The Effect of Barcode-Enabled Point-of-Care Technology on Patient Safety

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Literature review published by Bridge Medical, Inc.
October 2002

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Foreword

In recent days it seems as if our nation has reached many critical milestones in the concerted effort to first do no harm. Hospitals and health systems are embracing the role that information technology can play in safeguarding patient care. Legislators are recognizing the need to appropriate funds to evaluate the success of such systems, and organizations spanning the industry are uniting to set standards, and pave the way for safe and cost-effective healthcare. Discourse over cultures of blame, technology readiness, budgetary limitations and resource allocation has been lengthy and impassioned, but the debate is subsiding to accord as patient safety goals and the means to achieve these goals win popular consensus.

As stakeholders in the quality improvement of this nation's healthcare, we must recognize the vulnerability of the patient in all of us. When a practice or technology exists that is proven to reduce error, it is our shared responsibility to communicate its efficacy. A technology has begun to take center stage demonstrating impressive results and demanding our attention. Barcode-enabled point-of-care (BPOC) systems provide a safeguard against error at the most vulnerable stage in the medication use process—during administration. Peer-reviewed studies validating BPOC technology efficacy, industry movement to establish a healthcare barcoding standard and the announcement of a future FDA ruling mandating manufacturer-applied barcodes testify to BPOC systems' coming of age. Its effective use can save lives and dollars while increasing overall staff efficiency.

If organizations haven't already begun the process of adopting BPOC systems, now is the time to do so. We must educate ourselves and the hospital community at large about the available technology and the great benefits it will bring. We must plan for adoption by thoroughly examining the current medication system to identify weaknesses, needed improvements and cultural changes that will facilitate adoption. This monograph should be useful in helping us carry a message to healthcare executives, payers, regulators and other decisionmakers. It organizes the findings of many researchers in a way that clearly illustrates the extent of the medication administration problem, defines the contribution that barcode-enabled technology can bring to patient safety and describes the obstacles to implementation.

I believe Bridge Medical, Inc., has provided a useful service in making this tool available to us. I hope we will all use it to good advantage.

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Introduction

In 1999, the Institute of Medicine published its report "To Err is Human: Building a Safer Health System." In doing so, they focused the nation's attention on the subject of medical error.

The news that 44,000 to 98,000 hospital patients die annually as a result of preventable medical errors came as a shock to many Americans.[1] Less surprising to the medical community was the fact that the largest number of deaths stems from adverse drug events (ADEs) due to medication errors. And while the numbers continue to undergo scrutiny, the concerns of patients speak to the extent of the problem. A study by the American Society of Health-System Pharmacists found that the top concern of hospitalized patients is experiencing a medication error.[2] An April 2002 survey substantiated this perceived concern. It found that one in five American families (8.1 million households) reported experiencing a serious medication error during hospitalization.[3] New research published in September 2002 brought further credence to patient concerns. The study concluded that healthcare facilities are experiencing as many as one error per every five doses administered. More importantly, 7 percent of erroneously administered doses were judged to be potential ADEs.[4]

Under these conditions, healthcare organizations are faced with increasing pressure to proactively address medical errors, with special emphasis placed on reducing preventable medication errors. Research indicates that 6–10 percent of hospitalized patients experience one or more ADEs per admission. One-third to one-half of these ADEs are preventable.[5] In fact, serious medication errors resulting in death have increased over time—more than doubling in number from 1983 to 1993.[6]

Today's nurse is saddled with increasingly larger patient loads and caring for individuals with higher degrees of acuity than ever before. Complicating the care of these patients is the skyrocketing number of new pharmaceuticals entering the market. The number of drugs has grown 500 percent in just the last decade to more than 17,000 trade and generic names for pharmaceuticals marketed in North America.[7] It is therefore no surprise that Leape and associates found that approximately half of all ADEs resulted from inadequate availability of drug and patient information. Even when faced with complete knowledge of a medication, as many as 18 percent of preventable ADEs arise from the clinician having insufficient information about the patient.[8] Of primary importance is basic demographic and clinical information, such as age, weight, allergies, diagnosis and pregnancy status. In addition, laboratory values, vital signs and other parameters that gauge the effects of medication provide invaluable decision support in making drug therapy choices. Nowhere is this information more necessary than at the point of care during medication administration. To overlook the point of care in information technology planning limits the nurse's ability to exercise optimal clinical judgment and opens the door for errors to reach the patient.

After lack of information access, failure to accurately verify medication dose and patient identity are the next most common administration errors. Another 10 percent of nursing administration errors can be attributed to faulty identification from look-alike and sound-alike medications.[9] These errors—incorrect dose, failure to positively identify the patient and faulty medication verification—currently depend on manual inspection and are subject to high levels of inaccuracy when nurses are rushed, overly tired or unfamiliar with a medication. Given the current nursing shortage, it is not surprising that hospitals report distractions, workload increase and inexperienced staff to be the most frequent contributing factors associated with medication errors.[10]

Barcode-enabled point-of-care (BPOC) technology allows for real-time confirmation of patient identification, medication, dose, time and route of administration. When augmented with sophisticated computer logic, BPOC systems can protect patients from prescription, transcription and dispensing errors, as well as administration errors. For example, if a physician prescribes an overdose of colchicine, a well-designed BPOC system will alert the nurse based on pre-programmed maximum daily dose guidelines *before* the overdose is administered. Likewise, if a physician's order for the look-alike medication Isordil® is misinterpreted during transcription as Plendil®, this type of system would alert the nurse with this warning: "Isordil can be confused with Plendil. Isordil is used to treat angina. Plendil is used to treat hypertension." This check enables the nurse to verify the prescription with the pharmacist or physician in the event an error has been made.

Making Sense of BPOC Technology

BPOC systems vary greatly in their use of information technology and clinical complexity. They may also vary in terms of the communications media they use to transmit data. For instance, BPOC systems may utilize store-and-forward communication, or radio frequency (RF), wireless and even cellular communication. They have been built for both the personal computer (PC) and Internet environments, and deployed using hand-held computers, mobile laptops and centrally located stationary PCs. Systems also span a wide range of functionality that can be described most simply in four levels of sophistication.

