Proceedings

Bar Code Medication Administration

Selected Works from BCMA Conference,
ALARIS® Center for Medication Safety and Clinical Improvement
April 25, 2003, San Diego, CA
Philip J. Schneider, MS, FASHP, Editor

Opportunity and Evidence

Government, Associations, Organizations

Nursing Perspective

Implementation – Lessons Learned

Complementary Technologies

Roundtable Discussion

Conference Report Published by:
www.alarismed.com/alariscenter
The ALARIS® Center for Medication Safety and Clinical Improvement
San Diego, CA
2003
Inter-Professional Conference on Bar Code Medication Administration

The second conference at the ALARIS® Center for Medication Safety and Clinical Improvement in San Diego, held on April 25, 2003, brought together a distinguished faculty from clinical practice, academia, industry, organizations and government. Philip J. Schneider, MS, FASHP, Director of the Latiolais Leadership Program and Clinical Professor at the Ohio State University, chaired the conference and moderated the roundtable discussion. Nationally recognized experts from multiple disciplines focused on the benefits and challenges of bar code medication administration.
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Building a Safety Net for Medication Use: Challenges and Opportunities

Philip J. Schneider, MS, FASHP, Clinical Professor and Director, Latiolais Leadership Program, College of Pharmacy, The Ohio State University, Columbus, OH

Patient safety has been front and center among the public, providers and health care professionals alike since the publication of the first report of the Committee on Quality of Health Care in America, entitled To Err is Human—Building a Safer Health System, in 1999. Medication use safety has been front and center in hospitals, however, since the 1960’s, when the first medication error studies were published. As a result of this pioneering work, safer systems—including unit dose and IV admixture systems—were developed that were shown to be considerably safer than the procedures that these systems replaced.

To be frank, much of the impetus for the adoption of these systems was based on financial, not safety concerns. The fee-for-service reimbursement systems in place at the time produced increased revenue to the hospitals resulting from additional technology-related charges to patients for each dose dispensed. Improved safety was a bonus. Fortunately, the clinical impact of these systems was studied, and we now have evidence to support unit dose and IV admixture systems as best practices for safe medication use.

Times have changed. Fee-for-service reimbursement systems are being replaced by risk-sharing systems that include copayments, prospectively established bundled rates for the treatment of certain conditions, and/or capitated payment schemes based on the number of patients enrolled in the health plan. These new compensation schemes have shifted the focus from generating revenue from services provided to controlling costs. This has resulted in a critical reexamination of programs that are labor intensive and could only be justified through the fees that could be charged. Furthermore, because systems such as unit dose and IV admixture programs are often centralized, they are now being viewed as being unresponsive to the rapid changes in drug therapy presently occurring in the acute care setting. “Best practices” are being reexamined.

The new emphasis in quality improvement is the application of technology. Some technologies are specifically directed toward improving medication safety. Examples include computerized prescriber order entry (CPOE), automated dispensing, bar code identification systems, and so-called “smart” IV pumps. Most lists of recommendations for changes to improve medication use safety include the adoption of these innovations. Payer groups are even proposing that some of this technology be a prerequisite for being an acceptable provider.

A critical review of the literature reveals that the evidence supporting these technologies is not as strong as the evidence supporting other, older systems, including unit dose and IV admixture systems. Furthermore, the expense of these new systems is significant and poses a challenge to hospitals already financially strapped. The technologies often require cultural or work changes that are difficult for health care professionals. The challenge for health care professionals and health care administrators is to find effective ways to adopt these new, expensive technologies in response to public pressure to improve quality and safety.

The purpose of this conference was to bring together patient safety experts who are innovators and early adopters of these new technologies. The focus of the meeting was the use of bar code technology to reduce errors in the administration of medications. Speakers were asked to address the evidence supporting the use of this technology, efforts to stimulate its adoption, experiences implementing and using bar coding in hospitals, and the application of bar code systems to improve the safety of intravenous (IV) medication administration. Ample time was offered to attendees to ask questions of the speakers and to share their experiences with bar code medication administration (BCMA).

Despite the costs and organizational challenges of implementing a BCMA system, the consensus of those attending the meeting was that there is emerging evidence that such a system reduces error and documents so-called “near misses.” Concerns remain regarding the labor increases necessary to support the current technology. While most of the nurses said that using BCMA was difficult, they seemed to agree that they would need to find ways to overcome those difficulties and that the benefits of using BCMA would ultimately make adoption of this technology worthwhile.

Improvements in the technology itself (size of scanners, amount of information in the codes, and the method of coding itself) may help to speed the adoption of BCMA. Some of the issues and challenges being experienced by early adopters will need to be addressed as we move to the early majority on the “diffusion of innovation” curve, as discussed in the opening presentation. The promise of integrating this BCMA with smart infusion technology to reduce programming errors was viewed as an important application of this innovation.

Finally, participants emphasized careful evaluation of competing technologies, vendors, and products and active involvement of multiple disciplines—Medicine, Pharmacy, Biomed, Information Services, and most significantly, Nursing—in selecting and implementing innovative systems to improve patient safety.
Framing the Opportunity for Bar Code Medication Administration

Philip J. Schneider, MS, FASHP, Clinical Professor and Director, Latiolais Leadership Program, College of Pharmacy, The Ohio State University, Columbus, OH

Key Points:
- Innovation has been and will continue to be needed to improve the quality and safety of medication use.
- Past experience suggests that the rate of adoption of innovations in health care is unacceptably slow.
- The adoption of new technology innovations that have been shown to improve medication safety is currently low.
- Methods to increase the rate of adoption of patient safety innovations are needed.

The use of bar code technology in health care is being advocated to improve the efficiency and safety of medication administration. The process by which innovation spreads has been described by Everett Rogers in his book, *The Diffusion of Innovations*. The process starts with the creation of a concept by innovators, followed by the spread to early adopters, early majority, late adopters, and last to laggards. The rate of adoption follows an "S-shaped" curve, i.e., starts slowly, rises quickly, and tapers off over time. In the last 40 years, many innovations to improve medication use safety have been shown to be effective and widely adopted as evidence-based practices in health care, e.g., the unit dose system, IV admixture, CPOE, and BCMA. Understanding the diffusion of these innovations may provide some insight into how bar code technology will be adopted in health care to improve medication use safety.

**Unit Dose System**

Innovation is not necessarily a technology. It may just be a safer way of doing things. For example, in the unit dose system, medications are packaged in individual unit packages, instead of requiring caregivers to take medications from bulk supplies for individual patients. Medications are dispensed in as ready-to-use format as possible, and no more than a one day supply is dispensed at a time. Starting in the early 1960s, studies have documented error rates (deviations from the physician order) of 10% or more with the traditional system, compared to 1.9% and 3.5% with a unit dose system. The diffusion of this innovation followed the "S-shaped" curve described by Rogers. The good news is that by 1995 the unit dose system was used in 91.6% of US hospitals (see Figure 1), demonstrating that the innovation was better than the previous practice. The bad news is that this diffusion took 40 years. The diffusion of innovation in health care can be very slow.

**IV Admixture System**

This innovation improves safety, because doses are prepared by a person specially trained to prepare sterile medications. Like the unit dose system, each dose is individually labeled for each patient, and no more than a 24-hour supply is dispensed. Studies demonstrate the superiority of an IV admixture system compared to preparing sterile doses in patient care areas. However, once again diffusion took 20 or 30 years (see Figure 2).

The diffusion of both unit dose and IV admixture has been too slow. These safety systems may not be sufficiently responsive to the acute care needs of critically ill patients. This may be a factor in the growth of new innovations, e.g., point-of-care dispensing technology and drug preparation at the bedside, which can be more responsive to the changing needs of critically ill patients.

Hospital size may also play a role. Smaller hospitals typically have more IV admixtures prepared at the bedside. Since evidence shows that this is a less safe practice, smart pumps that provide a last "test of reasonableness" for drug, dose, and infusion rate may be even more important than in larger hospitals with IV admixture programs in place.

**CPOE**

With this technology innovation, orders are transferred electronically. Decision support logic provides the real value of CPOE by providing warnings to physicians. CPOE has been reported to reduce the incidence of medication errors, preventable adverse drug events (ADEs) and potential ADEs. But the diffusion of this innovation is a little different. In the 1980s very few hospitals used computer systems in the medication use process, and most of these were in the pharmacy. By 1998, 2% and by 2001, 4%
of hospitals had CPOE in place. Larger hospitals were more likely to have CPOE than smaller ones. In 2002, 6.9% of hospitals had CPOE (see Figure 3). The rate of adoption may be more rapid for CPOE than other innovations in health care. Smaller hospitals are also adopting this innovation.

But there are problems with any innovation, including CPOE. Some systems (31%) are not optimally configured, so pharmacists have to re-enter orders to a pharmacy computer system. Only 56% of CPOE systems have decision support, and half do not require prescribers themselves to enter the orders. Only 94% require the pharmacy to check the order prior to dispensing it. This sounds like a high number, but a reverse concern is that many people assume that CPOE with decision support makes pharmacist review of the medication order unnecessary. Thus, even when an innovation diffuses more rapidly, the method of implementation may not result in the intended benefit.

**BCMA**

With this innovation, medication, patient, and the person administering the medication are scanned, reconciled, and each dose is documented. Safety is improved by ensuring that the right patient gets the right drug at the right time. There are other ways to assure that drug administration is safe: the identity of the patient can be verified by verbally questioning the patient, the medication order can be double-checked, or package integrity can be maintained all the way to the bedside so that there is no confusion if a nurse is interrupted. Unfortunately, despite these safe practices, nurses often take shortcuts. BCMA is one way to efficiently restore these safeguards into drug administration. This innovation is very early in the adoption stage with only 2% of hospitals reporting the use of BCMA technology.

To rapidly improve medication safety, it is no longer acceptable to wait 20, 30 or even 40 years for an innovation to become widely adopted, when there is good evidence that the innovation itself has benefited. The current rate of adoption of many innovations is relatively low: about 7% for CPOE and 2% for BCMA. Some older innovations may be replaced by newer innovations. Unit dose and IV admixture programs will have competition from systems that are more responsive to urgent care needs. One innovation may be replaced by another innovation over time.

A key question is how to enhance the rate of diffusion of innovation, so that it takes less than 30 years before a safety technology such as BCMA can benefit patients.

