effort to improve efficiency are referred to as _____.**
    a. hard stops
    b. soft stops
    c. overrides
    d. work arounds

To complete this post test, go to **www.ashp.org/advantage/ce**

12. Which of the following is the best strategy for reducing errors associated with technology bias?

a. Using a two-way interface
b. Using real-time communication
c. Requiring double checks of data that are input
d. Providing education programs in more than one format

13. Role-based medication conflict alerts are an example of innovative CPOE system design provisions for _____.

a. accuracy
b. context
c. efficiency
d. security

14. Which of the following scenarios is an example of multi-stage medication order entry?

a. Ordering of a drug; dose, strength, or concentration; route of administration; dosing interval; dosage form; and package size by a physician and subsequent review and approval of the order by a pharmacist.
b. Nurse verification of the drug; dose, strength, or concentration; route of administration; dosing interval; and dosage form sent by pharmacy by comparing them with the physician's order.
c. Entry of a temporary order, with the drug; dose, strength, or concentration; route of administration; dosing interval; and dosage form, by a unit clerk, and subsequent approval by a pharmacist.
d. Ordering of a drug; dose, strength, or concentration; route of administration; and dosing interval by a physician and subsequent selection of a dosage form and package size by a pharmacist.

15. Which of the following proposed JCAHO National Patient Safety Goals for 2005 was perceived by health-care information technology professionals to have the greatest impact on patient care and will be addressed by the next generation of CPOE systems?

a. Accurately and completely reconciling medications across the continuum of care
b. Improving the accuracy of patient identification
c. Improving the effectiveness of communication among caregivers
d. Improving the safety of infusion pump use

16. Which of the following pairs of factors must be balanced when deciding whether to permit overrides for decentralized dispensing devices that allow nurses access to some medications prior to pharmacist review of the order?

a. Efficacy and safety
b. Efficacy and cost
c. Convenience and safety
d. Safety and cost

17. When allocating resources to review the impact of technology and make necessary corrections, most implementation plans _____.

a. vastly exaggerate the need for these resources
b. vastly underestimate the need for these resources
c. rely on temporary staff to complete these functions
d. fail to make any plans for this function

18. Which of the following statements best characterizes the potential for medication errors caused by new technologies?

a. The resulting errors are few in number and generally do not impact patient safety.
b. The implementation of new technologies does not result in the introduction of new errors.
c. The resulting errors can be caused by technology bias and be large in number because of the systems nature of technology.
d. The resulting errors frequently result in severe patient harm and death.

19. A skill or aptitude required by pharmacists as CPOE systems continue to evolve will include _____.

a. drug literature evaluation skills
b. drug repacking skills
c. order entry skills
d. dispensing and work flow skills

20. Which of the following future changes in the role of pharmacists is most likely from implementation of CPOE and other innovative automation technologies?

a. An increased role in drug distribution
b. An increased role in drug therapy management
c. An increased role in drug repackaging
d. An increased role in drug order processing

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