

RFID and Bar Codes— Critical Importance in Enhancing Safe Patient Care

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ABSTRACT

Medication administration recording and supply management are complex and interrelated processes. The integration of bar codes and radio frequency identification tags are viewed as critical in achieving effective and safe patient care. However, these systems are complex; all parts need to be aligned, and the systems must work together to produce the desired outcomes. In healthcare, automation using bar coding and RFID capabilities is of growing importance because of the Institutes of Medicine study and the integrated electronic medical record. Healthcare systems today are increasingly complex, and while bar codes and RFID technologies provide opportunities for enhanced patient care, systems using these capabilities must be carefully planned to achieve optimal outcomes.

KEYWORDS

- Radio frequency identification
- Bar codes
- Electronic medical records

Introduction

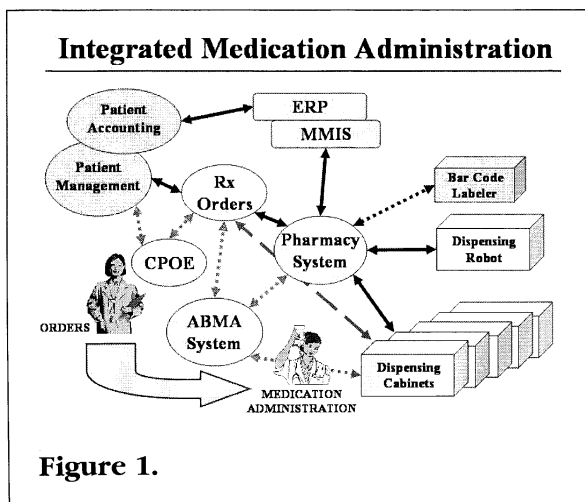
Healthcare providers continue to struggle with rising healthcare costs and the need to provide dwindling numbers of healthcare professionals with resources and systems designed to ensure the most efficient, effective, and safest means of providing care. Healthcare providers are facing rising costs, burgeoning care needs for an aging population, and shrinking numbers of healthcare professionals.

In this environment, providers need to make careful strategic choices about the acquisition, implementation, and effective use of information technologies. Information technologies, in integrated systems coupled with redesigned workflows, can make a significant contribution to safe and efficient healthcare and ultimately will result in reduced costs. Auto-ID technologies, encompassing both radio frequency identification (RFID) tags and bar codes, have

been recognized for their potential to radically improve patient safety, especially for medication administration and healthcare operations.

For hospital-based patient care activities, automated systems using bar coding and RFID capabilities are of growing importance because of the Institutes of Medicine (IOM) study.¹ The report by the Institutes of Medicine provided an in-depth review of the issues, and the results indicate healthcare providers are lagging behind other industries in the adoption of safe practices and quality assurance methods through the use of automated systems.

The Institute of Medicine Report stated that “as many as 44,000 to 98,000 people die in hospitals each year as the result of medical errors,” with an estimated 7,000 of these deaths related to medication errors.² This bellwether report on medical errors and the need for enhanced patient safety indicated that many medication errors are not a result of



individual performance but rather occur because providers fail to incorporate systems that could be designed to prevent such mishaps and tragedies.

In responding to the findings published by the IOM, the Agency for Healthcare Research and Quality (AHRQ) said providers need to focus on making systems improvements and not simply blame caregivers for medical errors. "Healthcare professionals are simply human and, like everyone else, they make mistakes. But research has shown that system improvements can reduce the error rates and improve the quality of healthcare."³

Issues to Consider in Systems Design

The industry has been galvanized by the extent, magnitude, and cost of medical errors in our delivery system. The findings are forcing healthcare providers to focus on applying the principles of error analysis and elimination. Although not all errors cause injury, accidental injury can result from error.

Focusing on the root of the problem, errors are either the failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim or desired outcome.⁴

In healthcare, assuring that a planned medical action is without error means assuring the accuracy of medication prescription and administration, which to date has been a very labor-intensive manual process that does lead to occasional medication errors. Medication errors are particularly prevalent in our delivery system and have received the most focus in discussions of bar code technology. Every nurse (and a host of other healthcare providers) knows about the "Five Rights" of medication administration.

For medication administration to be considered error-free involves a number of "right interventions" in addition to ascertaining the right patient and right time. The drug, the dose, and the route of administration all must be correct to

qualify as the "right intervention." Using bar codes for automated data capture of the patient, medication, and nurse identities has been shown to radically reduce medication administration errors.