**References**

The Use of Bar Code Technology to Improve Medication Safety: Reviewing the Evidence

Eric Poon, MD, MPH,
Division of General Medicine and Primary Care, Brigham and Women’s Hospital, Clinical Informatics Research and Development, Partners Information Systems, Boston, MA

Key Points:
- Ample data exist to show that serious medication errors are common at every stage of the medication use process.
- While CPOE can reduce serious medication errors at the physician ordering stage, errors distal to the physician ordering stage may be addressed by the use of bar code technology.
- Limited evidence suggests that bar code technology may prevent medication errors at the transcribing, dispensing, and administration stages.

Medication Errors and Adverse Events

The results of the Harvard Medical Practice Study revealed that the most common cause of adverse medical events in hospitalized patients was associated with the use of medications. The adverse drug events (ADEs) that are caused by medication errors are preventable. Not only are preventable ADEs (PADEs) potentially deadly, they are also extremely costly. Bates et al. have reported that each ADE results in additional costs of $4500 because of increased length of stay and treatment costs. This figure does not include the cost of legal actions, re-admissions, and the suffering and loss of productivity incurred by patients.

Human factors studies show that the more steps that are involved in a process, the more opportunities there are for errors to occur somewhere during the process. Even a cursory overview of the hospital medication use process shows this to be a complicated process (see Figure 1).

Leape et al. found that serious medication errors are most likely to occur at the ordering and medication administration stages (see Figure 2). It was noted that 61% of the serious medication errors occurred after the physician ordering stage. While about half of the ordering, transcribing and dispensing errors were intercepted by the nurse before the medication error reached the patient, almost none of the errors at the medication administration stage were caught.

This underscores the vulnerability of the medication use process at the administration stage.

In a study of medication administration errors in 36 health care facilities, Barker et al. found that some type of medication administration error occurred in almost one in five doses of medications administered. While many of these errors were deemed fairly harmless, 7% had the potential to cause an ADE. In a 300-bed hospital, this translates into 40 potential ADEs per day. These errors occur after the ordering process and are not addressed by CPOE.

Impact of Bar Code Technology on Medication Errors

Administration Errors. The Veterans Administration (VA) healthcare system has been a pioneer in the use of bar code technology to improve medication administration safety. Johnson et al. studied medication error rates based on the number of incident reports related to medication errors before and after implementation of BCMA. They showed that following the introduction of BCMA, reported medication error rates declined from 0.02% per dose administered to 0.0025%. This is an almost a 10-fold reduction in errors over 8 years (see Figure 3). While these are impressive findings, the lack of a control group makes it impossible to know whether improvements may have resulted from other factors, such as other VA quality improvement efforts. The rates of self-reported errors may not be reliable. Studies have shown that 95% to 99% of ADEs and medication errors are not documented through voluntary reporting systems.

Transcribing Errors. Medication orders, whether communicated through a computer with CPOE or written on paper, almost always need to be transcribed to a medication administration record (MAR). Leape et al. found that errors in transcribing medication orders cause 12% of all serious medication errors. Implementation of a system that supports an electronic medication administration record (eMAR) automates this transcription step. In a study performed by Mekhjian, 9% of orders that were written on CPOE had subsequent transcribing errors when the MARs were examined. In the same study, Mekhjian showed that the implementation of eMAR technology completely eliminated
These errors. While bar code technology was not explicitly studied, these results indicate that medication transcription errors are both common and completely preventable with eMAR technology.

Dispensing Errors. Much has been done to improve dispensing accuracy, most notably the creation of the unit dose system in the 1960’s. While slight variations in practices exist across different hospitals, most use a unit dose drug distribution system. In this system, a pharmacist or a pharmacy technician picks the medications off the stock shelves according to the physician order. Next, a second person, usually a pharmacist, checks the accuracy of the medications picked. Finally, the medications are delivered to the patient care area.

Studies have shown the error rate for both picking and checking to be approximately 3% to 6%. Despite double-checking procedures at this stage, dispensing errors can and do reach the patient care area. In the Leape study, 11% of serious ADE’s were due to dispensing errors, and only one-third of these errors were intercepted by nurses before they were administered to patients.

The most relevant study of the impact of bar code technology on dispensing errors in a hospital pharmacy comes from the Texas Department of Criminal Justice. This department dispenses inmates’ medications from one central location. In an effort to reduce errors associated with this process, one bar code representing the medication and another representing the inmate were put on all blister packs that were delivered to the inmate facilities. All bar coded medications were scanned and automatically removed if a dispensing error was detected. Dispensing error rates as reported to the central facility from the receiving prisons were compared before and after the implementation of the bar code system. Results showed that the the reported dispensing error rate decreased from 6.3 to 3.3 per 100,000 medications dispensed, a reduction of 52%.

Limitations to this study include the reliance on self-reports. It is also unclear whether prison experience can be generalized to the acute hospital setting, because of different turn-around-time requirements and different medication types. In addition, the before-and-after study design cannot rule out any secular trend.

Summary

The evidence suggests that bar code technology holds great promise for improving medication safety and efficiency. However, the evidence so far is limited by the lack of data obtained through direct observation and the lack of concurrent control groups. More research is needed to more fully assess the impact of bar code technology on improving medication safety.

References

Observations on the Proposed
FDA Bar Coding Rule

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Key Points:
- The FDA is proposing regulations to require that labels include specific symbology (linear bar code) with the National Drug Code (NDC) number for drugs used in acute care settings.
- Existing use of BCMA is low because of the lack of bar codes on medications and the lack of bar code scanning technology being used in hospitals.
- Some manufacturers are printing bar codes on their products, and hospital purchasing alliances are beginning to preferentially award contracts for medications that have labels with bar code identification.
- Use of BCMA will have an impact on the prevention of medication errors.

Proposed Rule

In December 2001 the Food and Drug Administration (FDA) published a notice notifying manufacturers and other interested parties that a regulation requiring bar code identification on medications was being considered. In June 2002 the FDA held a public hearing to hear comments about the requirements that should be included in the regulation. Representatives from industry, healthcare, professional organizations, vendors, and patient safety advocates attended the meeting. A proposed rule was published in the Federal Register in March 2003 with comments being accepted until mid-June 2003 (see Table 1).1

Requirements in the proposed regulation include:
- Linear bar code identification must be used on prescription drug labels, including OTC products commonly used in hospitals;
- Sample medications are excluded from the requirement;
- Bar code identification must be on the immediate container, as well as on any outer container, and;
- At a minimum, the bar code must contain the NDC number of the medication.

The FDA proposed rule also contained bar coding requirements for blood products and summarized the financial benefits resulting from decreased errors if the rule were imposed.

Current Capabilities

A recent article in the American Journal of Health-System Pharmacy, “Practical guide to bar coding for patient medication safety” by Neuenschwander et al, provides a primer on point of care BCMA.2 Linear bar codes can be read with the available bar code scanners currently used in hospitals. To include bar code identification on smaller packages, such as small vials and ampules, it is necessary to use reduced space symbology (RSS), which may require upgrading scanners currently in use. If a requirement to include lot number and expiration date were also mandated, then a composite RSS would be required on the medications and additional upgrading of current scanners would be needed.

Despite the need for hardware upgrades in scanning devices for some current users of bar coding, many patient safety advocates and professional organizations are recommending that the proposed FDA rule include lot number and expiration date on bar codes. Two-dimensional symbologies such as DataMatrix would be ideal for including the NDC number, lot number, and expiration date on all package sizes. This symbology is not considered a bar code but rather a digital identifier. Imaging scanners would be necessary to read these two-dimensional identifiers.

Initial Responses

Many manufacturers and group purchasing alliances are already assisting hospitals in the adoption of BCMA. Several manufacturers have already committed to providing bar code identification on many of their products. Labeling and packaging vendors have begun to offer bar coding capabilities for the software used by hospitals to repackaged medications. Group purchasing alliances have notified manufacturers that products which contain bar code identification will be preferred or even required in awarding contracts. A recent survey by the American College of Health Executives
reported that 55% of respondents said drug bar coding was a technology they would consider within the next one to two years. This group also felt that bar code technology would have a positive impact on quality and would decrease overall costs (see Table 2). In a survey done by the Institute for Safe Medication Practices (ISMP), almost 90% of respondents reported that they would pay extra for medications that had bar coded unit dose medication packages, and almost half said they were actively considering BCMA.

Others have been less enthusiastic about this technology. The Pharmaceutical Research and Manufacturers of America (PhRMA) have already asked for an exception for “small” labels. The United States Pharmacopeia (USP) is seeking an exception for vials and ampules less than 5 mL, despite the fact that some manufacturers have already begun to provide linear bar codes on these products. In addition, clinicians sometimes develop workarounds that reduce the effectiveness of this technology (see Table 3).

**Prevention of Errors with Bar Coding**

ISMP has reported many transcription, dispensing, and administration errors that could have been prevented with the use of BCMA. Currently, because of the checks and balances in the medication use system, the interception of prescribing errors is more than 50%, but less than 2% for drug administration errors. Examples of these types of potential and actual errors have been reported in the ISMP Medication Safety Alert! Errors resulting from look-alike packaging of IV solutions and unit dose syringes could be prevented by the use of bar code identification technology to verify that the medication to be administered is the same as the one on the patient’s medication administration record. The use of bar code technology will not prevent all medication errors and it does not detect prescribing errors, but it will have a positive impact when used with other technologies in safeguarding the system.

