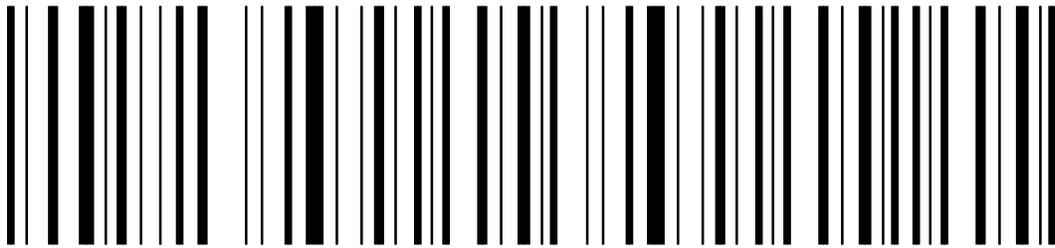


Patient Safety Applications of Bar Code and RFID Technologies



APPLICATION WHITE PAPER



Zebra Technologies



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Executive Summary

The recent focus on patient safety in U.S. hospitals has yielded a flood of new technologies and tools aimed specifically towards improving the quality of patient care at the point of care. This has been accomplished by integrating the physical process of patient care delivery with medication information and software applications that deliver clinical decision support, and quality and safety checks. Error reduction at the bedside is the lightning rod of industry efforts to address patient safety. Among technology approaches, bar coding solutions have risen to the top of industry preference due to their relative ease of implementation, demonstrated return on investment (ROI), and broad array of applications.

Bar code solutions are being deployed in a variety of healthcare settings including producing hospital wristbands and labeling for pharmaceutical unit-of-use medications, IV mixtures, lab and pathology specimens, blood products, asset tags, file labels, and more. Bar codes can be matched with radio frequency identification (RFID) tags to create two-tiered identification resulting in more robust point of care, patient-specific medical media. Pharmaceutical companies can locate and track each dose of medication produced in vast batches. Hospitals can monitor and utilize equipment with greater efficiency, and healthcare staff can more efficiently create and maintain healthcare records.

The application of RFID technologies in hospitals has been modest, however, primarily due to cost issues. Like most electronic technologies, RFID unit costs have fallen dramatically within the past few years, but have not yet reached the “tipping point” of economic rationality for cash-conscious hospitals. RFID in healthcare has been restricted primarily to asset management and supply chain applications. In fact, a mix of both technologies—RFID and bar coding—will provide the optimal return on investment (ROI) for most healthcare providers.

From an ROI perspective, bar coding has been proven to generate not only clinical benefits but also measurable financial benefits. Hospitals spend an average of \$9,705 per 100 admissions in treating the effects of medical errors, and approximately 30 percent of all malpractice suits involve drug-related injuries. In addition to the cost-avoidance aspect of patient safety that bar coding provides, bar code data greatly improve the accuracy of charge capture, pharmaceutical inventory management, drug utilization, and best practice compliance.

The market for healthcare bar code solutions is ripe with opportunity, not only in terms of patient safety, but also in terms of unmet demand for broader applications of the technology within healthcare organizations. Integrated medication management, automated identification, asset management, and inventory control are just a few industry opportunities that are poised for growth. Only 5 percent of U.S. hospitals currently have deployed bar code patient safety solutions, but the clinical utility, cost advantages, and collateral benefits of bar coding will spur growth of these technology solutions. Industry-wide adoption is likely to occur within the next four to six years.



I n t r o d u c t i o n

In 2001, the Institute of Medicine (IOM) issued a landmark report titled "To Err is Human," that described the prevalence throughout the U.S. healthcare industry of widespread and often preventable medical errors. The IOM report stated that preventable medical errors cause up to 98,000 deaths and 770,000 adverse events in the U.S. each year. Since the IOM Report was published, subsequent industry evidence has revealed that the problem not only persists—it appears to be getting worse. According to a 2001 report of the Journal of the American Pharmaceutical Association, medical errors translated into \$177 billion in costs to the healthcare industry. In a more recent study conducted by HealthGrade, Inc. (2003) that tracks medical quality, nearly 200,000 patient deaths each year are attributable to medical errors—that's twice the worst-case forecast in the IOM report. Finally, the Managed Care Institute has estimated that as many as 28 percent of all hospitalizations are attributed to drug-related morbidity—which translates to a cost of \$50 billion per year (2002).

In each of these studies adverse drug events (ADEs) have been identified as a primary cause of preventable medical errors and one of the single greatest threats to patient safety. The term ADE describes drug administration errors that take a variety of forms including incorrect drug selection, incorrect dosage or frequency, and negative drug interactions. ADEs can result from the wrong medication being prescribed, the wrong medication being distributed by the pharmacy, or the wrong administration of the medication at the bedside. A report from the Archives of Internal Medicine found that almost one in five medication doses administered in hospitals is given in error. The two most common errors cited were medication dispensing at the wrong time (43 percent of incidents) and omitting a dose (30 percent). Seven percent of errors were found to be potentially harmful. In a 300-bed facility, this translates into 40 potentially harmful errors each day.¹ Similar findings have been reported by the FDA, which in its own study found that ADEs range from 2.4 percent to 6.5 percent per facility.