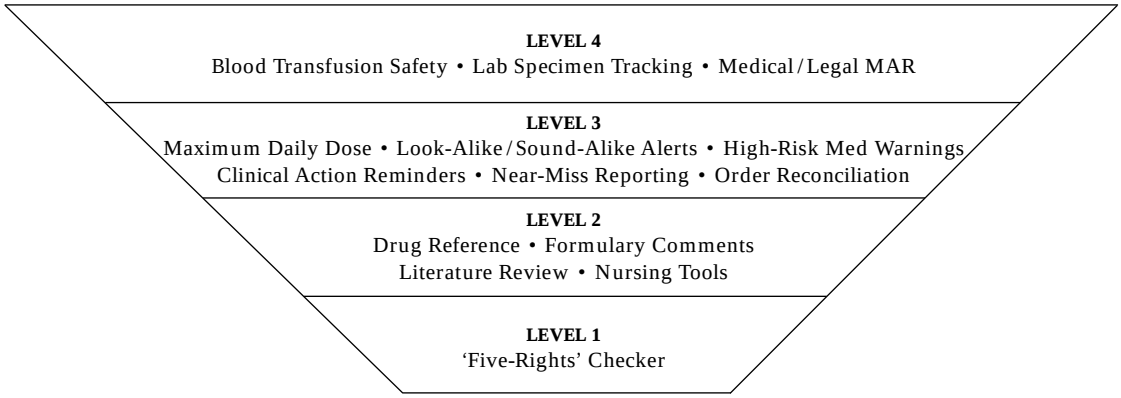

FIGURE 1 Types of BPOC Systems

Level 1—'Five-rights' checker systems
These basic systems simply verify the "five rights" of medication administration: right patient, right medication, right dose, right time and right route of administration. When orders and schedules are sent from the pharmacy system to the BPOC system, the patient's wristband and medication barcodes are scanned, and the system provides an automated double check, ensuring the patient receives the medication treatment specified in the pharmacy order.

As a byproduct, Level 1 systems provide a complete and accurate electronic or online medication administration record (eMAR). This affords point-of-care visibility to all patient information in a real-time, single-source presentation. Additional features may include customizable work lists for nurses, alerts for missed doses and online access to the hospital formulary. The data collected by the barcode scanner may or may not be amassed in an electronic format for retrospective analysis. Errors in the order—e.g., a tenfold overdose due to a transcription error—will not be intercepted by a basic five-rights checker.

Level 2—Integrated online medication reference systems with enhanced pharmacy communication
More evolved systems go beyond checking the five rights to give caregivers more information about medications and facilitate electronic

communication with the pharmacy. For example, a pharmacist can enter a customizable comment for any medication in the formulary; this comment displays to the caregiver at the time the medication is ordered. In addition, when selecting a medication, information about the drug is provided online from the medication reference libraries. This may include a picture if in pill form, usual dosages, contraindications, adverse reactions and other warnings, pregnancy risk factors and administration details. Level 2 systems may also allow patients to review educational pamphlets online or print them at the nursing station. The most sophisticated Level 2 systems integrate dose calculation tables. While these systems will not alert the caregiver to a potential error in the medication order, they do provide tools for the nurse to proactively research a medication order.

Level 3—Embedded computer logic and alert engine systems

The third level of BPOC technology incorporates rules engines into the process of verifying the five rights. These systems are able to test the pharmacy order and the nurse's actions against preprogrammed standards. For example, suppose an order specifies "colchicine 0.6 mg orally every 2 hours until diarrhea develops," and the recommended dosage per course of therapy is 4 to 8 mg. At each administration, the software will refer to a rolling 24-hour count of doses given and signal the nurse when an additional dose would exceed the maximum 8 mg range.

A Level 3 system will also alert nurses to the potential for confusion over look-alike/sound-alike medications and inform them of the intended use of the medication they are about to administer. Having been made aware of the potential for an error, the nurse may opt to verify the order with the physician or pharmacist. These advanced systems may also include high-risk medication warnings, prompts to record additional clinical information needed to administer certain medications, near-miss error reports and order reconciliation. Without order reconciliation functionality, caregivers are unable to use the system safeguards when administering pending or STAT orders (i.e., a physician order not yet verified by a pharmacist). In some facilities, these may account for up to 30 percent of all orders. Without the ability to enter a STAT order into the system upon administration and then later link it to the pharmacy order, it is possible to introduce errors due to double-dosing medications.

Combined with online reference materials and tools, these systems provide proactive error prevention as well as enable nurses to exercise heightened clinical knowledge during the medication administration process.

Level 4—Expanded point-of-care safeguard: Blood transfusion and specimen collection

The fourth and most sophisticated level of technology has evolved to address bedside errors beyond medication administration. These systems include other critical point-of-care safety checks including blood transfusion verification and laboratory specimen collection identification.

The most common transfusion error is giving correctly labeled blood to the wrong patient. A blood transfusion software application may be used by hospitals to ensure patients receive the specific unit(s) of blood typed and cross-matched for them. Prior to beginning a transfusion, the patient's barcoded identification bracelet and the Transfusion Identification Number on the unit of blood are scanned to electronically match the patient and blood product. The software will generate an audible alarm and visual display to warn of any

potential identification error. Vital signs are documented before, during and after a transfusion, and any reactions recorded. Systems may be programmable to remind the clinician to perform hospital policy-specific checks. Finally, transfusion documentation is generated for charting.

Likewise, a positive specimen identification component can ensure specimens are labeled with the correct patient information to solidify the link between patient and specimen. Mislabeled laboratory specimens can lead to inappropriate results and misguided therapy, and subject patients to additional specimen collections. These systems may also allow the caregiver to add tests not ordered via the laboratory information system and generate labels that include all pertinent information, thus eliminating the hazard of difficult-to-read handwritten labels. The clinician may view collection instructions and correctly calculate the amount of blood needed for all tests ordered to prevent having to redraw the patient again if blood is collected inappropriately. These features are of tremendous benefit to hospitals with a decentralized phlebotomy function because less phlebotomy experienced clinicians are coached through the correct selection of container types, specimen amounts and clinical instructions. A real-time system also prevents “re-sticks” of a patient by another caregiver viewing stale data by making it immediately obvious that the specimen has already been drawn.

The final feature of a highly evolved BPOC system is the existence of a true medication administration record (MAR). This critical, legally required record is available electronically via BPOC technology. BPOC systems collect critical charting information as a byproduct of scanning the medication, as well as through the entering of clinical observations such as pain scale ratings, adverse reactions, apical pulse, etc. With a robust and validated electronic MAR or eMAR in place, hospitals can eliminate paper processes entirely, saving hours of nursing administrative work per shift.