**Table 1. FDA Proposed Rule**

- Federal register notice – December 3, 2001
- Public Hearing–July 2002
- Proposed rule in Federal Register–March 14, 2003
- Comments until June 12, 2003
- Effective three years following final rule
- Noncompliance would mean adulterated or misbranded drug label
- Send comments to: www.fda.gov/dockets/ecomments

**Table 2: ACHE Survey**

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<th>1-2 years</th>
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<th>Cost Impact</th>
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<td>Filmless X-rays</td>
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<td>74%</td>
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<td>Drug Bar codes</td>
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<td>87%</td>
<td>(46%)</td>
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<tr>
<td>CPOE</td>
<td>62%</td>
<td>85%</td>
<td>(45%)</td>
</tr>
</tbody>
</table>

**Table 3. Workarounds**

- Must prepare for implementation
- Review current processes
- Many workarounds are not unique to using bar coding but due to the workarounds we currently practice

**References**

The American Society of Health-System Pharmacists (ASHP) is a professional membership organization representing 30,000 pharmacists that practice in hospitals and health systems. Bar coding of medications to improve medication safety has been a significant issue for ASHP members, and as a result, the organization has actively advocated for the inclusion of bar codes on manufacturer packaged unit dose medications. Members have published the benefits of BCMA systems in ASHP's journal, the American Journal of Health-System Pharmacy (AJHP), for more than 15 years. A primer recently published in AJHP provides an excellent overview of the technology, symbology, and issues associated with implementing point-of-care systems.1

ASHP Advocacy Efforts

The first ASHP professional policy on bar coding was approved in 1998 and active advocacy for the inclusion of this information on unit dose packages began (see Table 1). ASHP has also collaborated with groups such as the National Coordinating Council on Medication Error Reporting and Prevention (NCC MERP) and the National Alliance of Health Information Technology (NAHIT) on position papers and advocacy supporting the use of bar codes. There has been work with other stakeholder groups such as the National Quality Forum (NQF) for the inclusion of bar codes in their safe practice statements on unit dose drug distribution systems.

ASHP's advocacy with the Food and Drug Administration (FDA) on this issue has been clear and consistent. ASHP corresponded directly with the Secretary of Health and Human Services, Tommy Thompson, on the patient safety benefits of bar coded medications in July 2001. ASHP also testified at the July 2002 FDA public hearing on the FDA Proposed Rule, sending a strong message on the urgent need for action. ASHP has met with the FDA Commissioner, Mark McClellan, on several occasions to promote the patient safety benefits of bar coding of medications. Having the proposed rule from the FDA is the culmination of many years of advocacy and collaboration.

ASHP Policy

ASHP's position includes three basic elements (see Table 2).

1. Medications should be electronically verifiable. ‘Unit dose packages should be available from the manufacturer with a bar code or other mechanism that allows for electronic verification.

2. The bar code should include the National Drug Code (NDC) number, the lot number, and the expiration date for the medication. While greatest emphasis is on the NDC number and its role in verifying accuracy, ASHP members believe there are additional benefits derived from having the other two data elements.

3. Promote the rapid adoption of point-of-care verification throughout health systems, so that there are not significant delays in the diffusion of this lifesaving technology.

Current Use of Bar Code Drug Administration Systems

As summarized in Table 3, the adoption rate of bar code technology remains low, with about 2% reported in the ASHP National Survey, not including federal facilities.2 If VA hospitals are included, the nationwide adoption rate is approximately 5% to 6%, but still a relatively small number.

Bar codes are currently included on only about 35% of commercially available unit dose packages, so hospitals choosing to implement these systems must commit...
to repackaging the remaining doses on site or through a third-party vendor. This results in thousands of doses being repackaged for each hospital each day, which is a significant barrier to adoption. Having bar codes included on packages when they are purchased from the manufacturer will virtually eliminate this barrier.

Unit Dose Packaging

ASHP members have voiced significant concern about the declining availability of drugs in unit dose packages. There is fear that this will be accelerated by an FDA requirement for bar codes at the unit dose package level, because some manufacturers may not want to invest in the re-tooling of their labeling processes.

ASHP and others recently participated in a survey with the Health Distribution Management Association (HDMA), the association that represents wholesalers. The survey included a question to manufacturers whether the proposed rule on bar coding would change their level of unit dose packaging. Results showed that 83% indicated that the FDA rule would not change their product line of unit dose packaged drugs, meaning that they would include the bar code as indicated and keep the products available, while 11% reported that they would reduce their product line of unit dose packages if the proposed rule is adopted. This is a major concern since it will require hospitals to package these items without the level of quality control available to manufacturers, not to mention the additional labor cost. About 6% responded that they plan to increase the availability of unit dose packaging.

Next Steps

ASHP will be actively promoting the adoption of this technology as bar codes become available on unit dose packages. The ASHP web page is being refined to serve as a resource center for those implementing bar code systems, and practice guidelines are currently under development. These steps, in conjunction with educational programs at ASHP meetings, will provide pharmacists with the practical tools needed to implement these systems. There are many lessons learned by the early adopters that can be shared to enhance and speed along implementation and adoption.

ASHP is encouraged that this day has finally come and is looking forward to the future as these systems evolve.

References
Analysis of Impact of the Food and Drug Administration's Proposed Bar Code Label Requirements for Human Drug Products and Blood

Steven A. Tucker, Economist,
Office of Planning, Food and Drug Administration, Rockville, MD

Key Points:
- An estimated 372,000 preventable adverse drug events occur per year in hospitals. Bar code identifiers on drug products could be expected to avert about 22% of these events.
- Hospital expenditures for bar code systems are large. An average-sized hospital is expected to pay almost $370,000 to install a BCMA system. In addition, operating and productivity costs for an average-sized hospital could cost over $300,000 per year.
- We expect the proposed regulation to accelerate the acceptance of bar code technology by hospitals. Overall, we expect average annualized increased expenditures of $680 million for the entire industry.
- Over 20 years, we expect over 413,000 fewer adverse drug events because of bar coded products. The average annual benefit of avoiding these events is $3.9 billion dollars in patient pain and suffering and direct treatment costs.

Note: This presentation was based on analyses done in support of a Notice of Proposed Rulemaking published on March 14, 2003 (Federal Register Volume 68, Number 50, pages 12499-12534). The author cautions that agency policy decisions for final rulemaking may be different than the estimates contained in this discussion. Also, this discussion does not represent official policy of the Food and Drug Administration or the Department of Health and Human Services. The analysis is subject to amendment in support of final rulemaking. The Eastern Research Group, Inc., of Lexington, MA, collected data and conducted analyses under Task Order 21 of Contract No. 223-98-8002.

The proposed regulation will require unique product identifiers to be portrayed in linear bar codes. The National Drug Code (NDC) would identify dosages and products for units-of-use dispensing and administration. The proposal does not include OTC drugs sold directly to consumers, and it does not require variable information to be included in the bar code.

Private markets have not established standardized bar codes. This has impeded the acceptance of scanning technology in hospitals. Therefore, the FDA is proposing to require standardization to allow hospitals to make this investment to improve patient safety. The regulation does not require hospitals to purchase this equipment but removes a barrier in their investment decision.

The regulatory cost to manufacturers and labelers of drug and blood products is the cost of changing their manufacturing process to accommodate bar code labeling and any revisions to their current labels. Some hospitals that have installed systems would be required to prematurely replace equipment in order to read reduced-space symbology (RSS) that would be used on small packages. FDA would be required to oversee compliance with the regulation. The expected annualized costs of these actions are $5.1 million.

Requiring bar coded information will not improve patient safety if hospitals won’t invest in bedside bar code reading technology. To estimate the expenditures needed to acquire these systems, we estimated the costs of installing a computerized system of scanners, bar coding equipment, and patient wristbands. The costs estimate also includes training and...
operating costs. For an average, 191-bed hospital\textsuperscript{13} that currently uses pharmacy computers that can interface with bedside systems, the estimated first-year costs are $369,000. The annual operating costs are estimated to be $312,000. Most of the operating costs are incurred by expected staff productivity losses, mostly in nursing wards (see Figure 1).

Despite these costs, hospitals have been accepting this technology. According to the American Hospital Association (AHA), the proposed regulation is expected to accelerate the acceptance of bar code systems (see Figure 2). The necessary investments are expected to occur over the next 10 years with the proposed regulation rather than the next 20 years. The estimated average annualized total expenditure by hospitals for the expected accelerated acceptance of bar code technology is $680 million. This is equivalent to a one-time investment of over $7.2 billion. An average hospital would have average annual expenses of over $103,000 over a 20-year period.

The proposed regulation is not expected to avoid medication errors. Bar code use is expected to increase the interception rate of errors. While 38% of all errors that result in preventable ADEs (PADEs) occur during the prescribing stage, almost 50% of prescribing errors are currently intercepted before reaching patients.\textsuperscript{10} In contrast, 38% of all errors that cause PADEs occur during the administration stage, but only 2% of all administration errors are currently intercepted. Therefore, we expect bedside bar code scanners to increase interception rates of errors that occur in the dispensing and administration stages by 50%. Overall, bar codes should result in 22.6% fewer preventable ADEs per year. For an average hospital, this equals avoiding 12.8 ADEs per year.

The value of each avoided ADE includes avoided direct treatment costs of $2,257,\textsuperscript{2,4,10} as well as patient pain and suffering. The expected loss in well-being due to the expected likelihood of adverse outcomes was derived from preference scores developed from the health economics literature.\textsuperscript{12} The expected health loss was valued by multiplying the stated preferences by the event's expected duration and society's derived willingness-to-pay to avoid a statistical fatality from hedonistic wage models\textsuperscript{13} as discounted by life expectancy.\textsuperscript{14} While the willingness to pay to avoid minor toxicity is $102 per incident, avoiding permanent disability is over $2 million. The average societal benefit of avoiding an ADE was estimated to equal $181,600. When added to the direct treatment costs, the average value of avoiding an ADE is almost $184,000. Avoiding 12.8 ADEs per hospital per year implies benefits of over $2.3 million per hospital per year from bar code utilization.

As hospitals acquire the technology, an increasing number of ADEs will be avoided. Using the same rate of acceptance as in estimating hospital costs, over the 20-year evaluation period we expect 413,400 fewer ADEs due to accelerated use of bar code systems. The average annualized benefit of avoiding these preventable ADEs is $3.9 billion. We expect hospitals to be able to use these systems to generate medication administration records, pharmacy reconciliation reports, and other internal records. The expected productivity savings of these activities for an average hospital were estimated to be between $209,000 and $334,000 per year. With the rate of accelerated acceptance, total average annualized savings would be between $451.5 million and $721.5 million per hospital per year.

Other internal hospital considerations such as reduced litigation risk, potential decreases in malpractice insurance rates, and efficiency gains in cost capture rates were also examined. According to data from litigation sources,\textsuperscript{15} the average pretrial settlement and jury award per ADE was slightly over...
$500 per incident. Bar code systems could save roughly $7,000 per hospital per year in average litigation awards. Hospital malpractice insurance premiums have increased to as much as $18,800 per bed from the most recent national audit. Research has indicated that automated record systems could increase pharmaceutical cost capture rates from 63% to 97%. If so, an average hospital would increase revenues by $65,000 after installing a bedside system.