Despite the mounting evidence that medical errors are a persistent and growing problem throughout the U.S. healthcare industry, surprisingly little has been done to reverse the trend. Nationwide, less than 25 percent of hospitals have even rudimentary technology to reduce errors—and this is five years after the IOM report. Nevertheless, in the wake of these reports and their message that the issue of preventable medical errors remains unsolved, the U.S. healthcare industry has focused its collective attention toward developing tools, technologies, and techniques to promote patient safety. Industry leaders have taken note—for the second consecutive year, the 2004 Annual HIMSS Leadership Survey placed a high priority on the implementation of technology to reduce medical errors.²

F D A R e g u l a t i o n a n d I n d u s t r y G o a l s

In recognition of the urgency of patient safety issues, government agencies and industry regulators have established goals and guidelines to reduce medical errors. On February 25, 2004, the U.S. Food and Drug Administration (FDA) issued a Bar Code Rule that requires drug manufacturers, re-packers, and re-labelers to apply unit-of-use bar codes containing products' National Bar Code (NDC) numbers to the immediate package of most prescription drug products, including biological products. The rule, which takes effect within two years, imposes no requirements on hospitals, but encourages hospital compliance. The FDA estimates that "the bar code rule, once implemented, will result in more than 500,000 fewer adverse events over the next twenty years, thereby reducing medical errors by 50 percent in savings."³ An estimated \$93 billion is likely to be saved by reducing healthcare costs, patient pain and suffering, and the lost work time due to adverse events.

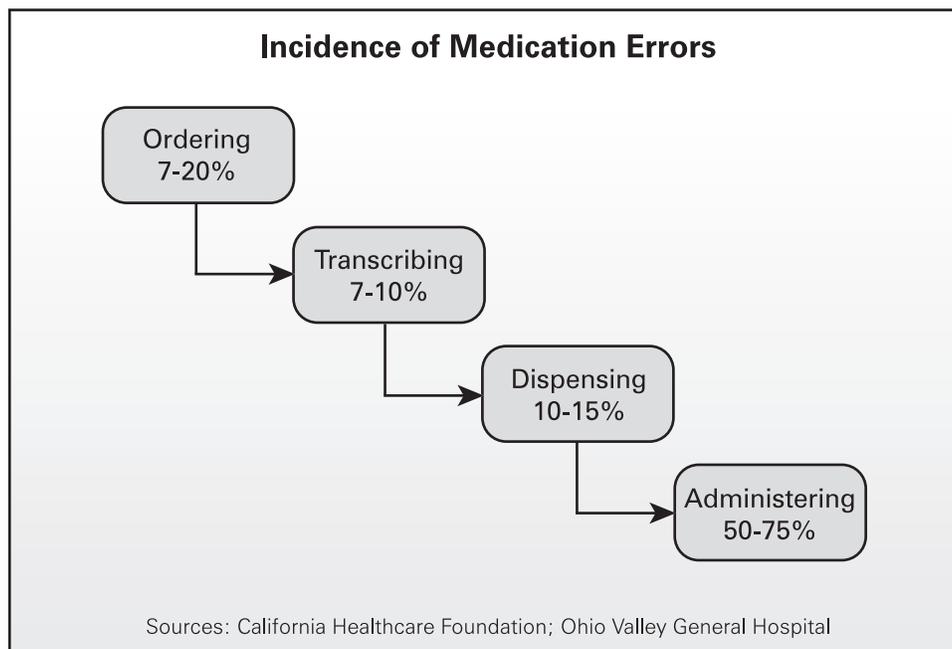
The Joint Commission for the Accreditation of Hospital Organizations (JCAHO), a healthcare regulatory agency, has established National Patient Safety Goals, including bar coded wristbands that can improve accuracy and safety by identifying patients before administering medications, drawing blood samples, performing surgery, transferring patients, taking x-rays, or performing other diagnostic tests. The U.S. Department of Defense requires that its suppliers mark their medical and surgical products with a UPN bar code. Large pharmaceutical companies like Pfizer, large health plans like Kaiser Permanente, and large health systems like HCA have also taken a leadership position in implementing bar code solutions.

P a t i e n t S a f e t y a t t h e P o i n t o f C a r e

The recent focus on patient safety has yielded a flood of new technologies and tools aimed specifically towards improving the quality of patient care at the point-of-care by integrating the physical process of patient care delivery with medication information and software applications that deliver decision support, and quality and safety checks. In the hospital environment patient safety tools and technologies must translate into the correct administration of medications at the bedside, and from a strategy perspective, the key element of patient safety at the bedside is the process of medication administration.

The cornerstone of medication administration safety is the principle of the “Five Rights”—right medication, right dose, right time, right patient, and right route. These describe the elements of an optimal patient medication administration process. Information about the patient and the medication at the point of care is critical to the success of such a program, and must be accessible in a concise, on-demand, and process-specific manner in order to expedite rather than impede the clinical activity of hospital staff. Figure 1 depicts the stages of medication management during which errors typically occur—and can be prevented. Without technology, it is at the final stage of this process, during which the nurse administers the medication, that no “second check” is available to ensure the “Five Rights” of patient safety.

Figure 1





Industry efforts to address patient safety are focused on error reduction at the bedside. Among technology solutions for medication errors, bar coding solutions have risen to the top of industry preference due to their relative ease of implementation, demonstrated ROI, and broad array of applications. Bar coding is also viewed by healthcare CIOs and clinicians as a forerunner of more comprehensive patient safety initiatives such as e-prescribing, computerized physician order entry (CPOE), and the electronic medical record (EMR). With such technology tools, healthcare organizations can achieve true digital and clinical transformation of patient care—and make healthcare “faster, better, and cheaper.”

How Bar Coding Works

Bar codes record text information in an encoded format, and the bar code serves as an index key in clinical databases. In a medication administration application, bar code architectures often include a bar coded wristband issued to the patient at the time of admission. Nurses’ ID badges and medications also carry bar codes. At the time that a medication is administered, all three bar codes are scanned at the bedside. This assures an identical match between patient and medication, and also identifies the practitioner administering the medication. The system is supported by software that references expert databases to comply with the “Five Rights” of patient medication administration. In other clinical applications, hospitals and health systems use bar coding to “tag” unlabeled unit-of-use medications, manage clinical inventory and assets, and record interventions for each patient receiving medications. Hospital pharmacies scan unit-of-use packaging to improve security, build an audit trail, update inventory, and automate inventory record keeping.