Auto-ID/Bar Code Enabled Medication Administration, or ABMA, systems have delivered enormous value to early adopters. With a much smaller investment than that required for fully integrated computerized provider order entry (CPOE)⁵ or electronic health records systems, ABMA systems should be considered for implementation as a key strategy to enhance the quality of the patient care medication administration process.

The relationship of the ABMA system as part of integrated medication administration systems, including CPOE, patient accounting/management, pharmacy, and materials management information systems (MMIS) or enterprise resource planning (ERP) systems, is shown in Figure 1.

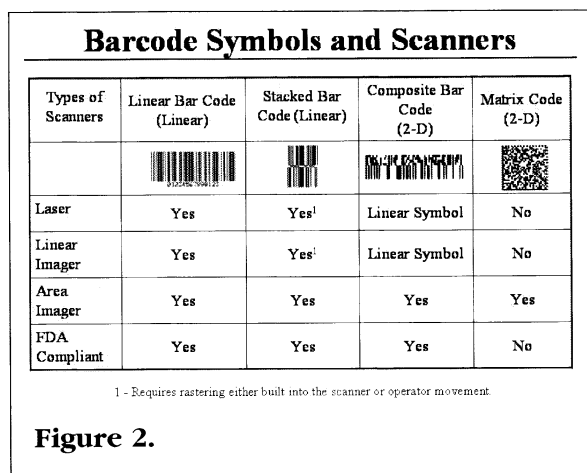
In relation to the capabilities typical in hospitals' information systems strategic plans, ABMA systems are the fastest to implement and offer the least expensive but highest return on investment for patient safety. However, they are not without challenges. The major areas of challenge include:

- Application integration with patient management, order communication (CPOE), pharmacy, and other systems.
- Bar code labeling of all medications at the unit-of-use level.
- Process and workflow changes.

While each of these challenges deserves considerable discussion, this article focuses on the dimensions that tie ABMA systems for point-of-care activities to the pharmaceutical and medical device supply chain. With very few exceptions for hospitals, supply-chain management begins with purchasing and ends at the receiving dock and storeroom. At the same time, information systems addressing medication ordering, distribution, and administration address different details and share only a subset of the information processed.

A typical scenario highlights the challenge. A physician medication order may have very basic information. The hospital's policy, procedure, or customs dictate requirements to the nurses and pharmacist who know what to do with such an order. For example, at a particular hospital, the Q4D may translate to specific times each day. When the order is received in the pharmacy, many translations and perhaps substitutions may be made. Two 100mg tablets may be used for a 200mg order. A standard generic substitution may be made if the order was not DAW (dispense as written). In some cases, the pharmacist may contact the ordering physician to request authorization for a therapeutic substitution.

The architecture of most hospitals' information systems



has inherent separation between systems such as order communication and the pharmacy (see Figure 1). Thus, the scenarios described above will not be processed through the information systems. In our example, the order communication system would show the 200mg brand name drug while the pharmacy system might show two 100mg tablets of the generic version of the drug. Moving to the actual administration of the drug, the situation can become even more complicated.

ABMA systems require that each medication have a bar code or RFID tag at the unit-of-use level. Until recently, bar-coded unit-of-use medications were not readily available. As a result, hospitals would not invest in markedly safer medication administration because bar coded medications were not available, and pharmaceutical manufacturers and distributors would not invest in putting bar codes on unit-of-use medications because hospitals did not have systems to read them and were unwilling to pay extra for bar coded medications.

A secondary issue is the format of the bar codes used to mark medications. The diversity of existing bar code formats is illustrated in Figure 2. It shows several different standards that may be used, all of which have different requirements for hardware and software to read and interpret the bar coded information.

RFID tags now are starting to appear at the manufacturing and wholesale distribution levels of the supply chain because of the emphasis on efficiency in wholesale distribution and the interests of pharmaceutical manufacturers to reduce and eliminate drug counterfeiting. Adaptation of RFID tags at the patient bedside is most likely years away, although early trials are under way focusing on use of this evolving technology to automatically link the correct patient with the supplies being provided. As with barcodes, RFID tags have a variety of standards that are evolving, presenting challenges to manufacturers and distributors in the short term and to healthcare providers in the future.