The FDA is committed to improvements in patient safety while minimizing unnecessary costs to the health care system. We expect that hospital industry response to the bar code regulation will generate significant benefits (see Figure 3). Net annual societal benefits in excess of $3.2 billion are in addition to internal operating efficiencies that may be enabled. The final regulation is expected to take public comments into consideration prior to publication.

References

New technology promises to offer enhancements in nursing care. Nurses want to enhance speed and accuracy of communication and have information together in one location. This often does not happen unless enabled by technology. Nurses also want to reduce errors and reinforce a culture of safety. Nurses also need to trust technology. As for many health occupations facing worker shortages in the future, reducing physical effort and redundancy in the work for nursing is essential. Nurses do not tire of caring for patients, rather, they tire of dealing with inefficient systems. Technology enhancements must be able to help nurses focus their time on direct patient care.

The benefit of most technology solutions is improved safety. CPOE helps clarify hand writing and communicate essential information to others. The speed of communication is enhanced, as is accuracy. CPOE helps to reduce the frequency of prescribing errors. BCMA also reduces errors, i.e., those associated with correct patient and medication identification. Documentation can also be improved with BCMA.

There may be 30,000 to 50,000 preventable deaths annually linked to the clinical use of drugs, vaccines, blood and blood products, and medical devices. Biologics and nutraceuticals are also causing concern with drug interactions and side effects.

Barker et al studied the administration of 3216 doses of medications to patients in 36 hospitals and nursing homes in Georgia and Colorado. They found a 19% medication error rate with a very large range of error rates (0% to 67%). The primary types of errors were wrong time, omission, and wrong dose. When evaluating the magnitude of possible errors, the increasing shortage of nurses only exacerbates the concerns. One must ask the question, will there be a sufficient work force to ensure accuracy and timely administration of medications to patients?

The imperative for safer medication administration is clear (see Table 1). The human and economic cost estimates are significant. It is projected that almost $180 billion dollars are spent each year as a result of morbidity and mortality related to drugs.

The combination of bar coding and bedside scanning achieves error reduction during the medication administration phase. Automating safety checks provides improvement in the use of safe medication administration practices.

The Veterans Affairs hospitals have been pioneers in implementing and integrating CPOE and BCMA with their pharmacy system. A study of 67 cases at 163 centers showed that 38% of errors occurred during the medication administration phase. Implementation of a BCMA system was estimated to prevent 380,000 errors over five years. Although it is recognized that there will still be human error, the significant reduction in wrong medication, wrong patient, and wrong dose with BCMA is evidence that supports implementation of this technology.

The challenges to implementing BCMA are the same as other issues associated with making change. Nurses, like most other professionals, like to remain in their comfort zone. This is even more true since the largest component of this work force is over 40 years old. Many nurses were educated before technology was readily embraced. Making the change to trust technology and abandon paper may be very difficult.

Organizational changes can facilitate overcoming challenges to implementing BCMA and other technologies. Organizational leaders must set expecta-
tions for the use of technology and provide support. The culture must support change and promote technology, and a culture of safety must be pervasive throughout the organization.

Advantages of bedside BCMA include detection of errors, electronic updating of the medication administration record, electronic communication of missing doses, safety prompts, and automatic documentation of medications administered or reasons why they were not. For the system to work and be embraced, a number of system characteristics are important. The technology-assisted process has to be faster than the manual process. Bar code scanners must be able to read all surfaces and sizes of bar codes. Improvements in the sizes of wrist bands and the ability of scanners to read curved surfaces are making the technology more acceptable.

The interaction between nurses and technology at the bedside is also important. Nurses will develop "workarounds" for ineffective or inefficient systems. The size and portability of the equipment, and the ease of use when standing face to face with the patient are important. The display of information must be easy to read. Institutions want to create bar code labels for specific preparations such as those for pediatrics.

Patterson, et al. identified some unanticipated side effects that can occur when introducing technology into a complex system. Even though BCMA will reduce the frequency of some failures, there can be new errors associated with the technology.

Other technical challenges with implementing these systems include dealing with emergent orders (see Table 2). There is some concern that the nurse may skip some of the steps in BCMA when busy, or when the system is compromised (see Table 3). For example, if a bar code label cannot be scanned, a nurse will enter the numbers manually. In situations where a patient has no identification band (isolation, swollen extremities), the complete process of patient identification may be short-circuited. These all create potential efficiency challenges to the RN, and jeopardize the safety measures of the system.

Another unanticipated controversy with BCMA is the 30-minute window for timing of medication administration. Historically, little attention has been focused on the 30-minute pre- and post-administration window as a source of wrong time error. Paper systems do not provide alerts or track the frequency of these errors. Using a 30-minute window to define and document wrong time error may result in an inappropriate focus on the time doses are given, instead of more important medication issues.

Other issues surrounding bar code technology still must be resolved. The need to assure bar code readability in all situations and to create uniform symbolism, e.g., what labels will look like, how much information will be encoded, etc., will drive further technology development. The ability to quantify and publish the results of improved safety is crucial. There is a need to know how many medication errors are really prevented, as well as prevented adverse drug events. The public wants to know how health professionals optimize care, particularly with the use of such technology. It is equally important for nurses and others to be able to demonstrate that this technology is not only an important step toward achieving safer patient care, but it is also a very responsible healthcare decision.

References
Addressing Human Factors in Bar Code Medication Administration Systems

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Key Points:
- All new technologies, regardless of how good, will have negative, unintended consequences or "side effects" when introduced.
- The study of human factors is a body of research, largely new to healthcare, that can help to identify side effects.
- Five side effects were directly observed when BCMA was introduced in three Veteran’s Administration hospitals.
- Others can learn from the VA’s experience prior to implementation of new technologies by anticipating these side effects and using both medical and human factors expertise to predict and identify others.

Methods
A study of the experience of nurses using a newly implemented BCMA system was conducted at a VA hospital. With this system, nurses are provided an alert when there is a mismatch between what is ordered and what the nurse is about to administer to the patient. Before implementation of BCMA, 7 nurses were observed for a total of 21 hours during 10 medication passes at one hospital. After implementing BCMA, 26 nurses were observed for a total of 60 hours during 23 medication passes at three hospitals. During the observations, time-stamped, detailed, handwritten field notes of verbal and physical behavior were recorded, targeting negative, unanticipated side effects and information captured in the electronic patient record. The data were analyzed using the conceptual theoretical frameworks from the human factors literature to recognize and abstract emerging patterns. Process tracing protocols for all of the observations were created that detailed the activities, grouped into several broad categories. Particularly interesting interaction sequences were represented and analyzed as mini-cases. The mini-cases were then grouped by emerging themes, and supplementary data from the detailed notes based on the themes were collated. Finally, the themes were matched to similar patterns documented in other complex, high-consequence, socio-technical domains.

Negative, unintended "side effects" following BCMA implementation
Five significant negative effects of implementing BCMA at VA hospitals were observed that might create new paths to ADEs.

First, nurses were sometimes surprised by automated actions taken by the BCMA software. For example, BCMA removed IV medications from a patient’s prescription list four hours after the scheduled administration time, even when the medication was never administered. For example, if the patient returned to his room from a dialysis procedure more than four hours after a scheduled administration time, then the nurse would have no indication that the medication had been removed and the ordered medication would not be administered.

Second, BCMA degraded coordination between doctors and nurses compared to a paper-based system. For example, BCMA removed IV medications from a patient’s prescription list four hours after the scheduled administration time, even when the medication was never administered. For example, if the patient returned to his room from a dialysis procedure more than four hours after a scheduled administration time, then the nurse would have no indication that the medication had been removed and the ordered medication would not be administered.

Adopting a Proactive Approach to Patient Safety
The introduction of a new technology into a complex setting is never a panacea. New technologies have unanticipated side effects that affect technical, social, organizational, economic, cultural, and political dimensions of work. The Institute of Medicine report recommends a proactive approach to patient safety, including the injunction to "examine new technologies... for threats to safety and redesign them before accidents occur."

The implementation of bar code-enabled point-of-care medication administration systems eliminates some failure modes, but also creates new, potentially predictable paths to adverse drug events (ADEs). The following question might be asked: What negative, unintended side effects, if any, resulting from the introduction of BCMA might create new paths to ADEs?
Although BCMA data were available electronically through the computerized patient record system (CPRS), for several months physicians could only access a seven-day hard-coded window of data unless they asked the nurses directly for the information.

Third, nurses used strategies to increase efficiency that circumvented the intended use of BCMA. For example, some nurses routinely input a patient’s social security number by typing rather than scanning the patient’s bar-coded wrist band, because typing was more efficient.

Fourth, nurses felt that timeliness of medication administration was greatly increased in priority, because BCMA required nurses to type in an explanation when medications were given even a few minutes late. Particularly in long-term care settings, some nurses were observed to scan and pour medications for unavailable patients so that they would appear “on time” in the record, thereby relying on memory to administer the unlabeled medication cup with opened, unlabeled medications to the intended patient.

Fifth, nurses found it harder to deviate from the routine sequence of activities with BCMA. For example, when a patient refused a medication that had already been automatically documented as given when scanned, the nurses had to manually document the change in a time-consuming process in another software package. Based on our recommendation, the software was then revised so that the nurse could easily document the change in BCMA by selecting the medication and selecting a menu option.

Lessons for System Designers

Others can learn from the VA’s experience before implementing new technologies. First, designers can avoid the use of automation that is "strong and silent" in that it initiates actions that are not easily observable to its human partner, e.g., dropping a medication order after a given period of time. Second, designers can consider the impact of introducing new technologies not only with the target user population (in this case, nurses), but also others who interact with them, such as pharmacists and physicians. Third, the designers can make human-computer interaction and workflow efficient, so that it is less beneficial for users to employ "workarounds" to increase efficiency that have undesirable consequences. Fourth, designers should avoid trying to control user behavior through design, such as by requiring additional verification steps beyond what is required with current systems. Finally, significant personnel and other resources need to be allocated on a continuous basis after implementation in order to address side effects when they are identified and to continuously improve system designs.