Bar Coding for Patient Safety

Bar codes of various types are being deployed in producing hospital wristbands, pharmaceutical unit-of-use medications, specimens, blood products, and IV mixtures, patient chargeable medical supplies, surgical supplies, asset tags, file labels, and more. Bar codes can be matched with RFID tags to create 2-tiered identification and more robust point-of-care, patient-specific medical media. Pharmaceutical companies can locate and track each dose of medications produced in vast batches, equipment can be monitored and utilized with greater efficiency, and healthcare staff can more efficiently create and maintain healthcare records.

Wristbands

Wristbands containing one- or two-dimensional bar codes are issued to patients upon hospital admission. Prior to administering a medication at the bedside, a nurse scans the patient's (JCAHO and HIPAA compliant) bar coded wristband to confirm the patient's identity; the scan acts as a key to open the patient's record in a centralized medical database where each patient record contains indications, advisories, and restrictions concerning care administered to that patient. Once the accuracy of the patient/medication has been confirmed, the nurse scans his/her badge to record the time and source of the medication administration. In a study conducted by the U.S. Veteran's Administration, this method of medication administration was found to reduce the incidence of medication errors by 86.2 percent.

Unit-of-Use Medication

Bar codes accurately identify medications by type, recommended dosage, and frequency of administration at the unit-dose level, thus providing nurses with a “second check” and decision support tool in the administration of patient meds. Nurses can combine the information contained in the unit-dose bar code with the patient wristband to assure the “Five Rights” of patient safety.





Specimen Collection

Bar code systems compare specimen collection orders, stored in a handheld or bedside laptop, with information scanned from the patient wristband, and confirm that the specimen container is the correct one for the tests ordered. A new bar code label for the specimen container is printed at the bedside with the time and date of collection. In the lab, bar coded tracking technology can eliminate errors of processing, starting at sample collection and continuing through the process of accession, testing, and results reporting.

Blood Administration

One of the six JCAHO patient safety goals is the improvement of accuracy in positively identifying patients prior to drawing blood or administering blood products. The FDA estimates that there are 414 annual blood transfusion errors. A bar coding system for blood administration can reduce such errors by as much as 90 percent. Point-of-care bedside bar coding applications are being integrated with blood product administration activities to combine patient identification, medication and blood product verification. Phlebotomy and blood banking are current focal points of bar coded blood administration, and operating room (OR) bar coded blood type/patient confirmation is currently in development.

Track and Trace Systems

In compliance with the FDA ruling requiring bar coding of unit-of-use medication packaging, anti-counterfeiting bar code technology is being developed and deployed in pharmacies, hospitals, and elsewhere to improve tracking and tracing. Bar coded lot numbers, expiration dates and unit-of-use identifiers help healthcare manufacturers, distributors, and consumers manage medications throughout the supply chain. The healthcare industry spends \$23 billion annually on order management, distribution, transportation and inventory management; approximately \$11 billion of these costs are caused by redundant activities, according to a report issued on the Efficient Healthcare Consumer Response (1997).⁴ Track and trace systems are the key component of anti-counterfeiting programs, by providing an accurate drug "pedigree" that is a secure record documenting the drug's source and date of manufacture.

Pharmacy

Today, many medications arrive at the hospital pharmacy without a bar code—which requires the pharmacy to produce its own. Pharmacies use bar coding to tag unit-of-use medications, bulk items, and mixtures. For many medication fulfillment processes in the pharmacy, bar code printers and automated dispensing equipment produce on-demand, unit-of-use bar codes that are legible, secure, and cost-effective.

Bar coding is an extremely adaptive technology whose total applications in the hospital environment have yet to be fully explored. Today, bar coding in hospitals encompasses many areas of clinical and business activity, including:

- Patient registration
- Patient identification
- Patient tracking
- Patient charge collection and billing
- Medical record document assimilation and indexing

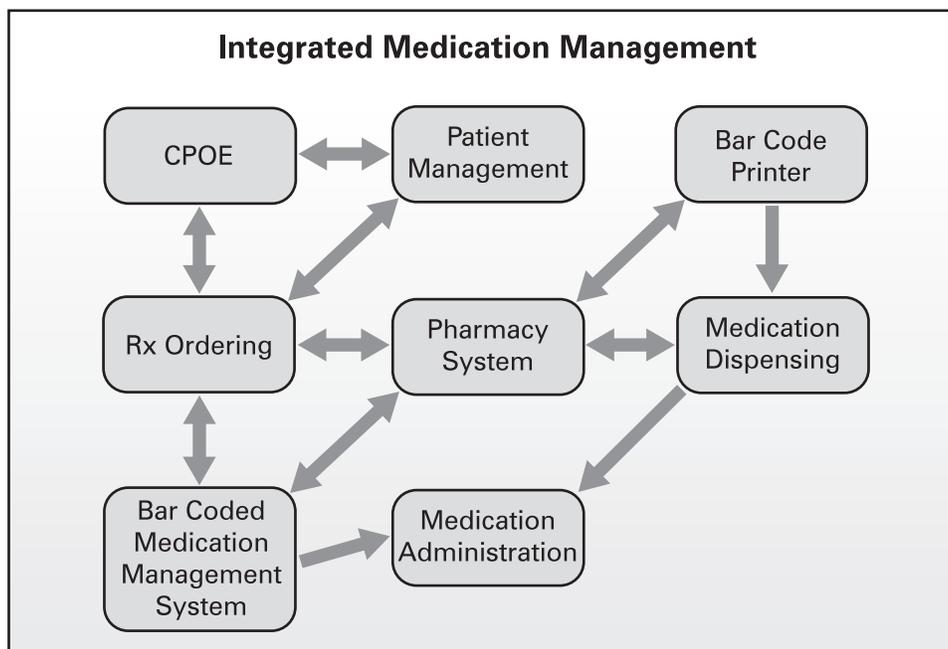


- Physician and care giver order entry
- Laboratory specimen tracking and verification
- Radiology—film tracking
- Medication administration verification
- Blood transfusion verification
- Respiratory therapy treatment at the bedside
- Dietary management
- Supply chain management
- Receiving
- Storage and unit labeling
- Picking and internal transfer
- Replenishment order
- Cycle counts
- Annual equipment inventories
- Preventative maintenance
- Linen inventory and distribution
- Sterile reprocessing
- Security
- Employee identification