FDA Regulations

The Food and Drug Administration stepped in to break the bar code dilemma by issuing a Bar Code Rule for human drugs, blood, and blood products. The Food and Drug Administration's February 25, 2004, bar code rule is the first step in facilitating the implementation of bar coding systems to automate hospital pharmacies and improve hospital supply chain efficiency.⁶ This rule requires manufacturers, repackers, and relabelers to apply bar codes containing products' National Drug Code (NDC) numbers to the immediate package of most prescription drug products, including biological products.

While this is a tremendous step forward, the FDA's role as a public health agency limited the scope of its rule making. The rule imposes no requirements on hospitals and does not require unit of use or unit dose bar coding.⁷ Putting these systems in place is complex, and hospitals implementing bar code-enabled medication administration have many decisions that must be considered in the design and structure for the use of bar codes in their patient care information systems (see Table 1).

The earliest adopters of ABMA systems had to apply bar codes to all their medications. Internal hospital identifying numbers—such as the charge master numbers—were used. As unit-dose medications become available with NDC bar codes, hospitals' ABMA systems had to accommodate both internal and manufacturer applied NDC numbers. However, NDC numbers can be very different for the same medication. Table 2 provides an example of how the same drug/dose/tablet can have multiple NDC numbers.

Connecting the Point of Care

The challenge is having an ABMA system that is exact and precise enough to accommodate all the obvious and subtle variations of the "simple" medication administration process.

When the bar code scanner or RFID reader returns a character string, a computer application will have to parse out the NDC number and verify that it is the Right Drug, Right Dose, and Right Route. A rather brute-force approach to accomplish this is to dedicate staff to table maintenance. But this compromises the premise that eliminating manual steps and using electronic auto identification systems reduce errors and saves money.

The safer approach and far more cost-effective approach is to use supply chain EDI or XML transaction sets that move information all the way to the ABMA system. When hospitals require that deliveries of pharmaceuticals be preceded by an EDI Advance Shipment Notification (ANSI X12 Set 856), the NDC codes of the actual medications shipped and delivered can be captured in the provider's ERP/MMIS and pharmacy information management systems. This captured information must go beyond the receiving dock and purchasing and accounts payable by moving the knowledge of the NDC

Applications	Structure & Symbology determined by	Standardized Structure and Symbology
1. Medication purchased with bar code on unit-of-use A. NDC Code B. Lot & Expiry	FDA Rule	EAN.UCC or HIBCC "Linear"
	Mfg. - Packager Choice	EAN.UCC: 2D Composite Component HIBCC: Separate Code 128 Mfg using non std micro PDF & Data Matrix
2. Hospital bar coded Unit-of-use medication	Hospital Choice	EAN.UCC or HIBCC if hospital subscribes HIBC PAS
3. Blood and Blood products	FDA Rule	Codabar or ISBT 128
4. Hospital prepared IV mixes	Hospital Choice	HIBC PAS Implementing proprietary content & format
5. Patient ID Band	Hospital Choice	HIBC PAS Implementing proprietary content & format
6. Employee ID	Hospital Choice	HIBC PAS Implementing proprietary content & format
7. Specimen Container	Hospital Choice	NCCLS

Table 1 – Structure & Use of Barcode Applications for Medications

numbers for drugs "in-stock" to the ABMA system. Thus, integrating the systems will result in moving supply chain management capabilities to the point of care.

Systems Complexity and Patient Safety

Healthcare information systems today are increasingly complex, and while bar codes and RFID technologies provide opportunities for enhanced patient care, systems using these capabilities must be carefully planned to achieve optimum outcomes.

Before the advent of automated systems, hospitals used myriad manual paper-intensive processes to order, track, and bill for supplies and medications. During the past few years, there has been increasing emphasis on integrating these activities by using information systems designed to automate order processing, data capture, and supply consumption for patient charging.

CPOE, materials management information systems or

enterprise resource planning, and pharmacy information management systems all benefit from efficiencies that result from use of automated identification technologies.

This is especially true for ABMA systems built on the premise of using bar coding or other auto-ID technologies to automate data capture and record medication administration transactions. Systems designed to incorporate ABMA will provide significant benefits to providers, both financial through more efficient patient care, reduced litigation and insurance costs, and in terms of improved quality of patient care.