Bar Coding is Not "Bad"

It is not surprising that negative side effects were identified following the implementation of BCMA. The results of this study are consistent with other research of technology in use in complex settings where the consequences of failure are high. New technologies, regardless how “good,” will have unanticipated side effects on the complex systems that they are intended to support. In fact, the commitment exhibited by the Department of Veterans Affairs to proactively share their lessons learned regarding side effects is a marker of their leadership in patient safety. The results from this study do not suggest that bar coding is bad. Rather, the results show that bar coding is complex and that its introduction into the interwoven fabric of technical work has far-reaching consequences. The advantages that bar coding provides, such as easier input of numeric data, are purchased at the price of trade-offs on other dimensions, only some of which are foreseen by designers.

References

Tracking and Controlling UPS Packages:
A Close Parallel to Drug Delivery

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Key Points:
- Bar code labels enable packages to have a large amount of useful shipping information.
- This information improves efficiency and accuracy of delivery and reduces inventory.
- The use of bar code labels to improve efficiency and accuracy of medication delivery would seem to be a logical application of this technology.

UPS has experience with the use of bar coding, scanning, and the benefits of this technology to improve the efficiency and accuracy of delivering packages.

For UPS it all starts with the label (see Figure 1). There are a number of different attributes on the label, which is an enabler for all of the systems that have improved package delivery. The UPS label includes different types of bar codes, including proprietary bar codes, which are used for different reasons. It has a postal service code, which is important because zip code and addresses are tracked and sorted just like the postal service does. There is also a "maxi code," which is a proprietary code that UPS developed to automate sorting, so that packages can be sorted at our facilities without human intervention. With this technology, people skilled at memorizing zip codes are no longer needed, which improves efficiency.

The main bar code is the UPS One Z tracking number, which identifies the customer, the service level they are providing or looking for, as well as a unique identifier. The unique identifier is tied into the package level detail (PLD). When a package is shipped, all this information is transmitted to UPS. The information is stored and transferred to different databases, depending upon where it is needed within our system. The bar code is indexed to all databases, which is how this technology is used to improve efficiency and package delivery accuracy.

Early in 2002 a fully automated sorting facility, WorldPort, was opened in Louisville, Kentucky. In this facility, the only human intervention is a person taking a package off of a vehicle and putting it on a vehicle. Sorting and all other packaging handling is done by automation that indexes bar code information.

For our customers, implementation of bar code technology has meant fewer damaged packages, fewer mis-sorts, and more on-time deliveries. That translates into reduced costs to them. For example, it reduces their inventory carrying costs, because a customer can trust that a package being shipped will be delivered correctly. They do not need to keep extra inventory on hand in case a package is damaged or misdirected during transit. This reduces their costs and improves their efficiency.

There are really two customers being served—the customer that pays us for shipping a package, and their customer that is going to receive the package. This translates into better customer satisfaction for UPS, UPS's customer, and the end user, as well as improved loyalty to UPS (see Figure 2).

The UPS experience is important, because of general concerns about the capital costs associated with technology and about the implementation of scanning systems using bar coded information. Our experience shows that costs can be reduced and service improved in ways that originally might not have been considered. Our customers asked us to be able to track packages when we went into the air business in the 1980's. We have been able improve our productivity. The more we can improve, the better it will be for our customers and for us.

For example, the UPS TrackPad (see Figure 3) is an application that was developed to track packages within a large campus facility. It improves accountability by making it possible to track a package's location after it has been delivered by a carrier. Customers are now using the TrackPad for other purpose beyond tracking UPS packages. They are tracking equipment, assets, visitors, and other people throughout their facilities. Conference managers and hotels can track packages coming in for different meeting participants.

In health care, a lot of valuable equipment is moved from room to room in a hospital, depending on patient care needs. This technology provides a way to track equipment at any point and time to
determine its location and the person accountable for it. This application of bar code and scanning technology was not part of the original vision and illustrates how additional opportunities to improve efficiency and reduce costs may be identified, following technology implementation.

In summary, the UPS experience shows that the cost-savings resulting from the use of bar coding technology are just as great or probably greater than the capital costs of its acquisition and implementation.
Bar Code Medication Administration: 5 Deal Breakers, Pearls, and Perils

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Key Points:

- Deal Breakers for implementation and acceptance of BCMA are the lack of communication and administrative support, staff buy-in, equipment, training and support, and ongoing support.
- Perils result from staff-created workarounds when hardware, input devices and software do not perform well.
- Pearls of wisdom (lessons learned) are that documentation is available and legible; BCMA integrates the entire medication process for safer patient care; and reminders are generated for patient safety.

Disclaimer

The author’s opinions do not necessarily reflect those of the Department of Veterans Affairs. Neither the Federal Government nor the Department of Veterans Affairs endorses any company or manufacturer’s products and/or services.

Deal Breaker #1 – Communication and Administrative Support

At the outset, planning for a complex technology such as BCMA requires an appropriate interdisciplinary team comprised of staff nurses, pharmacy staff, computer specialists, biomedical engineers, and engineering staff. The discipline-specific members should be change agents and opinion leaders respected by other staff (see Table 1).

Medical center management should plan for and allocate substantial financial and human capital on a long-term basis. Adequate resources during planning and implementation are required, in addition to the operational "going live" phase.

Deal Breaker #2 – Staff Buy-In

Plan a vendor fair to demonstrate available products at the facility where staff can see and try out products. Develop a Requirement Analysis (RA), and during the fair have staff provide input through use of RA for product evaluation. Verify that all software is customizable to the clinical practice at the facility, rather than asking nurses, physicians and pharmacists to change current acceptable practice in order to "fit" the software.

The decision-making and implementation processes should be a joint effort involving the planning team, content experts, and clinical staff.

Deal Breaker #3 – Equipment

It is important to monitor the organizational system vital signs:
- Look at needs in each clinical area,
- Listen to problems and find solutions,
- Feel for the end user and support the end user.

A significant commitment is required at all levels to move from a culture of blame to a culture of safety.

Deal Breaker #4 – Training and Support

Provide end users a computer-training laboratory that mirrors the practice environment. Training should include actual performance that reinforces the laboratory learning. Around-the-clock, on-site physical support during implementation on each clinical unit for one week is highly advisable, and individual support is needed during the first medication administration pass.

Deal Breaker #5 – Ongoing Support

Provide immediate technology assistance to clinicians on site via a help desk from 6:30 a.m. to 5:30 p.m., spanning all three shifts. Medical staff can call on the telephone or on a pager to reach the clinical informatics staff. If necessary, informatics staff will come to the clinician if the problem cannot be resolved by a telephone discussion. A good practice is hav-
ing interdisciplinary BCMA rounds on each unit weekly. On every unit, Pharmacy, Information Resource Management (IRM) staff, and Informatics Nurses approach the nursing staff using each medication cart on every unit to identify hardware, software, scanning and pharmacy issues. Over time, credibility can be built with the end users by the team. The informatics team can request links to national software programs and can create customized products for end users. The BCMA system generates reports to track and trend critical measures such as missed medications and the effectiveness of PRN medications.

### Perils

Hardware such as laptops, scanners, batteries; input devices such as a mouse or touch pen; and computer software do not always integrate well or perform as expected (see Table 2). Each component should be tested for performance, adequacy integration, and durability. Staff creates workarounds when the computer response time is slow; technical problems with components such as laptop, batteries or scanner are encountered; wrist bands become illegible or are missing; and when scanning of the bar code does not perform as expected.

### Pearls

Documentation is available and legible with BCMA (see Table 3). The integration of the entire medication process—ordering by CPOE, dispensing by pharmacist, and administration by nursing staff—leads to safer patient care. Pop-up boxes and reminders also ensure patient safety.

Nursing staff uniformly supports the use of BCMA for patient safety and their own peace of mind. They report feeling more secure in giving the right drug to the right patient at the right time, at the right dose, by the right mechanism by using this technology. BCMA does not serve as a substitute for the nurses’ professional judgment. Medication administration via BCMA may take up to 30% longer, which is not attributable to the learning curve.

### Table 1. Deal Breakers

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<tr>
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### Table 2. Perils

- Hardware does not integrate or perform as expected: batteries, computers, input devices
- Each component tested for adequacy integration, performance and durability

### Table 3. Pearls

- Documentation legible and available
- Entire prescribing, dispensing, and administration of medications can be computerized
- Nurses support use of BCMA for patient safety and their own peace of mind
The University of Wisconsin Hospital and Clinics (UWHC) recently implemented BCMA as a beta site for the McKesson Admin-Rx™. This hand-held scanning device assures the “five rights” in drug administration. The caregiver’s identification badge, patient’s wrist band, and medication label are scanned, reconciled and documented. At this time, 98% of all doses sent to patients have bar codes, including all IV medications. Anticipated benefits for UWHC in implementing BCMA technology include improved administration accuracy, documentation accuracy, and nursing satisfaction. Implementing BCMA “closed the loop” on all of the automation installed to date, and we have used this extensively in public relations. Patients report increased confidence in the care they receive, and Finance is working toward 100% accuracy in charges.

Medication Error Study
In a 28-bed hematology unit, which has extensive medication use with many high-risk medications, medication administration accuracy was observed before and after implementation of BCMA. Baseline error rate pre-BCMA was 9.09%, which was reduced by 87% post-BCMA (see Figure 1). Is is estimated that 11,518 errors per year are eliminated on this one unit. Wrong dose and wrong dosage form were eliminated entirely, and omitted doses and wrong time were greatly reduced. While wrong drug errors were reduced by only 51%, many of these errors were not serious (e.g., a verbal order not yet entered into the system when the drug was administered, so that drug administration was recorded as an error).

It was found that 3.2% of doses were errors that were intercepted by the BCMA system (near misses). The nurses saw individual near misses on their scanners, and it was very revealing to see that there were 4,600 near misses per year. More than half the averted errors were underdoses, about a quarter were the wrong drug, and overdoses and wrong patient errors were each less than 10% (see Figure 2). The study also showed that BCMA forces compliance with existing policies for nurses to witness the administration of high-alert medications, check patient ID band, and document doses immediately after administration. Pre-BCMA, checking the wrist bands occurred with only about 30% of patients. The study also showed that this system does not allow a common bad practice of preparing medications for multiple patients at one time.