In addition to the stand-alone applications of bar coding, systems can also be linked to CPOE and EMR systems, and pharmaceutical and supply systems. This allows institutions to access financial information and to drill down to the patient level to report on the cost of providing care, as shown in the following illustration.

At the bedside, integrated medication management links bar code scanning, clinical knowledge databases, wireless networking, and patient record technologies. Reporting capabilities from such input can include real-time queries on patient care activities, pharmaceutical and supply usage trends, and internal performance benchmarks. This capability can contribute to the development of standardized care paths by tracking and reporting on pharmaceutical, equipment, and supply usage by various patient groups.

Figure 2



Who Benefits from Bar Code Solutions for Patient Safety?

First and foremost, the patient benefits from bar coding because it helps in preventing ADE-related patient pain, suffering, and extensions of hospital stays. Throughout the healthcare value chain, manufacturers, distributors, and providers of healthcare products and services have a professional responsibility to adopt best practices, enact processes, and deploy tools and technology solutions that positively impact patient care. That's a lofty concept, but in many cases technologies like bar coding must be sold on the basis of benefits that can be measured by traditional clinical and financial metrics. Today, there are clear regulatory and business drivers that are serving as a catalyst of bar coding adoption, particularly in the hospital and pharmaceutical verticals.

Hospitals

For hospitals, bar coding represents a potential windfall in terms of patient safety, with an estimated value (according to the FDA) of \$93 billion over the next 20 years. In addition, hospitals are expected to avoid litigation associated with preventable adverse events (reducing malpractice liability insurance premiums), and increase receipts from more accurate billing procedures (in excess of the bar code implementation and maintenance costs, according to the FDA). Hospitals also benefit from the marketing and patient preference benefits associated with quality care and industry leadership in the adoption of new technologies and clinical processes. Less obvious but of vital importance are the collateral benefits of bar coding to nursing and pharmacist productivity, charge capture, inventory management, asset utilization, commodity tracing and tracking, and the market value of patient safety leadership.



Pharmaceuticals

The FDA has mandated that pharmaceutical manufacturers bar code their products at the unit-of-use level by 2006. But rather than this being a punitive measure, the pharmaceutical industry is expected to realize annual benefits of more than \$10 million per \$1 billion in revenue from unit level bar coding applications. These will be realized in the areas of improved patient safety, brand protection and fraud detection, supply chain, and return and recall processes.

Business Case

Return on investment is never far from any serious consideration of a new technology deployment, and bar coding has been proven to generate measurable clinical and financial benefits. An FDA study of hospital ADEs found that medication error rates ranged from 2.4 percent to 6.5 percent per facility, resulting in an average cost of \$2,257 per event. Based on this evidence, hospitals spend an average of \$9,705 per 100 admissions in treating the effects of ADEs. A facility that averages 20 daily admissions could expect to incur \$708,100 in annual expenses related to adverse drug events. The FDA analysis does not include the cost of liability or legal expense related to such events; an article published in the journal *Legal Medicine* reported that approximately 30 percent of all malpractice suits involve drug-related injuries. In addition to the cost-avoidance aspect of patient safety that bar coding provides, bar code data greatly improve the accuracy of charge capture, pharmaceutical inventory management, drug utilization, and best practice compliance.

In the pharmaceutical industry, counterfeit pharmaceuticals account for 6 percent to 10 percent of all medicines sold worldwide, according to the World Health Organization. Bar coding of pharmaceuticals establishes their pedigree, combats drug counterfeiting, and creates an audit trail through the value chain. Drug makers who implement bar code and RFID control systems can reduce diversion by 18 percent in the first year and lower inventory holding costs by 6 percent, according to a study by A.T. Kearney.

Recent studies have shown that 68 percent of lab errors are related to pre-analytical procedures, and about half of those errors are the result of misidentification of the patient or mislabeling of the specimen. Bar coding can reduce such errors by one third.⁵

Bar Coding Versus CPOE

Bar coding is not the only patient safety technology available to hospitals; there are several alternative strategies including e-prescribing, electronic patient records, and CPOE. As shown in the following illustration, bar code systems are faster and cheaper to implement and offer a higher ROI for patient safety.

Representative cost data describing the total cost of ownership of bar coding systems is difficult to obtain—there are simply too many variables, including the number of nurses to be equipped, the extent of infrastructure and systems architecture investments, training, maintenance, and other factors. The FDA has estimated that the average hospital will spend \$448,000 to implement a computerized medication administration system, but according to HIMSS, the projected cost for a hospital to implement bar coded medical administration (BCMA) systems to read and capture bar code data at the bedside is slightly less than \$2,000 per bed (including hardware, software, data management systems, service costs, and user training), with operating expenses of approximately \$1,000 per year. For a 200-bed hospital, this translates into acquisition costs of \$400,000 and annual operating costs of about \$200,000. Still, contrast this with the CPOE base cost of \$2 million to \$5 million, and the business case for bar coding becomes even more compelling.