Studies show that using BPOC technology in medication administration is an effective tool in decreasing medication errors and enhancing patient safety. Early success of BPOC systems at various levels of sophistication has resulted in a 65–74 percent documented decrease in medication errors.[11,12] Most recently, the Veterans Health Administration has published peer-reviewed findings that its BPOC system has averted as many as 86 percent of all medication errors from reaching the patient.[13] As a result of the growing body of support for this technology, key agencies and associations active in promoting medication safety have endorsed the benefits of barcode-enabled point-of-care technology.

What Is Barcode Technology?

In essence, barcode technology is a replacement for traditional keyboard data entry. It requires conversion of an identifier to a symbolic representation—the barcode—that can then be printed on, or affixed to, an item, subsequently read by a light source and fed into a computer.

Standard barcodes usually do not contain descriptive data. Instead, like the license plate on your car, the data in a barcode is a reference number the computer uses to look up associated descriptive data and other pertinent information.

The use of barcode technology brings a number of valuable advantages to the healthcare environment.

First, the rate and accuracy at which information can be collected is outstanding. Barcode scanners are faster than the human eye and far more accurate. Tests have shown that barcoded information has an accuracy rate of 1 error per 10,000,000 characters. Compare that to keyboard entry error rates of 1 error per 100 characters.[14] Barcode technology eliminates the opportunity for error in recording data while performing data entry in a fraction of the time required for manual entry.

A second attribute is barcode technology's ease of use. Unskilled operators can master the equipment in a matter of minutes.

A third advantage is accrued through the standardization of codes and well-developed technology. Barcode equipment purchased today will likely not be obsolete next year.

Benefits of BPOC Systems

Once a hospital has invested in reliable patient, caregiver and medication barcoding processes, a BPOC system can deliver unprecedented patient protection. In addition, with the computing and scanning equipment present at the point of care, the BPOC system can be expanded to safeguard additional clinical and administrative processes—e.g., blood transfusions, laboratory specimen collection, error reporting, clinical documentation, etc.

Automated Identification

Barcode technology provides a needed mechanism for fail-safe individual identification in the hospital environment. Positive patient identification is essential to safe medical care. Too often clinical practitioners fail to check patient identification prior to drawing blood, giving a medication or rendering treatment. Instead, they rely on their own memory or an appropriate acknowledgment from the patient. In the case of confused, medicated or unreliable patients, this method is fraught with potential problems.

The importance of positive patient identification is illustrated in the following scenario. A hospital invests millions of dollars and several years in establishing a robust, computerized prescriber order entry (CPOE) system that, among other features, can identify the therapeutic treatment best supported by evidence-based medicine, auto-calculate the correct medication dosage, check for various harmful interactions and flawlessly communicate the order to the pharmacy. Still, safety is not served if the perfectly prescribed dose is then administered to the wrong patient. In July, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) called national attention to this basic source of serious error by establishing "correct patient identification" as one of six National Patient Safety Goals for 2002. BPOC systems are uniquely able to provide a fail-safe verification of patient identity satisfying this critical goal.

In addition, barcode technology is effectively being used to identify nurses and other caregivers. Many organizations now include a barcode on staff identification badges that can be scanned to log in to computer applications. The use of barcodes in this manner facilitates log-in and helps to accurately capture user information for audit trails and reporting purposes.

Nursing Medication Administration

Barcoding was discussed as a useful tool in medication error prevention as early as 1985.[15] Far more complicated than basic barcode scanning applications such as inventory control, BPOC usage combines barcode scanning with sophisticated medication administration software that provides nurses with decision support information that augments, but does not replace, clinical judgment.

Every practicing nurse is taught that the first safeguard against medication error are the "five rights": right patient, right medication, right dose, right time, right route. This sounds easy enough, but all too often one or more of these simple checks are missed, resulting in an error. For example, BPOC systems can assist in the detection of medications that have not been

prescribed for a patient and alert caregivers when the dose they are about to administer does not match the dose ordered or is not yet due. These systems eliminate the need for handwritten records and manual data entry while enhancing the MAR by documenting precise administration times and making it easier for all caregivers to trace a patient's care over time.[16] BPOC systems also create a vital audit trail to facilitate follow-up should an adverse event occur.

Users of these systems commonly voice amazement at the number of errors their BPOC systems are preventing—not only drug administration mistakes, but also errors originating with the physician or pharmacist. Patients, too, have expressed relief that they are receiving the medication intended for them. Finally, nurses themselves have described respite from their constant concern that they may unknowingly misadminister a medication and harm a patient.

Blood Product Transfusion

More patients die from receiving the wrong blood than from any other transfusion error. A New York study found that approximately 1 in 12,000 transfusions went to the wrong person.[17] Given the distribution of blood types, the authors calculated that 1 in 600,000 transfusions could be expected to be fatal. With 14 million transfusions in the U.S. annually, that implies about two dozen fatalities each year are due to mistaken identity. These data may be underestimated according to former FDA Commissioner David A. Kessler, MD, JD, who has said he believes only one of every 100 fatal reactions is reported. In the U.S. alone, as many as 2600 fatal transfusion episodes each year may go undetected or unreported. While most people suffer no lasting injuries following transfusion mistakes, the consequences for those affected can be severe, even deadly.

Testifying in 2000 before a U.S. Health and Human Services Department blood safety committee, Jeanne Linden, MD, MPH, director of blood and tissue resources for the New York State Health Department, described the problem in New York. "The No. 1 problem is the right blood gets all the way to the hospital floor and a nurse administers it to the wrong person," Linden said. "Our experience is that the wristband often is not checked. They should match the blood bag to the wristband. Sometimes the nurse just compares paperwork on the requisition order."

Indeed, industry experts and standards organizations emphasize that healthcare organizations should have unique patient identifier processes and computerized verification in place. In a study conducted by Marconi, Langeberg, Sirchia and Sandler, errors in 177 cases of incorrect transfusion were analyzed. Each case involved at least one and up to seven failures to detect incorrect identity of blood or patient, leading to transfusion to the wrong patient. The bedside check failed to detect discrepancy in blood or patient identity in a total of 80 of the 177 cases, despite being carried out by two people.[18] In contrast, a trial of BPOC technology found that up to a 71 percent reduction in errors could be realized by standardizing current processes while simultaneously implementing a BPOC system.[19]

In support of this research, JCAHO identified the need for BPOC transfusion safety systems in August 1999.[20] It identified ten cases resulting in patient deaths in summarizing a dozen incidents related to transfusion errors (11 were hemolytic reactions, one an infectious reaction). JCAHO asserts that transfusion errors are generally the result of multiple failures to follow established procedures, but identified incomplete patient / blood verifications as at least one of the causes of eight of the 12 cases.