Challenges with implementation of this system included software problems that resulted from the early stage of development and that required extensive work with the company. It was a challenge for the pharmacy to bar code all medications. This required improving the efficiency of the packaging operation. Computer-system interfaces are always a challenge to overcome, and this has also been true at UWHC.

Nursing issues included budgeting a full-time project manager and two to three part-time staff to assist with the project. Having nurse champions on the study unit proved very helpful. Spending enough time in training and re-training provided helpful lessons before expanding to other units.

There were also challenges with the medical staff. Training sessions were scheduled for all physicians, but many did not participate. This resulted in frustration when they were unable to use the scanners. The medical staff now uses the system quite well, although the attending physicians still present challenges. A webpage system is being developed to access information that will make the system more user-friendly for physicians.

The nurse project coordinators have done a good job in preventing workarounds, such as taping extra bar code wristbands on the walls by the medicine cabinet to avoid having to scan...
patients' wrist bands. The system now documents when and where a second bar code is printed. When an extra bar code is printed, nurses now check to see what is happening, give people immediate feedback, and eliminate that practice when necessary. Management engineering and nursing staffs have assisted with redesigning workflow to improve the system.

**Nursing Satisfaction Study**

A survey (see Figure 3) showed a 42% improvement in nurses' satisfaction following implementation of the BCMA system. The greatest improvements before and after implementing BCMA were seen in "Easy to determine what meds are due" (48% improvement) and "View Med Administration History" (67% improvement). "Efficiency" received the lowest ratings. The administration process takes a bit longer with BCMA, but the process of planning medication administration is significantly less, so that overall efficiency may not be reduced.

Next steps are to continue to monitor and tighten practices and to explore new areas to implement bar code checks, such as in the laboratory, phlebotomy, and the operating room. Another goal is to link errors detected by BCMA to the web-based electronic error-reporting system so that medication safety information is available in a more timely manner. Efforts to improve the software and reporting capabilities will continue. Lastly, integration of the ALARIS Medical Systems® Medley™ Medication Safety System with the Guardrails® Safety Software with the Admin-Rx™ is planned. IV infusion errors are often more significant medication errors, as shown by pre-installation data. Implementation of the new smart pump technology is expected to reduce the frequency of IV infusion errors, improve IV administration documentation, and provide the pharmacy system with better information on the status of infusion devices.
Bar Code Medication Administration: Lessons Learned from 3 Years of Preparation

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Key Points:
- Implementation of a BCMA system is technically and procedurally difficult and requires support from administrative, medical, and nursing leadership.
- BCMA requires integration between multiple electronic databases, including patient medical information, pharmacy medication/profile system, drug inventory purchasing/management, drug packaging devices, and automated drug dispensing hardware.
- Implementation of an electronic medication record in institutions should probably precede the initiation of BCMA.
- Lack of bar code product packaging standards for oral and injectable medications complicates full-scale implementation of this technology in institutions.
- BCMA is a patient care improvement that significantly affects the workflow of nurses and does not reduce time associated with medication administration.

St. Josephs/Candler Health System (SJC) is a 3-hospital acute care system located in Savannah, Georgia. SJC is a long-term Pyxis client and has participated in the development of several innovations in automation developed by the company. In April 1999 SJC and the company initiated an agreement to develop the Pyxis Veri-5 product at Candler Hospital, one of SJC’s acute care hospitals. Pyxis Veri-5 is an automated system integrated with Pyxis MedstationRx 2000 that uses bar codes to identify drugs, patients, and persons who administer medications at the bedside. Pyxis Veri-5 electronically documents medication administration and provides alerts when errors may be about to occur. The pilot project was conducted on a 14-bed oncology medical/surgical unit. Hand-held Pyxis bar code scanners communicate directly by radio frequency to unit-based Pyxis cabinets in real-time. Patient medication and clinical information resides in the Meditech Medical Information System that is interfaced to the Pyxis console in the pharmacy.

Important Lessons Learned

The developmental project at SJC provided a number of important insights for future implementation of BCMA at our site. During this time both our employees and Pyxis personnel refined and redesigned various mechanical, technical, and procedural aspects of the Veri-5 device and our drug administration processes.

Implementation is a long and often difficult process. BCMA requires the development of processes to assure that all medications, patients, and appropriate caregivers are bar coded for electronic identification at the bedside. Unfortunately, there are few, if any, systems that address all of the variables necessary to make this possible. Many medications are not provided in bar code packaging; institutions must either purchase unit dose packaging equipment or outsource this process. Patient identification using bar coded wrist bands may also present problems with difficulty in reading the band, particularly on pediatric patients. Several vendors are marketing this innovative technology, including companies that sell “stand-alone” systems and those that are part of “integrated” institution-wide medical information systems (MIS). Product selection decisions are best made using a pre-defined, objective process for evaluating available technology.1

Data coordination and integration is necessary. While the use of bar codes at the bedside to improve medication safety is just beginning to be implemented in hospitals, electronic storage of data important to making this process work smoothly is already stored in various formats in multiple information systems. Medications are purchased electronically using drug identification symbology developed by drug distributors and resident in inventory management systems in hospitals; this symbology is often a bar code on a box containing multiple doses of a specific drug. Since there is currently no industry standard for bar code content
on doses of drugs, those companies that are currently packaging unit doses in bar coded packaging are not using uniform symbology, and there is not uniform content for the bar codes (see Table 1). The same generic product made by different companies may have different bar codes. The BCMA system must be able to recognize multiple sources of the same generic drug and automatically update the electronic drug identifier for the bedside bar code database; this function is most efficiently done using the inventory management system at the time of receipt of drugs from the supplier. Medication administration information recorded at the bedside needs to flow electronically to the medication administration record (e-MAR); however, the e-MAR may reside in a different computer system in the hospital that may require development of an interface between the BCMA and MIS systems. Currently some integrated MIS vendors market BCMA software; however, these systems may not be as user-friendly to the nurse as other “stand-alone” options; there may be internal conflict between Information Services Departments and clinical users about the choice of integrated MIS vs stand-alone, best-of-breed BCMA systems.

An electronic medication administration record (e-MAR) is essential to the successful implementation of BCMA. The primary intent of BCMA is to improve medication safety using technology; an important additional benefit is its positive contribution to documentation of medication administration. Because documentation of clinical events, including drug administration, form the basis for future clinical interventions, including the administration of doses of drugs, the e-MAR should be implemented at least concurrently, and preferably before, BCMA. The structure, flow, and access of electronic drug administration data must be resolved before BCMA can function successfully.

Until drug manufacturers and packagers bar code all products in a uniform format, institutions must develop their own individual solutions. A minority of oral and parenteral doses have labels that include bar codes. Doses compounded at the hospital need to be identified with a bar code by an internal process. Various alternatives are available for creating bar codes for medication labels including on-site automated packaging equipment that may be stand-alone or integrated with dispensing machines; outsourcing of unit dose packaging to local “niche” companies or large distributor/packagers; devices intended for small volume packaging at the site; and pharmacy information systems that may print bar codes on labels of preparations compounded at the site.

Lessons Learned

- Implementation is a very long process
- Is technically and procedurally difficult
- Pharmacy and IS agendas may conflict regarding use of technology as a tool
- Beware of false claims by vendors
- Use an objective process to evaluate available technology

Coordination with IS

- BCMA requires data integration
- “Best-of-breed” vs Integrated Systems
- Cooperation of MIS vendor(s)
- “Best-of-breed” decisions directly conflict with many IS priorities

BCMA is primarily a tool used by nurses to assure the “5 Rights” of medication administration and dramatically affects their work processes (see Table 2). Nurses are committed to assuring that the 1) right medication is given to the 2) right patient at the 3) right time in the 4) right dose by the 5) right route. However, one or more of these “rights” are frequently violated, resulting in up to 40% of all medication errors occurring at the bedside by the nurse or person administering medications. BCMA is interposed between the nurse and the patient to improve this process and reduce errors thereby assuring the “5 Rights.” Many nurses have a difficult time conceptualizing how BCMA, which takes more time and is an apparently less efficient process, will help them do their job better. If given the opportunity, nurses will find ways to circumvent steps in BCMA that will negate the inherent safety features of this technology. BCMA will require a redesign of workflow for nurses; therefore, it is imperative that they are intimately involved in the design, selection, implementation, and evaluation of this technology as it is incorporated into patient care. Appropriate representation will include staff, managers, administrators, and opinion leaders in the nursing department.

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BCMA is an important innovation that will improve medication safety in institutions. Our experience suggests that implementation of BCMA is complex, multifaceted and complicated by unresolved issues concerning product packaging, data integration and system integration/interfacing.

**References**


**Table 1. Logistical Issues**

- Maintenance of electronic bar code files
- Integration of electronic drug identifiers into a single database (inventory management, charge-file, Pyxis identifier)
- Multiple bar codes from manufacturers for the same generic product
- Some hospital locations may not participate: ED, PACU, OR

**Table 2. Nursing Issues**

- Recognition by nursing that patient safety improves and BCMA is beneficial to the nurse
- The “5-Rights” do not always occur in the manual system
- Med documentation does not always occur in the manual system
- Electronic verification is not a time saver
- Requires significant changes in nursing work processes
- Workarounds will develop—requires constant nursing management
IV Infusion Pumps: The Missing Component in Bar Code Medication Administration Systems

Nat Sims, MD, Cardiac Anesthesiologist, Massachusetts General Hospital; Physician Advisor, Partners Biomedical Engineering, Boston, MA

Key Points:
- BCMA involving IV infusion pumps was a significant, but unsuccessful, infusion device industry initiative over 10 years ago.
- The current bar code systems do not address the complex issues related to IVs and device programming.
- Efforts to address BCMA involving infusion devices are currently underway through collaborative research and development between infusion device manufacturers and early innovators in bar code medication systems.
- The emerging IV applications of bar coding cover a wide spectrum from recognition of the drug and concentration to full programming of the infusion device.
- Adding BCMA in combination with the new “smart” IV pumps holds great promise in reducing both errors and harm associated with IV pump errors.