Figure 3

Comparison of CPOE & BCMA		
	CPOE	BCMA
Implementation Cost	\$7.9 million	\$1.9 million
Ongoing Annual Cost	\$1.3 million	\$180,000
Implementation Time	3+ years	6 months
Implementation Risk	High	Low
Payback Period	10+ years	<2 years

Source: Bridge Medical

Notes from the Field

Bar coding as a tool of patient safety has proven to be an unqualified success at hospitals across the country, in ways that can be measured in both clinical and economic terms. In some cases, bar coding has served as the forerunner of “closed loop” patient safety initiatives that include e-prescribing, CPOE, and EMR applications. In other cases, bar coding has been implemented as a stand-alone solution to patient safety at the point of care. In still other situations, bar coding is being deployed in new clinical applications. A few examples:

Northeast Medical Center (Concord, N.C.)

Following the publication of reports by the IOM and Leapfrog Groups, Northeast’s CEO championed an initiative to address patient safety directly. After considering several alternative solutions including CPOE and an EMR, Northeast selected bar coding as the most cost effective, manageable patient safety solution that would yield a collateral benefit to the hospitals' marketing efforts. The bar coding initiative was such an immediate success that all 26 nursing units were equipped with the bar code technology by March 2003. The system has yielded additional benefits, including nursing satisfaction (nurses appreciate the "second check" feature of the bar code system), fuller census (from the community recognition of Northeast's leadership position regarding patient safety), and a more efficient pharmacy. Northeast hopes soon to add blood administration as part of its bar coded patient safety initiative, adds Vickie Davis, director of Lab Services at Northeast.

Ohio Valley General Hospital (McKeesport, Pa.)

At Ohio Valley General Hospital bar coding was introduced with a healthy degree of skepticism. Nurses struggled to give up paper and rely on handhelds: At first it took longer to conduct the “Five Rights” of patient medication administration with the bar coding solution and handhelds than it had with the old



manual systems. But bar coded medication administration revealed a higher level of medication errors than was previously known. After some system refinements, the process has now streamlined medication management. In addition the second-check feature of bedside bar coding has turned nurses into advocates. At Ohio Valley General, bar coding and smart pump technologies have been linked—now orders for medication administration delivered through the pumps can be transmitted via the bar code. The technology also includes “guardrails” that define parameters for dosage, rate of administration, and best practices, and the system generates alerts if the parameters are exceeded. In the future, Ohio Valley General plans to implement RFID to track inventory.

HCA (Nashville, Tenn.)

HCA owns and operates 180 hospitals located throughout the U.S. In 2001 HCA conducted a pilot of bar coded medication administration; the program was such a success that HCA decided to deploy the technology throughout its entire hospital system the following year. By 2004, HCA had implemented bar coded medication management in 118 of its 180 hospitals, and it expects to complete deployment in all HCA hospitals by the end of 2005. And how has HCA performed? In October 2004, of 95 HCA hospitals monitored, 6.2 million doses of medication were administered. Of these, 192,000 warnings were issued by the medication administration system, and of these warnings, 152,000 (2 percent of all doses administered) resulted in the attending nurse not administering a potentially harmful medication. In addition to medication administration, bar coded data is being linked to the charge capture system, which has improved the accuracy of patient billing. HCA next will integrate bar coding for blood draws and blood administration.

Beloit Memorial Hospital (Beloit, Wis.)

In 2002, Beloit Memorial Hospital conducted a due diligence process to identify the best technology solution for their patient safety issues. The hospital conducted demonstrations of CPOE products but determined that CPOE technology did not meet the hospital's needs, was not easy to use, and in fact added complexity to the medication prescribing process. The decision to deploy a bar coding solution was based on the ability to effect a rapid deployment and the cost effective features bar coding offered. The decision was further reinforced by assessing the risk associated with the as-yet unproven value of CPOE solutions. As a result of implementing bar coding in the Family Care Center, medication administration errors declined by 67 percent in an eight-month period. The results have been both impressive, and immediate. Doris Mulder, Vice President of Nursing, put it this way: "Within one year we have realized a 74 percent decrease in reported medication errors in the Family Care Center, and we have documented an 89% decrease in errors within 6 months in the Special Care unit." Today, Beloit is using bar coding for medication administration at the bedside in all of its inpatient units. Ms. Mulder adds that she has seen “a decrease in reported errors in every unit.”

Methodist Medical Center (Peoria, Ill.)

In 1999, Methodist Medical Center recorded an incidence rate of five ADEs per 10,000 doses of medications administered. That same year, Michael Bryant, Methodist's new CEO, formed an executive IT Steering Committee which he headed in order to find solutions to the patient safety issue. "The bar coding strategy was selected because it provides the opportunity to finally close the loop of medication ordering and administration, and offers the added benefit of providing a second check for nurses," said Tom Rippetto, Methodist's chief information officer . The bar coding system also offered a more accurate, less subjective method of capturing and reporting medication errors. Within one year of rolling out the bar coding technology facility-wide, the rate of adverse drug events fell to 2.3 ADEs per 10,000 doses—



a 50 percent reduction. After an early swell of incidence reports, the error reporting system has recorded less activity, indicating that observations and recommendations from the error reporting system are being incorporated into mainstream processes.

Sutter Health(Sacramento, Calif.)

Sutter Health has embarked on a \$25 million patient safety effort that will place a bar code scanner at every bedside throughout Sutter’s 26-hospital system. First implemented in May 2003, Sutter’s bar coding solution has prevented approximately 28,000 medication errors over the course of 2.6 million drug administrations. Of these avoided errors, about 2,600 could have produced moderate or severe clinical effects. The program has been so effective that Sutter plans to complete deployment of its bar coding initiative in all its facilities one year ahead of its original schedule. More impressively, Sutter physicians have been so impressed with the bar coding solution that they are aggressively supporting the advanced deployment of a fully functional EMR.

St. Mary’s Hospital (Madison Wis.)