To reduce the risk of such sentinel events, in 1999, JCAHO recommended that hospitals redesign patient/blood verification procedures considering technical system redesign efforts such as enhanced computer support or new patient identification band systems. JCAHO recently backed up this assertion by establishing positive patient identification for all transfusion procedures as a 2002 National Patient Safety Goal.

BPOC systems can ensure that the correct blood product is administered to the correct patient by matching patient identification, specimen order and product identification. Recognizing patient vulnerability in this highly manual process, researchers Whitsett and Robichaux investigated the use of the direct observation method to identify deviations in standard operating procedure during blood transfusion. They found it effective in detecting errors but "expensive and labor-intensive." They concluded: "[T]he development of an affordable system that would not permit collection of samples, administration of medications or transfusion of blood without accurate identification of the patient via the wristband would lead to a substantial reduction in medical events."[21]

There are still other advantages of BPOC verification systems. A comprehensive BPOC system also documents every step of the transfusion and specimen collection process, thus providing an accurate audit trail for quality improvement purposes. Training time is minimized, as the system visually prompts the caregiver through each step. The need for a second nurse to verify the transfusion administration is eliminated, and phlebotomy activities can easily be validated for billing purposes. Transfusion must begin within 30 minutes of the unit being issued from the blood bank (unless refrigerated) or be discarded, so delays in administration—such as the nurse having to hunt for paper-based orders—may result in the loss of precious blood inventory. Electronic verification at the bedside through the BPOC system eliminates this waste.

In addition, patient and labeling misidentification risks are significantly reduced, thus lowering hospital liability exposure. A single catastrophic sentinel event, such as a 1995 transfusion error involving a young accident victim in New York City, can be devastating. As a result of this error, the victim's family reached a $2.2 million settlement with the hospital.

Laboratory

Laboratory use of barcode technology generally applies to specimen management and phlebotomy by streamlining laboratory activities and inventory control, and making staff more efficient. Laboratory specimen IDs generated by the laboratory information system (LIS) can be barcoded on specimen labels generated by the BPOC system when collecting samples from the patient. A less preferable option would be to use the LIS to print barcoded labels and scan these for validation at the bedside. Once the specimen is collected and barcode-labeled, it can be tracked throughout the analysis and reporting process.

Hospitals, especially those with decentralized phlebotomy services, often experience difficulties with handwritten labels and mislabeled specimens. The use of barcoded specimen labels increases staff productivity by eliminating time-consuming clerical activities, allows for more accurate and complete data collection, and increases patient satisfaction by minimizing redraws due to mislabeled specimens.[22]

The use of barcoded specimen labels with barcoded patient identification tags increases staff confidence that the correct patient is being drawn and tubes are correctly identified.[23] With this accurate, time-stamped specimen data, practitioners are less likely to erroneously alter therapies based on old or inaccurate laboratory results.

In a 1992 study involving 666 institutions, researchers focused on digoxin because of clear guidelines regarding appropriate drawing time and what constitutes a toxic dose. They found that 25 percent of the digoxin levels were drawn too early—less than six hours after the medication was given.[24] This finding confirms the clinical relationship between improved specimen management and therapeutic outcomes of medication administration.

Pharmacy

In the pharmacy, barcodes were first put to work to streamline the inventory control process of generating requisitions and purchase orders. More recently, robotic barcode technology has been used to reduce the 12 percent of medication errors ascribed to dispensing errors. Pharmacy leaders have also pushed forward machine-readable technologies—such as centralized dispensing robotics—in the interest of patient safety. By reading barcoded unit-dose packages, dispensing robots can stock medication carts with a high level of accuracy and even return unadministered doses to pharmacy stock.

In addition, BPOC systems enhance the pharmacy's ability to base medication charges on actual administration of patient dose. This function helps hospitals ensure accurate daily billing, and avoid inadvertent fraud due to the common failure to manually credit doses returned to the pharmacy.

Near-Miss and Error Reporting

For every ADE that reaches a patient, an estimated 50–100 process errors are made.[25,26] What hospitals don't know about these errors can seriously endanger patients. When a medication error occurs, hospitals are obligated to do all they can to ensure the mistake does not recur. But when errors commonly go unanalyzed, medication use systems do not improve, and the error is likely to harm again. Clinicians may make an error or pass an earlier error through to the patient without any knowledge of its existence. Data gathered by U.S. Pharmacopeia suggests that as few as 5 percent of medication errors cause harm to the patient.[27] Hence, for each error that is manifested in patient harm, many more go unnoticed and, therefore, unanalyzed.

Voluntary error reporting systems are not sufficient to expose most near-miss events. BPOC technology alerts nurses to errors, helping them avoid possible ADEs. Near-miss events are captured for analysis. And trends in error type and occurrence provide insight into the root cause of these errors, enabling hospitals to address each systematically.

Some errors happen too infrequently at an individual hospital to be thought significant; however, in aggregate they can illuminate previously unknown risks. As a result, the practice of sharing near-miss data between hospitals and health systems can yield extremely valuable results. Hospitals that have invested in a BPOC system often describe the substantial increase in reported errors as perversely positive since these errors provide critical insight into error causation and system failures.

Clinical Research

Barcode technology serves the clinical research community equally well. Prior to use of barcodes

and scanners, data collection in clinical studies was tedious and resource-consuming. Most medication error research has been dependent on manual data collection through direct observation, retrospective chart review, daily solicitation of staff of potential errors or daily chart review. These methods require highly trained human resources to collect, collate and analyze error data. And the data is limited to events that can be observed or discovered through analysis of patient records.

Using barcode technology to monitor medication administration enables more data to be collected with a higher degree of accuracy, thus shortening the data collection period.[28,29] Collection occurs simultaneously with regular nursing activity, so no additional staffing is required. Most importantly, BPOC systems warn nurses of errors to prevent patient injury. Observation and retrospective techniques simply catalog error.

Financial Benefit

Implementing a barcoding solution can provide financial benefits in addition to improved clinical outcomes. Preventable ADEs lengthen the average patient stay by 2.2 days, and are estimated to cost approximately $4,600 per event.[30] This can add up to millions of dollars per year for the average hospital, not including malpractice costs, readmissions and litigation costs, or the cost of injuries to patients.