“Smart” Infusion Pumps

Over 10 years ago, significant efforts were made to create BCMA systems that would include IV infusion pumps to address IV medication errors; however, these attempts were not commercially successful. More recently, smart infusion pumps have been introduced to address the source of most IV errors, those associated with device programming. Computerized smart infusion pumps contain specialized software that allows each hospital to program their devices with customized drug libraries developed from their own best practice guidelines (see Table 1). At a minimum, the library should cover all medications that are delivered by continuous infusion and include the drug name, available concentrations, dosing units, and minimum/maximum dose limits. The drug library is also structured by patient type or patient care areas (e.g., NICU, PICU, AICU, ED, etc.) When the caregiver turns on the device, he/she identifies the patient care area and selects the drug and concentration from the library. The smart pumps also provide continuous quality improvement (CQI) reports of use to the hospital to support improvements to best practice.

The Need for Bar Codes

Although the smart infusion pumps can prevent most programming errors, they are still dependent on the caregiver to select the correct drug and concentration from the library. Combining smart pumps with bar code drug/concentration recognition could address this issue (see Table 2). In addition to selecting the correct medication, this approach would only require a single bar code label on the IV container. This label can be the manufacturer’s label, and the major manufacturers of pre-mix IV medications have or soon will include a bar code label on the IV container. For IV admixtures that are prepared by pharmacy, the bar code identifying the drug/concentration can be generated as part of the pharmacy-applied label. In either case, scanning the bar code selects an entry in the drug library of the smart pump.

A variation on this application is to include the patient’s name as a bar code label on the IV container. The patient’s bar code wrist band can be scanned to assign the patient to the infusion device, and adding a bar code label of the patient’s name to the IV container can ensure that the drug was intended for the patient to whom it is about to be infused. In this implementation the patient wrist band need only be scanned at initial pump set up, and the caregiver would not have to scan the patient for every new IV dose.

In either case, the adoption of smart pumps with drug libraries and dose limits, combined with drug/concentration and the option to include the patient’s name, provides a pathway to addressing many of the most serious medication errors. A major advantage of this system is the fit with current drug distribution practices. This IV pump bar code system will function effectively in hospitals that depend heavily on access-controlled drug cabinets or in traditional admixture programs where each IV dose is dispensed directly from pharmacy. It is also an initial first step that introduces a small change in caregiver practice, can eliminate significant sources of IV pump programming.
errors, and does not depend on a wireless infrastructure and multiple system interfaces. Currently, there are no commercially available smart pumps that have integrated the bar code reader and the drug library, but development is proceeding at a rapid pace.

**Higher level of Innovation**

The above combination of bar code recognition with smart pumps has obvious advantages (see Table 3), but there are limitations to this system. The early adopters of BCMA technology envision integrating the infusion devices into their existing bar code system. Rather than using a separate infusion device bar code reader for the IV medications, their desire is to use the same scanning technology for oral medications and IVs. This can be a PDA with a built-in scanner or laptop computer with a tethered scanner. Since these systems require a wireless infrastructure and interfaces to ADT, pharmacy, and possibly other computer systems, adding the IVs and pump programming is viewed as a logical next step to their current system. The industry is responding to this opportunity, and research and development (R&D) will soon lead to commercially available products. The potential for further reducing IV errors includes real-time communication from the pharmacy information system directly to the infusion devices either to program the rate or dose, or to confirm that the programming is consistent with physician’s order. A bar code system built into a smart pump provides protection for when the bar code is not available, such as with STAT medications, system interruptions, and other unscheduled or emergency events. The wireless connection to the infusion pumps also will feed infusion data directly into the electronic medical record (eMAR), thus significantly reducing nursing time currently spent in documentation of infusions administered. It also provides pump manufacturers with a means to update data sets wirelessly and thus eliminates the need to physically find and update every infusion device.

**Summary**

The initial attempts to link BCMA and IV infusion pumps many years ago failed to become commercial successes. However, a convergence of new technology, manufacturer-applied bar code labels, and the medication safety culture has accelerated R&D in this area. Smart infusion pumps combined with bar code recognition provide hospitals with new opportunities to address both errors and harm. Hospitals will have options and technology-upgrade paths that until now have existed only for the oral and other non-IV medications.
There is currently an increased emphasis on patient safety, drug marking, verification of medication administration, improving the “five rights,” improving surgical site information, and safer transfusions. These all have significant implications for positive patient identification.

**Current Bar Code Issues**

There are two ways to print a bar code on a patient identification band (see Figure 1). One is in a “picket fence” style that it wraps around the wrist. One problem with this approach is that the identification band becomes unreadable because it is too long. The other is the “ladder” style, where the information is printed up and down on the wristband. The problem with this approach is there is not enough space to print enough data. For example, for an eleven character bar code such as a social security number, it is very difficult to put that in that space across the wrist band.

When users encounter these problems, they resort to key entry or workarounds, such as carrying around bar code cards with patient ID numbers. When this happens, there are increased chances for errors.

Another problem is that the bar code identification on the wristband may not be readily available. It may be under the pillow because that is where the patient’s hand is while sleeping. Or it may be under a patient who has rolled onto his or her side or under the covers because it is cold in the room. The nurse has to wake the patient up, find the wrist, find where the band is, find the bar code on the band, and turn on the lights. All of this can increase patient discomfort.

**What is RFID?**

RFID stands for “radio frequency identification.” It is an auto-identification technology, which includes bar codes, biometrics, voice recognition, magnetic stripe, on the back of credit cards, and RFID.

RFID has attributes that as a technology cover all of the different uses of bar codes (see Figure 2). It comprises a piece of silicon—a chip, similar to one in a computer or in a PDA—that is attached to an antenna. Data can be stored on the chip and communicated wirelessly. RFID is non-linear, so there are not issues with the location of the bar code or the wrist band, because the data can be obtained through radio wave transmission that goes through and around the human body. The read/write capability is another improvement over bar code technology. (see Figure 3). Data can both be retrieved from and sent to the RFID device. When a bar code is applied to a wristband and any information in the bar code needs to be changed, a new wristband would need to be printed. The RFID wrist band can be updated by sending data wirelessly.

RFID will be used to connect the patient to the flow of data within the hospital. As the patient moves through the continuum of care, patient information can be stored and updated on the wristband, creating a dynamic database that travels with the patient.

The amount of data that can be stored on an RFID is increasing. Currently 256 characters can be stored on a wristband. Information on a band can be locked and encrypted, so it cannot be changed or read by unauthorized personnel. The following information might all be stored on a band: patient name, medical record number, social security number, date of birth, doctors’ names, admission date, event number, a DNR instruction, surgical site, blood type, height, weight, body surface area, insurance code, and allergy alert. Even with all of this information, there is still room to store more data and a place to hold data that will be updated, such as last medication given, last EKG taken, or last pulse oximetry reading.

**Key Points:**

- Bar code use for patient identification and medication administration is growing.
- Although bar codes reduce medical errors, workarounds are emerging because of the difficulties and added workload associated with bar code scanning.
- Radio frequency identification (RFID) provides non-linear site scanning, read/write data transfer, updating of patient data on the wrist, and increased information at the bedside.
The RFID wristband is part of a system. This system could be accessed by a hand-held device no bigger than a PDA or by terminals connected to the HIS system. Data are collected by the system from the wristband and sent to the host system. The host system can verify the transactions and then return updated information to the wristband, completing the loop.

Advantages for Healthcare

RFID technology can prevent data entry and collection errors, improve system efficiency, reduce forms processing time, improve tracking of labor and supplies, and improve communications between doctors, nurses and patients.

借贷《健康》

RFID腕带是系统的一部分。该系统可以通过比PDA更大的手持设备或与HIS系统相连的终端来访问。数据由系统从腕带收集并发送到主机系统。主机系统可以验证交易，然后将更新的信息返回到腕带，完成循环。

图1. 条形码ID腕带

图2. 什么是智能腕带?

- 腕带1：
  - BC太长
  - 弯曲度难以扫描
- 腕带2：
  - 没有足够的空间放置数据
  - 多次扫描
- 两种腕带：
  - BC不可用
  - 需要2只手读取1次

结果：潜在的医疗错误增加，由于不正确的病人ID

解决方案：RFID腕带

ISSUES: Band 1
- BC too long
- Curvature hard to scan

PROBLEMS: Band 1
- Can’t scan
- Key entry required

RESULTS: Potential increase in medical errors due to incorrect patient ID

SOLUTION: RFID Wrist Band

ISSUES: Band 2
- Not enough room for data
- Multiple scans

PROBLEMS: Band 2
- Hard angles to scan
- Key entry used

RESULTS: Not enough hands

SOLUTION: Workarounds created

ISSUES: Both Bands
- BC not readily accessible
- Need 2 hands for 1st time read

图3. RFID患者ID腕带系统

1. Smart Band enters RF-field
2. RF signal powers tag
3. Smart Band transmits ID, plus data
4. Reader/writer captures data
5. Reader/writer sends data to computer
6. Computer determines action and sends data to reader/writer
7. Reader/writer updates Smart Band
How useful is BCMA as a patient safety measurement tool?

Participants agreed that the primary rationale for BCMA is to improve medication safety. In addition, BCMA can potentially serve as a patient safety measurement tool. The following points were discussed:

- BCMA can produce an accurate record of deviations from physician orders
- These data can be useful as a medication safety measurement tool
- These data include a record of all medication errors detected and prevented (near misses), some of which would have resulted in patient harm
- The importance of minimizing process variation in medication administration to improve medication safety was debated
- For this information to be useful, a non-punitive culture of improvement is needed

Need technology with a great database

Thomas S. Thielke, MS, RPh, FASHP, University of Wisconsin Hospitals and Clinics: "If we're selecting vendors in medication administration—smart pumps, CPOE, BCMA, or other technologies—I think the most effective systems are those that have a great database that is readily retrievable, so you can take the information to your P and T committees or QI committees to continuously see what's happening, so you can go back and revamp the system to make it better—in addition to determining whether you are really making a difference over time.”

Patient, nurse have to come first

Emily S. Patterson, PhD, Cincinnati VA Medical Center, The Ohio State University: "There have been hundreds of requests for change to BCMA, and I'd say about a third of them have been for better reporting, better tracking, and more user-friendly reports. I have assigned those all a relatively low priority level, because we need to keep in mind that in terms of operation, the end user, the nurse has to be taken care of first. Until there is widespread user adoption and the removal of frequent "workarounds", the data in reports will not be accurate.”

We have to remember that the patient who's being taken care of is the first priority with this system—that's the driver for putting it in. Those other things can come along for the ride, but only if you do not ask the nurse to type in more data, if you do not slow it down, and if you don't punish the nurse based on timeliness data. Trying to get a "two-for-one" with the system in ways that make nurses do more work for others' benefits makes the system less likely to be quickly adopted.