In 1996, St. Mary’s formed a medication safety improvement team to flow-chart processes and make improvements in medication administration. As a first step, the team made process improvements; these had no real impact on the incidence of ADEs. However, in 1999 St. Mary’s decided to implement a technology solution and teamed with Bridge Medical to develop a bar coded medication management tool. The tool has been in use since 2000 and is responsible for a 70 percent reduction in the medication error rate.

St. Vincent’s Hospital (Birmingham, Ala.)

Part of the Ascension Health System, St. Vincent’s is considered a flagship digital hospital and has served as a pilot for McKesson’s “closed loop” medication management integration initiative (order, decision support, distribution, and administration). In addition to medical management, St. Vincent’s has deployed bar coding in the OR with anesthesia and injectibles that can work with smart pumps during surgery to confirm the correct medication, and to monitor the rate of drug administration. St. Vincent’s has also tagged surgical instruments with two-dimensional bar coded ”dots” to identify which instruments are on each surgical tray and how often the instruments are being used.

Challenges and Barriers to Bar Code System Integration

Bar coding solutions span a variety of areas, including patient management, order entry, medication management, specimen management, asset management, accounting, and more. Integration of bar code technologies and tools across multiple application systems and technology environments requires interoperative software applications, robust infrastructure, adequate staff resources, process and workflow changes, and culture adaptation. Bar code formats are also an issue, since no standard exists and there is currently a wealth of bar code formats being used in healthcare. In most cases no single vendor solution can satisfy these requirements and as a result, bar code integration with other clinical systems in the hospital remains a future prospect. Hospitals often have to buy multiple components—scanners, printers, and software from different manufacturers to address bar code integration requirements. There is even a range of functionality peculiar to alternate types of bar code production.



To achieve true integration of bar code technologies and tools with complementary systems such as CPOE and e-prescribing, interoperability and system architecture issues must be resolved. This is a difficult task, since historically vendors have tended to build proprietary features into their products, in an effort to “lock in” customers. That market dynamic is changing, however, as hospitals demand open system architecture and vendor-neutral applications that can work seamlessly with other products. Similarly, equipment must be multi-functional to avoid duplication and unnecessary capital consumption for related patient safety processes. A case in point is bar code printing solutions.

Thermal, Laser, or Inkjet Bar Code Printing?

There are a number of bar code print solutions available today, including traditional packaging presses, ink jet, laser, and thermal printers. However, these methods differ greatly in terms of bar code production speed, quality, edge definition, flexibility, label formats supported, print sizes, and cost. Among the most common bar code production methodologies are thermal, laser, and ink jet printing.

Thermal is the dominant technology for producing bar code labels in all industries. Thermal printing technology has been developed specifically for bar coding applications, and is particularly suited to healthcare since it addresses the need for compact, highly defined, durable codes for vials, electronic components, sample containers, and small items such as unit-of-use medications. Printers can handle all bar code symbologies and data structures endorsed by the FDA. Thermal printers come in many configurations, including mobile units that can be carried or worn on a belt, small desktop models, and industrial-strength printers capable of 24-hour operation. The range of sizes makes thermal printers a convenient option for use in pharmacies, nursing stations, and other healthcare settings. They are the least costly method of producing both batch and unit-of-use bar codes at the nurse workstation, in the pharmacy, lab, or other healthcare setting. Thermal printers can produce on-demand wristbands, specimen labels, and unit-dose labels that meet the rigorous requirements of a healthcare environment.

Laser printers are available in both office and industrial configurations. Of the two, only industrial laser printers are suitable for unit-of-use bar coding. Industrial laser printers burn a permanent image into a variety of materials, and are capable of producing high-speed, high-quality, small images and two-dimensional bar codes. Office-style laser printers are not intended for labeling, require special sheets not typically used in office applications, and are prone to jamming. From a total cost of ownership view, laser printers are far more expensive to operate relative to both thermal and ink jet alternatives.

Inkjet is widely used for printing variable text on packaging but is not an ideal technology for printing a bar code. Ink jet coders work by spraying dots of ink onto the subject being marked. The process can be messy and does not always provide the print quality necessary to create small codes that must remain readable for weeks or months. Finally, few ink jets support the bar code symbologies used for unit-of-use coding.⁶

A key requirement of bar coding for healthcare is clarity and definition; as bar codes become smaller (in order to accommodate more data), the need for readability and precision increases. Edge definition, which refers to the clarity and contrast of the dark and light edges within a symbol, is a problem with ink jet, packaging presses, and laser toner, because each method applies ink to a surface; this causes spreading of the media, resulting in blurring of images, and can lead to misreads. Conversely, thermal printers produce outstanding edge definition, since the method of bar code application does not produce the spreading effect of ink based coding processes. In addition, ink jet printers may require higher quality ink; laser toner may degrade over quality adhesive labels; and, for unit-of-use applications, commercial printers that are suited to sheet feeding applications waste supplies.



Bar Code Print Solutions

While there are many bar code print solutions across industries, Zebra Technologies, a leading producer of on-demand bar code print solutions, offers the widest range of bar code label and wristband printers in the healthcare market. A variety of Zebra® models are ideally suited for use in hospitals for manual or automated dispensing operations, bedside delivery and documentation, blood bag and lab sample tracking, employee identification, file management, and more. Zebra is the preferred patient safety bar code printing solution of hospitals nationwide, thanks to the flexibility, durability, and reliability of its products. In fact, Zebra was recently recognized for its product excellence in the healthcare field. "Because of its unmatched quality and scanability, thermal bar code printing is becoming the technology of choice in this field, and with its innovative and reliable on-demand printing solutions, Zebra Technologies is fast emerging as a global leader in the field" (from Frost and Sullivan's 2004 Product Leadership Award in Medical Informatics).