Litigation alone can be financially devastating to a hospital. On average, jury awards for medication errors reached $636,844 per award in 2000.[31] BPOC systems can pay for themselves through avoided litigation alone. The literature shows that any given hospital is likely to experience an ADE rate of 6.5 percent of admissions.[32] Approximately 30 percent of ADEs are due to errors—i.e., they are avoidable.[33] Hence, hospital liability coupled with a litigious patient population often results in a lawsuit. If the case is high-profile, media attention can contribute to a multimillion-dollar jury award. Error-prevention systems can yield significant return on the hospital's investment when this cost avoidance potential is built into the financial model.

Barriers to Effective Use of BPOC Systems

Early Adopters

Healthcare took notice of barcoding technology in the 1980s as other industries realized massive efficiency gains from its implementation. This technological movement prompted visionary healthcare practitioners to write the first articles touting the potential benefits of barcoding in the pharmacy for improved medication dispensing. In concert with this growing awareness, the Health Industry Business Communications Council (HIBCC) was created in 1983 to develop a uniform barcode standard for all products shipped to hospitals. These efforts seemed to be paying off when, a few years later, an American Hospital Association (AHA) survey verified that barcodes were being used to effectively facilitate hospital materials management.[34] However, nearly a decade would pass before barcoding began to make an impact on the clinical care environment.

The primary factor hindering the use of barcode technology in clinical quality improvement was the pharmaceutical industry's unwillingness to adopt a universal barcode standard for all medications.[35] This left the task of barcoding pharmaceutical products at the unit-dose level to the hospital. Pioneering institutions could outsource the repackaging process or set up assembly line-like processes in their own pharmacies. Early adopters feared the possibility of introducing new sources of error. Managing the infrastructure changes was also challenging, as so was budgeting for repackaging equipment and additional staff to develop and administer quality control processes necessary to accommodate the technology.

Today's Challenges

The most frequently cited obstacle to implementing BPOC systems remains the lack of manufacturer-applied barcodes on unit-dose medication packaging. It is estimated that as few as 30 percent of medications come barcoded at the unit-dose level. The responsibility of barcoding therefore falls squarely on the provider.

In December 2001, the FDA announced its intent to create a rule mandating that all human drug and biologic products must carry unit-dose barcodes. As expected, pharmaceutical manufacturers balked at the potential mandate, saying the rule would complicate core processes by requiring changes in label design, production line retooling and, in some cases, increased package size due to printing space constraints. Given these challenges, it became clear some manufacturers and repackagers might cease to offer their products in unit-dose packaging rather than comply with the rule. A survey designed by the Institute for Safe Medication Practices validated the concern. Three-quarters of the respondents reported a waning of unit-dose packaging for both new and well-established brand oral-solid products on the market, including those previously available in unit-dose packages.[36]

However, recent industry action suggests that the disappearing unit-dose dilemma may not become a reality after all. After the FDA announcement, two of the nation's largest group purchasing organizations, Novation and Premier, Inc., announced a new unit-of-use barcoded purchasing requirement for future pharmaceutical contracts.[37,38] Augmenting these efforts, the AHA has been instrumental in

creating the National Alliance for Healthcare Information Technology. In July 2002, NAHIT set its inaugural agenda on advancing a medication barcode standard. And in the most recent show of industry support, Abbott Laboratories has committed to affixing unit-of-use barcodes to all its hospital injectable pharmaceutical and IV solution product lines by early 2003.

While the future of unit-dose packaging is uncertain, it is important to note that BPOC systems do not require this level of packaging to ensure safe medication administration. They merely require that the "immediate container" of all medications administered at the bedside be barcoded. Immediate container refers to the medication packaging the nurse would access at the point of care. This is not limited to unit-dose packages that further isolate the single tablet or tablets prescribed for administration directly from the package. Instead, the immediate container could refer to a 10 mL injectable vial from which the patient is to receive a 2.5 mL dose. When the 10 mL vial is scanned, the BPOC system will verify the correct medication, strength and form via the barcode on the immediate container then direct the nurse to appropriately draw the ordered dose from the vial. A unit-dose syringe would streamline the administration process, but the safety benefit of the BPOC system can be achieved regardless of the manner in which the medication is received from the manufacturer. The only critical concern is that it is barcoded.

Organizational Factors

Needless to say, competition for scarce resources is fierce in most healthcare organizations. Despite the attention medication errors have received in the popular press and healthcare literature, error-reducing technology is not always a top priority. Comprehensive point-of-care systems can cost hundreds of thousands of dollars. And past experience with new technologies—including poor interoperability between information systems—has made hospital CIOs risk-averse to technology adoption. To successfully reduce medication errors, executive-level commitment and willingness to expend resources on clinically proven technology are essential.

The decision to adopt information technology for the reduction of errors is not an easy one and should be approached only after analyzing medication errors in one's own facility. Depending on the most common and the most serious errors, hospitals may elect to implement a BPOC or CPOE system, centralized pharmacy robot, automated dispensing cabinets, electronic patient record or any number of other viable solutions. Each presents trade-offs in terms of implementation time, acquisition costs, ultimate impact on patient safety (Table 1), workflow disruption, cultural resistance and vendor relationships.

The metric by which most measure the origin of error throughout the medication use process derives from the aforementioned study conducted in 1995 by Leape and colleagues. They reported that 39 percent of errors originate in the ordering stage, 12 percent in transcribing, 11 percent in dispensing and 38 percent during medication administration. However, the 38 percent of errors ascribed to medication administration underestimates the ability of BPOC systems to intercept errors that originate earlier in the medication use process. In practice, Leape found that although prescribing and administering are virtually equal points of error origin, nearly half the prescribing errors are intercepted before reaching the patient. In contrast, only 2 percent of administration errors are caught, rendering the medication administration stage the most vulnerable to errors that may adversely affect the patient's care. Hence, the error reduction potential of a BPOC system

may be as high as 51 percent, more than any other information technology (Table 2).

Human Factors

Resistance to changes in practice can hinder the success of any new technology. The efficacy of a barcode system depends on its ease of use and incorporation of human factors principles and user workflow into the system. Learning to use barcode-scanning equipment is fast and easy for most users. However, if the equipment is positioned poorly, inconsistent with common nursing practices, designed without regard to visibility in low light or subject to frequent battery failures, user compliance is likely to be low.