What is the impact of BCMA on nurses?

It was noted that decisions to adopt new technologies often do not adequately involve the clinicians that must use it. Participants noted the following impact of BCMA on nurses:

- BCMA does NOT improve nursing productivity, particularly with systems with slow response time
- It takes time for nurses to learn to use and accept BCMA technology
- BCMA results in nurses placing higher priority on following medication orders accurately, instead of on meeting other urgent clinical patient care needs that may be more important
- Workarounds reflect a need for nurses to use clinical judgement when administering medications
- Nurses are more likely to accept BCMA if the systems are designed around their work and they are involved in the selection of a system
- Improvements in technology are likely to speed adoption of BCMA by nurses

Preventing major errors

Rebecca Long, RN, MS, CNS, CCRN, San Diego VA Medical Center: "For those major errors such as wrong patient, wrong med, or errors that can be very critical, we are seeing those being prevented. Most of the nurses are getting on board for bar coding due to this error prevention.”

Over time, nurses are more satisfied with BCMA

Wendy Wittwer, RN, BSN, St. Mary's Hospital Medical Center, Madison, WI: "Nursing satisfaction studies done at our hospital pre and post-implementation show that nurses are far more satisfied with the BCMA system than without it—similar to the University of Wisconsin findings. These studies also show that the longer the system is in place, the more satisfied nurses are. Given some time to get through the process change, nursing definitely understands and appreciates the value of the system helping them to deliver safer patient care.”

Nurses accept BCMA as part of working in our hospital

Marilyn J. Cushing, RNC, MSN, MBA, Piedmont Hospital, Atlanta, GA: "The nurses in our community hospital really didn't like it at the beginning. But we've been 'live' in all of our units including critical care for over a year, and staff really accept it now a lot better than they did. I do not believe that it's improved productivity: it takes nurses longer to initially check and verify medications entered by pharmacy against the doctor's order. There are still some issues with pharmacy getting the orders in quickly, so that nursing can give the meds with the order already in the system. But new people coming in are told this is the way we do business and they just accept it. They may not like it, they may wish that they were not using the technology, but they accept it as part of working in our hospital.”
BCMA can create operational barriers to care

Geraldine A. Coyle, RN, EdD, CNAA, Martinsburg VA Medical Center: "With BCMA, our nurses have noticed that the LPN who used to give us more help with medication administration, doesn’t give us nearly that amount of help, particularly in long term care. For example, if the servers are slow and she has to wait for the ‘go’ message-got the right patient, got the right med, it’s a go-she is waiting 10 seconds between every medication. In geriatrics, patients can have 14 different kinds of medications. You are standing there going gray waiting for just one patient, and you’ve got 20 patients."

Technology has to be integrated

Carol Dueck, Director, Clinical Health Information, Scarborough General Hospital, Toronto, Ontario: "Especially the critical care people—they do want bar coding, and they want the technology, but they want it integrated, and they want it to be part of the discussion at the table before it gets built."

Has to work for nursing at the point of care

Wendy Wittwer, RN, BSN: "The bottom line in all of this, and I hear it from nurses all of the time—it has to work for nursing. They are at the end of the line. They are the last person who could catch a mistake. That is why the best place to use technology is at the point of care."

Must be process-driven

Rebecca Long, RN, MS, CNS, CCRN: "We need to have the process drive the technology, and not the technology drive the process."

Is there a need for scientific evidence to support implementation of BCMA?

In health care, the emphasis has been on evidence-based medicine and basing decisions on scientific proof. This evidence is often lacking for patient safety technologies, including BCMA. The participants debated the need for scientific evidence for patient safety innovation, making the following points:

- Ideally, the use of a system that changes work and incurs significant costs should be based on scientific evidence
- Other industries use hunches and judgement to make quality improvement decisions
- Early adopters are likely to use hunches and judgement in deciding to use BCMA before scientific evidence supporting its use is available
- Later adopters are likely to await scientific or anecdotal evidence from early adopters before making a decision about BCMA

Evidence-based medicine (EBM) can be limiting

Chuck Denham, MD, Healthcare Concepts, Inc., Austin, TX: "We also need to consider the ‘force multiplier’ effect of coupling complementary technologies: What performance impact does adding bar code to a smart pump now give us that may multiply the benefits? Simply put, instead of 3 plus 3, we may be getting a 3 x 3 in impact."

Common sense: significant change

Thomas S. Thielke, MS, RPh, FASHP: "If we have three or four well done studies of BCMA and you see these huge differences in error rates, I think it’s very compelling to where common sense tells us that even if the reported error rate isn’t entirely accurate, it’s a really significant change."

Do study results transfer?

Thomas S. Thielke, MS, RPh, FASHP: "There are some studies with good data, but we have to make sure that the technology we are using is similar to what’s been used in the studies at Vanderbilt or Brigham and Women’s Hospital, and not the kind of turn-key systems that can’t really do the job and achieve similar results."

FDA interested in diffusion of technology, not a specific approach

Steven A. Tucker, Economist, FDA: "The FDA is extremely interested in the diffusion of technology. We don’t feel that we are necessarily backing bar coding over any other patient safety initiative. This was one we could do now through the manufacturing sector. We hope that it will help, and not necessarily hinder any other specific outcomes."

What is the business case?

It was agreed that new patient safety technologies are expensive and pose challenges to hospitals that operate under financial constraints. Participants discussed the following considerations in making a business case for BCMA:

- Acquisition of any technology needs to be compared to other technologies as it relates to potential impact on safety, ease of implementation, and cost
- Even with the same technology, not all products or vendors are the same
- Not all errors pose the same risk; need to focus on errors that cause harm
- Cost savings from adverse drug events prevented (cost of treatment, increases in length of stay)
- Reduced costs for litigation

Ken Barker, PhD, Auburn University: "Hospitals are still so dissimilar and still know so little about their own systems. Just because it works at Brigham and Women’s Hospital, University of Wisconsin, or these other outstanding places doesn’t at all guarantee success or deserve generalization to the other hospital situations. Our real problem is the need for better technology evaluations at the individual hospital level, or certainly at the system level, to follow up on these studies. Yes, it worked in our leading hospitals. Now, will it work in the VA? Will it work in a 200-bed hospital that’s not yet computerized?"
• Decreased liability claims
• Increased reimbursement
• Impact on nurses
• Improved image of the hospital to the public

**Must impact errors that cause harm**

Nat Sims, MD, Massachusetts General Hospital: “There are many options to apply technology to address medication errors, but the real opportunity is to address the errors that cause harm. Taking harm out of the system should be our first priority.”

**Enable best practice**

Chuck Denham, MD: “We should always start with the best or better practice that delivers known performance impact and then apply the best combination of products, services, and technologies that enable that practice. Technologies should always be seen as enabling a best practice, not a substitute for a practice.”

**Is bar coding the best approach?**

Calvin Franz, PhD, Senior Economist, ERG, Inc., Lexington, MA: “In our bar coding study, a 1% decrease in nurse productivity nationwide is $300-400 million per year. As an economist, it seems obvious to me that the bar coding will improve patient safety, but if it is costing us half a billion dollars a year, then that might be money could be invested into another system that would give us greater ‘bang for the buck.’ We keep researching to see if there are cheaper ways of improving patient safety, since capital is so scarce for hospitals.”

**Overly rapid diffusion could jeopardize the innovation**

Philip J. Schneider, MS, FASHP, The Ohio State University: “Putting an emphasis or pressure on healthcare providers to diffuse innovation before the environment is ready or the technology is ready, we could end up jeopardizing the innovation itself by trying to stimulate it too quickly.”

**Insurance discounts, cost savings**

F. Andrew (Drew) Gaffney, MD, FACC, Vanderbilt University Medical Center: “A single malpractice insurance carrier, State Volunteer Mutual Insurance Company, covers approximately 90% of the physicians in the state of Tennessee. They’ve started a discount program for surgeons who take a special course related to safety. The area of safety is called ‘crew resource management,’ an aviation-based communication and leadership course that teaches team members to speak up when a problem is recognized or identified. We are in the process of implementing that same program at Vanderbilt. We are self-insured but use actuarial data to set our malpractice rates for different groups of physicians. Our self-insurance trust is funding Crew Resource Management training for over 600 physicians, nurses, and other care givers as part of a large-scale pilot safety project. We hope to have insurance discounts in place for the coming year for those physicians and departments that complete the safety training and demonstrate incorporation of the training into their medical practice.

‘Just to put into context the magnitude of medical malpractice, medical errors, and resultant risk management expenses, we looked at what we were setting aside for actual and potential claims on an annual basis and converted those dollars back to gross revenue, i.e. how much revenue was lost, given that malpractice claims expenses really come from an organization’s bottom line. The amount of lost revenue can easily run into the hundreds of millions of dollars annually. It’s virtually impossible to get this kind of information in the public sector, but each institution has its own data. It’s money that is is essentially thrown away because most of the medical errors leading to claims are preventable. When you’re talking about numbers this massive, it becomes much easier to make the argument to administrators that safety measures and safety programs are cost effective, not to mention benefits of not actually causing harm to our patients.”

**Errors that cause harm are IV**

Chuck Denham, MD: “There are errors, harm, and errors that cause harm. Errors that cause great harm are in the IV area—they are really dramatic and there is a great return on investment in reducing them. The speed to impact is better with smart pumps than anything we have seen.”

**Grab every opportunity**

Ken Barker, PhD: “Any of these efforts that attempt to give us a good rational approach to improving even part of the process are well worthwhile. For instance, if we don’t decide that it’s the time for all kinds of bar code applications, and we do decide that it’s time for move ahead on infusion safety, I think that’s a very reasonable thing for us to do—that is, to grab every opportunity we have at process improvement and move forward. There is so much room for improvement, we can hardly go wrong.”

**Decisions based on philosophy and mission**

Geraldine A. Coyle, RN, EdD, CNA: “Tom Thielke’s CEO wanted the University of Wisconsin to be the safest hospital in the state. So you have a vision and a philosophy and a lot of the decisions about what to do and how to do it, what to buy and when to buy it, are grounded in your philosophy of care and the mission of your medical center.”
SPEAKERS

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