Zebra bar code patient safety solutions:

- accurately and automatically identify patients and staff with accurate, legible, and tamper-proof patient identification wristbands and employee ID cards;
- provide medication controls with label printers for use both in the pharmacy and at bedside;
- prevent administration of the wrong drug or procedure with identification systems for patient care, lab, research, pharmacy, and blood bank management;
- provide unit-of-use coding with RSS;
- support multiple bar code formats;
- offer unparalleled scalability and flexibility. Zebra printers can operate in a stand-alone environment or be integrated with EMR, lab, pharmacy, or patient accounting systems.

Zebra bar code print solutions are fully compliant with regulatory standards for patient safety and patient privacy. Zebra's proprietary thermal printers, in conjunction with its white thermal polypropylene face stock with a protective UV varnish, produce durable patient wristbands that are in compliance with the privacy issues outlined in the HIPAA Act of 1996. The bar code can provide a unique patient ID number that is the key to a database containing the patient's medical information, and that can only be accessed by authorized persons. Zebra thermal wristbands also comply with the FDA ruling designed to reduce medical errors. Zebra's direct thermal printers can also print a bar code wristband while simultaneously encoding an RFID chip embedded in either label material or the wristband itself where circumstances require the added patient security provided by RFID technology.





What Will Drive Healthcare's Adoption of Bar Coding?

Despite the demonstrated value and economic rationality of bar coding as a patient safety mechanism, less than 5 percent of U.S. hospitals have adopted the technology at the bedside. One reason is the perennial issue of allocating scant technology dollars; clinician resistance and system integration present additional hurdles. There are several obstacles that must be removed in order to spark wider adoption of the technology regardless of its economic attractiveness. These obstacles include:

“No Fault” Reporting

From the nurse and physician viewpoint, technology solutions often translate into layers of process that produce modest improvements in patient care. Technology solutions in healthcare are routinely oversold and clinicians are wary of disruptive alterations to established clinical activities. In the case of medication management, automated error detection is sometimes viewed as a punitive measure intended to aid management's attempts to interfere with patient care—or worse to punish clinicians. To address this issue, bar coded medication management schemes must feature a “no fault” reporting policy in which clinicians—mainly nurses—are encouraged to report errors with the following provisos: 1. there are no penalties for reporting errors in medication administration; 2. error reporting is intended to identify process issues and technology glitches—not to discipline staff; and 3. error reporting will generate stronger decision support tools and medication administration accuracy at the point of care.

Standards

There is at present no single industry standard governing the use of bar codes; this is a significant challenge to the wider adoption of bar code technologies in healthcare. In fact, there are over 200 bar code symbologies, but only a few are being considered for unit-of-use identification. Of these, the RSS family of symbologies was specifically developed to help identify pharmaceutical products. The most commonly used healthcare bar coding symbologies in use today include the Universal Product Number (UPN) which is used to identify medical and surgical products at each packaging level, and the National Drug Code (NDC) identification system that the FDA uses to uniquely identify all pharmaceuticals. Other bar coding schemes in use today include Data Matrix, the ISBT 128, the Healthcare Identification Number (HIN), and the Labeler Identification Codes (LIC) systems, developed by the Health Industry Business Communication Council (HIBCC) to identify trading partners in e-transactions. Despite this apparent lack of gravitation towards a unified bar code symbology and data structure, progress can be found in the EAN.UCC bar coding system, an internationally accepted standard with an estimated 22,000 adherents in the hospital and pharmaceutical industries. Additionally, there is RSS, an all-numeric bar code symbology that can encode an NDC code in a fraction of the space required for a traditional UPC symbol. The lack of a single all-embracing industry standard is not necessarily a significant hindrance to broad-scale adoption of bar coding tools and technologies—current printers and scanners can support multiple methodologies and bar code symbologies. But integration and interoperability issues loom as bar coding is blended with collaborative technologies such as CPOE, e-prescribing, and the EMR.

Industry Leadership

Collectively, through advocacy associations such as HIMSS, the National Alliance for Healthcare Technology (NAHIT), and the Institute for Healthcare Improvement (IHI), which have established bar code task forces and patient safety campaigns, the healthcare industry hopes to build the critical mass and industry awareness necessary to “bootstrap” bar code adoption. These grass-roots efforts will generate momentum towards bar code adoption in healthcare. In addition, a number of professional associations, regulators, and group purchasing organizations are supporting bar coding.



RFID in Healthcare

The term RFID (radio frequency identification) describes a wireless identification technology that communicates data by radio waves. Data is encoded in a chip, which is integrated with an antenna and packaged into a finished “tag.” RFID tags may be passive (requiring close proximity to a reader, and usually applied to track supplies), or active, in which the RFID tag contains a small battery to allow continuous monitoring (used mostly to track equipment). RFID technologies offer different rewritability options, memory sizes, and tag forms, and can be read from anywhere within range of the RFID reader.⁷ RFID labels can hold more data than bar codes, and can be read automatically without any user intervention required.

Today, the application of RFID technologies in hospitals is modest, primarily due to cost issues. Like most electronic technologies, RFID unit costs have fallen dramatically within the past few years, but have not yet achieved the “tipping point” of economic rationality for cash-conscious healthcare organizations. RFID in healthcare has been restricted primarily to asset management and supply chain applications. Even within this sphere, there’s a lot to keep track of. In 2003, Jackson Memorial Hospital in Miami reported that it could not account for \$4 million worth of equipment—and quickly decided to implement RFID tracking. Faced with the same issue early in 2004, Bon Secours Health System (Richmond, Va.) installed an RFID equipment tracking system to monitor 12,000 pieces of equipment at its three facilities. In less than a year Bon Secours has documented benefits that include capital avoidance (by being able to locate and use otherwise idle equipment) and utilization efficiencies (by distributing equipment where it is needed) among the three facilities. Additionally, the nursing staff has gained approximately 30 minutes per nurse per shift in time saved not hunting down equipment. In financial terms, Bon Secours estimates that it has gained a \$200,000 benefit per year over and above the cost of the RFID system installation and maintenance costs—and this does not even include staff productivity gains. An interesting side benefit for Bon Secours has been the ability to piggyback a WIFI network onto the RFID project, since both systems use the same architectures and hardware.