Thus, the strategic focus for healthcare providers should include implementation capabilities designed to make effective use of ABMA systems at the point-of-care. Patient care quality benefits will accrue mostly through ensuring the five rights of medication administration are adhered to in the patient care process. These include the right medication, the right dose, the right time, the right patient,

Brand Name: Vicodin® from Abbott Laboratories Lortab® from USB Pharma, Inc				
Generic Name: Hydrocodone Bitartrate and Acetaminophen Mix Hydrocodone Bitartrate 5mg / Acetaminophen 500mg From Able Laboratories, Inc.				
Description	Unit Pack	Qty in Package	NDC Code	NDC Labeler
Vicodin®	Bottle	500	00044-0727-03	Knoll Laboratories Div Knoll Pharmaceutical Co.
Vicodin®	Bottle	100	00044-0727-02	Knoll Laboratories Div Knoll Pharmaceutical Co.
Vicodin®	Unit dose		00044-0727-41	Knoll Laboratories Div Knoll Pharmaceutical Co.
Vicodin®	Bottle	100	62584-0023-00	Amerisource Health Services Corp
Lortab®	Bottle	500	0756-0186-50	D M Graham Laboratories Div
Lortab®	Bottle	100	0756-0186-01	D M Graham Laboratories Div
Hydrocodone Bitartrate & Acetaminophen	Box 10 x 10	100	51079-0420-20	UDL Laboratories Inc
Hydrocodone Bitartrate & Acetaminophen	Box 5 x 20	100	51079-0420-21	UDL Laboratories Inc
Hydrocodone Bitartrate & Acetaminophen	Box	6	51079-0420-96	UDL Laboratories Inc

Table 2. NDC code and labeler information.

and the right route. To record the medication event, patient-care activities also must be accompanied by the use of an electronic medication administration record system. These systems are linked to other patient care information systems, including CPOE and the electronic medical record, all of which contribute to safe patient care as well as providing financial benefits to the hospital.⁸

To reduce errors in medication administration, healthcare providers must improve their processes. This includes consideration of transcription of pharmaceutical orders, accurate dispensing by the pharmacy, and accurate administration by the caregivers. The use of ABMA capabilities can build on or be expanded to other systems within the hospital or provider domain.

Because healthcare activities involve the use of diverse equipment and supplies as well as medications, it is logical to build on the use of ABMA to enable the capture of related data, including patient identification, supply tracking and consumption, and laboratory specimen tracking capabilities. Of course each of the respective systems

should be integrated or interfaced appropriately using HL7 standards⁹ to ensure accurate transfer of data between systems in the most efficient manner.

Information systems using ABMA capabilities to provide auto-ID bar code data capture at the bedside should be used to enhance patient medication safety. The systems can be linked to other hospital systems, including the electronic health record and pharmaceutical and supply management systems, to provide financial information and related information system capabilities that can drill down to the patient level to report on the cost of providing care.

Thus, integrated healthcare information systems can provide access to both real-time and historical information for conducting queries on patient-care activities, pharmaceutical and supply usage trends, and internal performance benchmarks on quality of care and various types of supply efficiencies. Integrated systems can contribute to the development of standardized care paths by tracking and reporting on pharmaceutical and supply usage for various patient groups.

System Design and Implementation

There are numerous issues to consider when selecting an Auto-ID Barcode Medication Administration system. When adequately designed and implemented, the ABMA system should be fully integrated to other information systems and will enrich information available for quality performance and clinical and financial management at virtually all levels of hospital operations. The use of ABMA as a point-of-care system to track medication administration makes it a foundation for clinical information systems designed to work with other information systems and resources within the provider's network.

When hospital staff use an ABMA each time a medication is administered, information is tracked and recorded in the patient's medication administration record. The use of the drug is automatically sent to the hospital's billing system with the essential details, facilitating audits, and quality control reviews.

“Using bar codes for automated data capture of the patient, medication, and nurse identities has been shown to radically reduce medication administration errors.”

Using ABMA at the point of care coupled with the electronic health record and related pharmacy information management systems increases users' ability to monitor medication use at the patient, physician, and clinical unit level. The diversity of medications used daily in hospitals contributes to the complexity of patient-care processes, thus mandating automated systems to control use, prevent medication errors, and assure quality patient care.

Budgets for medications have risen steadily in the past several years, and this trend is expected to continue. As a result, hospitals have a critical need to understand pharmaceutical usage patterns as well as the efficacy of different treatment regimens on different diseases. ABMA systems coupled with a pharmacy information management system enable providers to track actual medication usage linked to patient and provider information. A pharmacy standards and therapeutics committee and individual physicians then can use this data to facilitate review and evaluate outcomes achieved. Accurate medication information is a strategic component of achieving quality patient care and influencing prescribing patterns of physicians.