To utilize the safety benefits of systems using barcode technology, the nurse must scan the patient identification wristband and each medication before administering the medications. Some nurses feel awkward scanning the wristband on every patient, so they select the patient from the computer screen, bypassing the "right patient" check. Others chart medications post-administration, thus bypassing all of the checks associated with the medication itself. Other nurses fear the ramifications of enhanced error tracking, believing increased error reporting will lead to punitive action.

TABLE 1 Comparison of Medication Error Prevention Systems

Technology	% Error Prevention[a]	Life Cycle Stage	Cost[b]	Time to Implement
CPOE	Ordering and transcription 33%	Early-stage adoption	$3–20 million	3–5 years
Pharmacy Information System	Ordering and transcription <33%	Mature product	$300–500K	10 months
Order Management Imaging System	Transcription 11%	Early-stage adoption	$100–250K	1 month
Automated Dispensing Cabinets with Profile Interface	Dispensing 10%	Last-stage adoption	$450K–3 million	3–4 months
Robots	Dispensing 10%	Mid-stage adoption	$1–3 million	6–12 months
BPOC	51%[c]	Early-stage adoption	$500K–2 million	4–6 months

[a]Based on the true error rate calculated in Table 2.
[b]Costs are approximate and will vary based on hospital size.
[c]An effective BPOC system, positioned as it is at the final step in the medication process, will address errors that occur in early steps in the process. Error prevention rates in excess of 70 percent are common in existing case studies.

TABLE 2 Error Rate by Medication Use Based on Interception Rates

	Prescribing	Transcribing	Dispensing	Administering
Error Distribution[a]	39%	12%	11%	38%
Per 100 Errors	39	12	11	38
Interception Rate[a]	48%	33%	34%	2%
Errors to Patient	20	8	7	37
True Error Rate	**22%**	**11%**	**10%**	**51%**

[a]L.L. Leape, D.W. Bates, D.J. Cullen et al., "Systems Analysis of Adverse Drug Events," *Journal of the American Medical Association* 274 (1995): 35–43.

In comparison, BPOC systems are able to deliver greater patient safety gains in a relatively short time frame for less investment than other medication error solutions require (Table 1).

BPOC Case Studies

With as few as 2 percent of hospitals fully utilizing medication barcoding in conjunction with barcoding on the patient's identification tag,[39] published research substantiating BPOC system efficacy is limited. Still, the mass of empirical data is growing as vanguard provider organizations present and publish their experiences. This compilation of case studies profiles both early adopter organizations and contemporary leaders in BPOC system use for the improvement of medication, transfusion and specimen collection processes. Each implemented a unique BPOC system that yielded positive results in point-of-care error reduction, as well as secondary benefits.

Medication Verification

Veterans Health Administration
National—172 Hospitals
BPOC System: BCMA (VA Proprietary)

St. Marys Hospital Medical Center
Madison, Wis.
291 Beds
BPOC System: Bridge MedPoint™

St. Luke's Episcopal Hospital
Houston, Tex.
653 Beds
BPOC System: McKesson Care Manager

North Colorado Medical Center
Greely, Colo.
276 Beds
BPOC System: CliniCare

Blood Transfusion Verification

Georgetown University Hospital
Washington, D.C.
359 Beds
BPOC System: I-TRAC

Specimen Identification

The Valley Hospital
Ridgewood, N.J.
442 Beds
BPOC System: BD-Tx (Becton-Dickinson)

Department of Veterans Affairs (VA) Hospitals

In 1992, the Department of Veterans Affairs (VA) provided $50,000 in startup funds to test the feasibility of developing a barcoding system for administering medications that would improve patient safety and care by reducing medication errors. The success of a prototype system developed at the Colmery-O'Neil Veterans Affairs Medical Center (VAMC), a division of the Eastern Kansas Health Care System, prompted the Veterans Health Administration to develop a proprietary Bar Code Medication Administration software for use nationwide.

Since implementing BCMA software, EKHCS has prevented some 549,000 errors. The improvement is evident when one compares 1993 data to 2001 data from the Colmery-O'Neil VAMC. In 1993 (the last full year of data using a completely manual system), the error rate was 0.0217 percent or 21.7 incident reports for each 100,000 units, that is, 409 medication errors resulting from the 1,885,651 units dispensed that year. In contrast, in 2001, the error rate was 0.0030 percent or 3.0 incidents per 100,000 units, that is, 22 medication errors resulting from the 460,795 units dispensed. This presents an 86.2 percent improvement in the reported error rate. Specifically, the institution witnessed a:

- 75% improvement in errors caused by wrong medication administrations;
- 62% improvement in errors caused by incorrect doses being administered;
- 93% improvement in wrong patient errors;
- 87% improvement in wrong time errors;
- 70% improvement in errors caused when scheduled medications were omitted.

The benefits of the BCMA system within the VA care environment have been well-documented. Using a real-time system ensures that order changes are communicated instantaneously and multiple users can access administration information, thus decreasing interruptions to the medication nurse. This "sharing" of information quickly identifies any discrepancies in transcription—during the verification process—before causing harm to any patient.

The system has also been shown to save time by eliminating the need to rewrite information or sift through paper documents. Likewise, the nurse can request a missing dose electronically in a process that takes approximately three seconds. The information is communicated directly to the pharmacy for immediate action. The nurse can then continue with the medication administration process without leaving the system, thereby decreasing workflow interruptions that often lead to errors.

However, the system has not eradicated errors. Errors still occur when users perform "workarounds." These include typing in barcode information instead of scanning a patient's wristband and medication for verification.

In August 1999, the BCMA project came to fruition when the VA successfully implemented the software in most of its 172 hospitals nationwide. Today, all VA hospitals benefit from the software, and the system continues to evolve. Version 2.0 focuses on the intravenous therapy component of the medication administration process. Despite mixed reactions from hospital staff comfortable with the "manual" method of administering medications to patients, the BCMA system still managed to quickly deliver dramatic reductions in medication error.

Source: Connie L. Johnson, Russell A. Carlson, RN, BSN, Chris L. Tucker, RPh, and Candice Willette, "Using BCMA Software to Improve Patient Safety in Veterans Administration Medical Centers," *Journal of Healthcare Information Management*, vol. 16, no. 1 (February 2002).

St. Marys Hospital Medical Center

A member of SSM Healthcare, St. Marys Hospital Medical Center is a 291-bed level II tertiary care center.* The hospital has implemented a BPOC system on four nursing units, totaling 100 beds, with plans to continue implementation across the rest of the organization over the next two years. An early adopter of BPOC technology, St. Marys first used the system in 2000.