Other deployments of RFID include:

- Advocate Good Shepherd Hospital (Barrington, Ill.) has utilized inventory RFID tags with the result that inventory losses (that were previously running at 10 percent annually) were cut in half.
- Holy Name Society Hospital (Teaneck, N.J.) purchased an RFID asset tracking system that allows nurses to use PCs in each nursing unit to locate one of 2,000 tagged pieces of equipment.

There are other intriguing applications of RFID in the patient sphere. For instance, RFID tags can be used:

- in long-term care to track elderly and disoriented patients.
- in the maternity ward to track mothers and babies.
- for surgical patients who can be tagged to ensure that the right procedure is being performed on the right person at the right time.

One of the more innovative uses of RFID today involves tracking and monitoring surgical equipment. At St. Vincent’s Hospital (Birmingham, Ala.), surgical instruments are monitored to determine their location, last sterilization, maintenance record, and other key statistics. This technology can further identify individual surgical supply items and their purchase date, description, cost, and utilization data.



Other RFID applications that are on the launch pad or in development include:

- Implantable RFID devices the size of a grain of sand that act as a portable medical record (FDA approval is pending).
- A “smart” patient wristband that when scanned by RFID reveals patient name, date of birth, admitting orders, insurance information, surgical site, allergic reactions, medication requirements, and blood type (Georgetown University Hospital).
- Staff bracelets to locate doctors, nurses, and patients anywhere in a hospital (Beth Israel Hospital, N.Y.).

The pharmaceutical industry is now testing RFID technologies to track and trace their product. The FDA Anti-Counterfeiting Task Force has strongly suggested the use of RFID to safeguard against pharmaceutical counterfeiting, and according to a report from the META Group titled "RFID in the Pharmaceutical Industry," RFID adoption in pharma may surpass retail adoption within the next 18 months. Tracking pharmaceutical product is a vital safeguard measure since it is estimated that upwards of 10 percent of pharmaceuticals distributed worldwide are fraudulent. In one trial deployment medicine bottles are being fitted with RFID tags in order to detect fake drugs moving through the supply chain. Other pharmaceutical deployments include recall management and return management (the FDA Office of Compliance reported 1,230 drug recalls between 1997 and 2002, or an average of 3.9 recalls per week), inventory management, product authentication, pedigree management, and sample management. According to an ARC Advisory Report titled "RFID Systems in the Manufacturing Supply Chain," over 12 billion pharmaceutical units are candidates for RFID tagging. The same study predicted that most pharmaceuticals will be tagged by 2007.

There are obstacles to deploying RFID in hospitals, including interference with other devices (such as cell phones and telemetry), user acceptance, and privacy (the Civil Liberties Union and Consumer Groups have taken positions against RFID). And, from a business perspective, the return on investment for RFID remains an elusive proposition, due to unattractive price points and tactical deployments in healthcare venues. Radianse, a startup RFID company, estimates that it will cost between \$500 and \$2,000 per hospital bed to install its RFID systems.⁸ Gartner doesn't expect RFID to take hold until 2010, and recommends that IT managers “trial” RFID in supply chain and ERP deployments as springboards from tactical to more global applications of the technology.⁹ Until unit prices and device reliability issues are resolved, RFID is likely going to remain a tracking and monitoring tool of hospital assets. Despite this restriction, Frost and Sullivan estimate that the market for RFID-based tracking systems in healthcare will increase from \$300 million this year to \$658 million by 2007.¹⁰



C o n c l u s i o n

The market for healthcare bar code solutions is ripe with opportunity, not only in terms of patient safety, but also in terms of unmet demand in broader applications of the technology. Integrated medication management, auto-ID, asset management, and inventory control are just a few industry opportunities that are poised for growth. Only 5 percent of U.S. hospitals currently have deployed bar code patient safety solutions, and the clinical utility, cost advantages, and collateral benefits of bar coding will spur growth of these technology solutions. To the extent that hospitals can receive a “second bounce” from their investment in bar coding and RFID (e.g., bar coding imbedded into CPOE, and RFID architecture that coincidentally provides the backbone of a WIFI network), these technologies will become increasingly attractive. However, industry-wide adoption is unlikely to occur suddenly; full-scale adoption in U.S. hospitals will likely take another four to six years.

Will RFID ultimately surpass bar coding as the primary auto-ID and point-of-care patient safety technology in healthcare? It is more likely that bar coding and RFID will complement each other, based on relative functionality, cost, and ease of use. Hospitals will be reluctant to abandon their investments in bar coding simply to introduce a sexier replacement technology—particularly if there is no substantial gain in utility, and certainly not if the ROI equation doesn’t add up. RFID will continue to make inroads into healthcare via track-and-trace solutions, first as asset and inventory management tools, then gravitating towards personnel, patient, and clinical monitoring devices.

Zebra Profile

Zebra Technologies delivers innovative and reliable on-demand printing solutions for business improvement and security applications in 90 countries around the world. More than 90 percent of Fortune 500 companies use Zebra-brand printers. A broad range of applications benefit from Zebra-brand thermal bar code, "smart" label, receipt, and card printers resulting in enhanced security, increased productivity, improved quality, lower costs, and better customer service. The company has sold 4 million printers, including RFID printer/encoders and wire-less mobile solutions, and also offers software, connectivity solutions, and printing supplies.



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