According to HIMSS, the projected cost for a hospital to implement ABMA systems to read and capture bar code data at the bedside is slightly less than \$2,000 per bed, with operating expenses estimated at more than \$1,000 per year. Thus, for a 200-bed hospital, the costs to acquire and

implement an ABMA will be in excess of \$500,000. Start-up costs for ABMA systems include system hardware, software and data management systems, service costs, and user training. The decision to lease or buy an ABMA system must undergo the same strategic scrutiny that any enterprise IT system would require.

The key to understanding the costs of these systems is to have a solid understanding of system lifecycle costs, including increased patient stays or death, insurance, litigation, labor, and drug costs for each clinical area to be enhanced with an ABMA system. Obviously, the preceding estimates depend on numerous factors, including the existing provider infrastructure and systems capabilities.

The FDA's review of potential benefits indicated that the introduction of the new technologies associated with the ABMA systems actually resulted in decreased productivity when the systems were first installed. "It is significant that in a time of nurse shortages, the FDA concluded there is a three percent degradation in patient unit productivity when BMAR systems are installed."¹⁰ Thus, hospitals need to plan carefully when implementing these systems to ensure that patient care activities are not adversely affected, especially in units where there are staff shortages and critically ill patients. In the long run, many hospitals that have implemented ABMA report overall nursing productivity increases as a result of collateral efficiencies.

According to studies and reports from the FDA and others, the use of ABMA capabilities to prevent adverse drug or medication events (ADEs) is dramatic.¹¹ Use of automated systems at the point of care by properly trained staff can significantly reduce the number of medication errors. As a result, healthcare providers can increase the quality of care and reduce hospital stays, and litigation, as well as achieve enhanced productivity from scarce healthcare resources.

Robert Krawisz, executive director of the National Patient Safety Foundation, contends that the benefits of automating medication administration using bar codes are significant, saying, "The technology's impact at VA hospitals so far has been amazing." In an article entitled "Strategies to Reduce Medication Errors" published by the *FDA Consumer Magazine*, it was noted that the Department of Veterans Affairs has substantially reduced medication administration errors by using bar codes as part of its medication administration processes in VA hospitals nationwide. "For example, the VA Medical Center in Topeka, KS, has reported that bar coding reduced its medication error rate by 86 percent over a nine-year period."¹²

To achieve error reductions, providers must link systems involved with initial physician orders (CPOE), transcription of orders, medication dispensing, and administration. In linking the ABMA system with other IS applications, the use of bar codes (and RFID tags in the future) provides both validation of the five rights and creates an audit trail for subsequent analysis of patient-care activities.

As providers plan for using ABMA system capabilities, providers should consider several different factors as part of their strategic planning. These include:

- The percentage of pharmaceutical products in the hospital formulary that can be acquired pre-labeled with bar codes.
- The existing capabilities in the pharmacy to support repackaging of medication, if needed, to support the ABMA system.
- Opportunities to use standard bar code readers for patient identification, other medical surgical supplies, biomedical equipment, and other uses.

After completing the initial evaluation of requirements and existing bar code capabilities, a plan can be developed to guide the subsequent acquisition of technologies, both software and hardware, necessary to achieve success with the ABMA initiative. Of course, this acquisition of technologies should consider the costs and benefits for integrating these capabilities or updating legacy systems as part of the overall strategic plans for the IS, nursing, and pharmacy departments.

With ABMA systems, as with any automated systems, there can be breakdowns or system failures. System up-time and service responsiveness must be defined and determined, using either trained hospital staff or the vendor service support technicians. Also, manual processes must be established so medications are always available whether or not the system is operational. Proper recording of all medication activities and immediate reconciliation of administration records after a system is returned to service, are important considerations after a service outage.

Balancing Needs in Trying Times

The integration of bar codes and radio frequency identification tags is critical for enhancing systems and support necessary for achieving effective and safe patient care. However, these systems are complex, and all parts need to be aligned; the systems must work together to produce the desired outcomes.

As hospitals and other healthcare providers evaluate their strategic needs for the future, the use of ABMA systems and related capabilities—while requiring upfront investment in IS capabilities—promises to deliver significant benefits to the quality of patient care. As such, these capabilities should be carefully considered and given priority as part of an organization's efforts to develop integrated capabilities for safe, efficient, and effective patient care. These systems also will have a positive impact on the financial performance of the provider organization as a result of avoiding costs by reducing lengths of stay associated with adverse medication events and cutting insurance costs for the institution in the long run.

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