St. Marys BPOC system goes beyond the "five rights." It offers clinical support on look-alike and sound-alike medications, maximum daily dose levels and medication-specific clinical actions. It also allows for electronic documentation of clinical observations. The system is deployed on mobile, bedside laptop computers with hand-held scanners. Communication with other hospital information systems occurs in real time for accurate order updates and documentation.

Steeped in a culture of process improvement, St. Marys saw the point of administration at the bedside as its greatest opportunity to decrease medication errors. Previous internal audits indicated breakdowns in the medication administration process accounted for 61 percent of the hospital's known medication incidents, while errors in the transcription process accounted for an additional 33 percent.

Since implementing the BPOC system, nursing units using the system have realized a 59 percent decrease in medication errors during the first six months of use. The system's reports application also provides near-miss data, demonstrating a 3 percent near-miss rate, or approximately 5 "close calls" for every 180 doses of medications dispensed. To put that into perspective, one nursing unit alone delivers approximately 18,000 doses of medications per month.

St. Marys cites other benefits of the system as well. Nursing staff articulate feeling a higher degree of comfort and safety when using the system as compared to their previous method. Management finds benefit in the reports that provide easy access to information regarding work performance concerns, such as which staff skip patient identification, barcode scanning or order verification prior to administering a medication. For example, analysis of systems data revealed that nebulizer treatments were regularly given late. Further analysis showed that staffing was the culprit. Since respiratory therapists are assigned to cover the ICU as well as the general medical/surgical units, they are frequently called away from routine rounds to deal with critical care matters. With staffing adjustments, optimal therapy can be readily achieved.

The BPOC system also helped St. Marys identify gaps in nursing knowledge related to the importance of timing insulin administration to meals. These findings then helped inform educational programs related to diabetes management.

Source: S. Anderson and R. Jensen, "Management Case Study: A Multidisciplinary Approach to Decreasing the Occurrence of Medication Errors and Variances," American Society of Health-Systems Pharmacists 2000 Mid-Year Clinical Symposium. Internal data of Bridge Medical, Inc., 2001.

*St. Marys nurses recently earned the prestigious Magnet Recognition for Excellence from the American Nurses Credentialling Center of The American Nurses Association.

St. Luke's Episcopal Hospital

To improve medication safety, in 1998, St. Luke's Episcopal Hospital began a detailed analysis of the people, processes and technology involved in the existing paper-based medication administration process. Commercially available systems were evaluated, and medication administration was identified as having the largest potential impact on patient care.

One of the major concerns was whether or not a computerized system with barcode verification at the point of care would require more time to administer and document medications at the bedside. A time study focusing on the nursing component of the medication administration process was conducted. Pre-implementation medication administration time data was gathered on all three shifts for the nursing unit where the system would be implemented first.

For purposes of this study, administration time started when the nurse referred to the MAR for a particular patient. Administration time ended when the nurse administered the medication(s) to the patient and completed documentation on the paper MAR. The steps involved in the process included identifying medications to be administered, removing medications from the medication drawer, entering the patient's room and identifying the patient, administering medications to the patient, and documenting medications administered on the MAR.

Time study data revealed an average administration time of 4.9 minutes per patient under the current paper system. Data would be collected again at one month, three months and six months post-implementation to determine the impact of the computerized system on medication administration time at the bedside. The data showed that after an initial learning curve, medication administration time at the bedside was at or below pre-implementation levels averaging 4.8 minutes per patient.

St. Luke's chose to pilot the system on a 20-bed rehabilitation unit in May 1999. This unit had fewer daily admissions and discharges than other acute care units, making it easier to manage patient flow issues. Patients on the unit did receive a high number of medications—on average, seven to ten different medications per patient. Prior to implementation, a two-week system parallel, or "shadow charting," period allowed the staff to practice using the computer system while the legal record remained on paper. After two weeks, the paper was removed, and the electronic MAR became the legal record.

Based on the success with the initial unit, the system has now been implemented on six additional medical/surgical units, representing 170 beds. Plans are to continue rollout throughout the hospital.

Source: Amy Thorpe, BSIE, MBA, "Poster Session: Enhancing Patient Safety Through Technology. Medication Administration," HIMSS Annual Conference, February 4, 2001.

North Colorado Medical Center

North Colorado Medical Center is a primary and tertiary care center serving northeastern Colorado and an early adopter of BPOC technology. In 1991, NCMC implemented a BPOC system that provides online medication profiles, medication administration scheduling and visibility to patient data.

Using barcode technology, medications are scanned at or near the bedside prompting a safety check, recording the administration and generating a drug charge. The system uses wireless terminals equipped with barcode scanners, a keypad or a touch screen to document medication administration, vital signs, patient assessment and other data. A complete eMAR is available online at the bedside and printed for inclusion in the medical record. A medication variance report is available to track early or late doses, system alert overrides and the number of doses charted at the bedside versus the central care unit terminal. In addition, the system reports a listing of omitted or overdue doses so nurses going off shift can either administer the medications or note that they were withheld and why.

Implementation challenges included the need to interface with a mainframe pharmacy system. This process required many hours of pharmacist, nurse and information system analyst time to build and test the interface. In addition, the entire system relies on each unit dose being barcoded appropriately. Hence, items such as bulk tablets, IV bags, ampules, vials and pre-filled syringes must be barcoded by hand. This operation requires the addition of 1.0 FTE technician position. It takes another 30 minutes per day for a pharmacist to check the repackaging work. The hospital was also faced with a steep learning curve for some nurses and a general reluctance to change from a manual system. This is especially true in times of staffing cutbacks, when the perception of a more efficient way (e.g., collecting data on scraps of paper for subsequent entry into the system) prevents use of the system as it was intended.

Still, NCMC has realized remarkable error reduction using the BPOC system. The hospital reports a lower medication error rate, improved medication records, improved scheduling, better communication between nursing and pharmacy, and more accurate and timely billing.

Before the system was implemented in 1991–92, the medication error rate was 0.17 percent. It dropped to .07 percent in 1993 and .05 percent in 1994, for an overall decrease of 71 percent. There was a decrease in the incidence of wrong dose being administered (33 percent), doses being given at the wrong time (43 percent) and doses being omitted (52 percent), but no change in "wrong patient"(5 percent) or "wrong dosage" (18 percent) errors. Static "wrong patient" error rates are explained by the nurse's practice of bypassing the "right patient" check by picking the patient from a pick list rather than scanning the patient's identification tag. No explanation was given for the lack of effect on dosing errors.

Aside from error reduction, nurses were able to save more than three hours daily by eliminating time spent photocopying and filing manual MARs for placement in the medical record.

Source: Fred Puckett, "Medication-Management Component of a Point-of-Care Information System," *American Journal of Health-System Pharmacy* 52 (1995): 1305–1309.

Georgetown University Hospital

Georgetown University Hospital in Washington, D.C., was an early adopter of BPOC technology aimed at wiping out transfusion errors. In February 2000, researchers published the results of a study that evaluated the feasibility of using an electronic identification system to improve the safety and documentation of blood transfusions. The study was conducted at IRCCS Ospedale Maggiore hospitals in Milan, Italy, and Georgetown.

A total of 621 blood components were transfused to 177 patients using 331 blood samples at the Milan and Washington sites. The BPOC system provided functionality to read wristband barcodes, generate blood sample labels, print labels for blood components and positively identify the blood transfusion recipient. In all 621 transfusions, these functionalities performed with 100 percent accuracy. The sample label barcode provided 100 percent positive identification in both laboratories, although the Milan and Washington sites used different laboratory information systems and different automated analyzers. Medical records at the bedside and in the blood bank were 100 percent accurate and complete.

Researchers reported that nurses at the Washington site were highly supportive of the system because it provided a reliable double check, allowing one nurse, instead of two, to transfuse blood components. In addition, this study demonstrated the versatility of the BPOC system and its ability to operate in highly complex environments. The system proved capable of converting screen and label text to Italian, increasing acceptance of the protocol by IRCCS nurses.

Currently, Georgetown uses hand-held computers and barcodes in an outpatient transfusion unit to track blood samples from the time they are drawn until they reach the laboratory. The same method is used to match blood in the lab and ensure it is transfused into the right patients. Since it began using the system more than three years ago, Georgetown has not had a single fatality due to a blood mismatch.

Sources: M. Marconi, A.F. Langeberg, G. Sirchia and S.G. Sandler, "Improving Transfusion Safety by Electronic Identification of Patients, Blood Samples, and Blood Unit," *Immunohematology*, vol. 16, no. 2 (2000).

Kathleen Kerr, "In Search of Error-Free Transfusions: A Look at One Approach—Considered the Most Foolproof Error Prevention System in Use," *Newsday*, April 9, 2002.

The Valley Hospital

Despite a nonpunitive environment for error reporting, the Valley Hospital in Ridgewood, N.J., had been unable to identify the cause of many errors. The problem deepened after decentralization of the phlebotomy department in 1997, as many more caregivers participated in patient draws. To address this concern, Valley conducted root-cause analysis and, as a result, implemented a BPOC specimen management system in a decentralized phlebotomy environment. The system is used to perform positive patient identification at the bedside by integrating hand-held information technology with current specimen collection devices and barcoded wristbands.

To begin, the study team created a flow chart of the entire specimen management process. Analysis revealed a total of 255 activity steps within the process. After conducting a root-cause analysis of the hospital errors, 63 steps in the process were singled out as potentially leading to an error. From this analysis, the team estimated that up to a 71 percent reduction in errors could be realized by standardizing the current process while simultaneously implementing the BPOC specimen management system. It was thought that critical errors (those that could cause direct harm to the patient—e.g., patient misidentification errors, specimen nonlabeling or mislabeling errors, and blood bank labeling errors) could be reduced by 75 percent. The hospital also found an opportunity to reduce noncritical errors, such as unnecessary draws, incomplete labeling and the use of incorrect specimen containers.

Six months after moving from LIS-generated labels to the BPOC specimen management system, the hospital had recorded zero misidentified patients and zero specimen labeling errors in its two pilot units. In calendar year 2000, and 59,490 patient phlebotomies later, statistics for the ten units then live showed a 77 percent reduction in critical specimen errors.

Labor time associated with specimen management was also examined prior to implementation of the specimen management system. The hospital measured the average time for the specimen collection and receiving process within the lab using time-and-motion studies. Average time to complete a patient collection was 5.8 minutes / patient. Average time to receive the patient's specimen(s) in the lab was 41 seconds / patient. It was predicted that 10 percent of the collection time could be eliminated due to not printing and manually sorting barcoded collection labels in advance of the phlebotomy round. Likewise, by eliminating a number of the manual steps in entering specimen data into the LIS, 52 percent of the specimen receipt time could be eliminated.

Once caregivers had overcome the learning curve of using new technology, the team reinitiated time and motion studies on the units. Results showed that the system yielded an average time savings of 13 percent within the collection process and 55 percent within the specimen receipt process in the lab.

By eliminating many of the errors and improving the efficiency of the specimen collection process, Valley Hospital predicted the annual savings for 2000 at approximately $129,000.

Source: Larry Bologna and Michael Mutter, "Reducing Specimen and Medication Error with Hand-Held Technology," Education Session: HIMSS Annual Conference and Exhibition, February 2001.

Summary

Patient safety is a critical issue for all caregivers and administrators. The healthcare industry must find solutions and tools that will reduce errors in all phases of the treatment process, but most importantly at the point of care where errors can become injuries. When embedded with sophisticated computer logic, a well-designed BPOC system can protect patients from medication, transfusion and specimen collection errors. This clinical application of barcoding is particularly important in light of well-documented staffing shortages, the greater complexity of medications being developed by pharmaceutical manufacturers and the increased acuity of hospitalized patients.

Just as barcode technologies have been proven in other venues, BPOC systems are becoming established agents in the quest for patient safety improvement. With the endorsement of healthcare leadership and a growing résumé of proven success, BPOC systems are poised to impact healthcare in an overwhelmingly positive manner. The literature testifies that in facilities where BPOC technology has been implemented and properly used, medication, transfusion and specimen identification errors have decreased by astounding rates.

Barcoding at the point of care is not merely a technology intervention. Rather—as those who have utilized it most successfully have discovered—it is one component of a greater process change.

Even the best designed state-of-the-art system will fail in an environment in which dysfunctional practices undermine proper use of the system. It is certainly possible to place the wrong armband on a patient during admission. And a pharmacist could apply the wrong barcode label to a medication prior to dispensing it to the floor. However, these sources of error can be effectively controlled. No source of error is insurmountable.

Experience shows that BPOC technology integrated within a comprehensive medication management system and properly adapted across the health system, with adequate training and continual system monitoring for improvement, can evolve into a near fail-proof safeguard.

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