PRIMER

Practical guide to bar coding for patient medication safety

MARK NEUENSCHWANDER, MICHAEL R. COHEN, ALLEN J. VAIDA, JEFFREY A. PATCHETT, JAMIE KELLY, AND BARBARA TROHIMOVICH

Abstract: Bar coding for the medication administration step of the drug-use process is discussed.

FDA will propose a rule in 2003 that would require bar-code labels on all human drugs and biologicals. Even with an FDA mandate, manufacturer procrastination and possible shifts in product availability are likely to slow progress. Such delays should not preclude health systems from adopting bar-code-enabled point-of-care (BPOC) systems to achieve gains in patient safety. Bar-code technology is a replacement for traditional keyboard data entry. The elements of bar coding are content, which determines the meaning; data format, which refers to the embedded data; and symbology, which describes the "font" in which the machine-readable code is written. For a BPOC system to deliver an acceptable level of patient protection, the hospital must first establish reliable processes for a patient identification band, caregiver badge, and medication bar coding. Medications can have either drug-specific or patient-specific bar codes. Both varieties result in the desired code that supports patients' five rights of drug administration. When medications are not available from the manufacturer in immediate-container bar-coded packaging, other means of applying the bar code must be devised, including the use of repackaging equipment, overwrapping, manual bar coding, and outsourcing. Virtually all medications should be bar coded, the bar code on the label should be easily readable, and appropriate policies, procedures, and checks should be in place. Bar coding has the potential to be not only cost-effective but to produce a return on investment.

By bar coding patient identification tags, caregiver badges, and immediate-container medications, health systems can substantially increase patient safety during medication administration.

Index terms: Biologicals; Codes; Drug administration; Economics; Food and Drug Administration (U.S.); Hospitals; Patients; Regulations; Safety; Technology

Am J Health-Syst Pharm. 2003; 60:768-79

First used to automate grocery checkout in the 1930s, early bar-code systems were considered economically unfeasible.[1] Forty years later, the creation of the Uniform Product Code (UPC) enabled grocers across the country to implement point-of-sale bar-code systems en mass. By the early 1980s, aviation, automobile manufacturing, and the Department of Defense were among the industries leveraging bar codes for unprecedented gains in efficiency. Health care also took notice of this innovation, and visionary practitioners published articles on the potential benefits of bar coding for improved medication dispensing and administration.[2-6]

In 1983, a standards organization, the Health Industry Business Communications Council (HIBCC), was created to develop a uniform bar-code standard for all products shipped to hospitals. It developed the Health Industry Barcode (HIBC) standard, a set of specifications for formatting data in a health-care-related bar code.[1] Four years later, a survey by the American Hospital Association showed that bar codes were being used to achieve operational efficiencies in hospital materials management.[7] However, similar gains were not evidenced in clinical applications. In fact, nearly a decade would pass before bar codes began to play a role in patient care.

MARK NEUENSCHWANDER, B.A., is President, The Neuenschwander Company, Bellevue, WA. MICHAEL R. COHEN, B.S.PHARM., M.S., D.SC., is President and ALLEN J. VAIDA, PHARM.D., is Executive Director, The Institute for Safe Medication Practices, Huntington Valley, PA. JEFFREY A. PATCHETT, B.S.PHARM., M.B.A., is Director of Pharmacy, Department of Pharmaceutical Services, NorthEast Medical Center, Concord, NC. JAMIE KELLY, B.A., is Director of Market Research and BARBARA TROHIMOVICH, B.S.PHARM., is Executive Director of Clinical Services, Bridge Medical, Inc., Solana Beach, CA.

Address correspondence to Dr. Cohen at The Institute for Safe Medication Practices, 1800 Byberry Road, Suite 810, Huntington Valley, PA 19006 (mcohen@ismp.org).

The assistance of Susanne Larrabee, Terry Buchanan, Sherry Anderson, and Michael Miller is acknowledged.

The Primer *section covers basic information in various fields of knowledge of interest to pharmacists who practice in health systems. Within the scope of the section are reviews of fundamental concepts in, for example, pharmacy, pharmaceutics, pharmacology, physiology, therapeutics, and health care technology. Also covered are topics somewhat out of the mainstream of pharmacy (e.g., advances in nondrug health care technology) but nevertheless of interest to practitioners.*

One reason bar coding has been slow to shape clinical quality improvement is that, amid the confusion over bar-code standards, much of the pharmaceutical industry has resisted retooling its packaging processes to accommodate bar-code labeling, especially at the unit dose package level. Hence, the onus has been on the provider organization to apply bar-code labels to products for scanning at the bedside. Staffing challenges, specially designed work areas, capital outlays for equipment, wide variations in pharmaceutical manufacturers' practices, and fears of introducing error into the medication-use process have kept hospitals from implementing bar-code systems. In contrast to reticence on the part of inpatient providers, the ambulatory care market has embraced the value of comprehensive bar coding of medications. Many mail-order pharmacies, community pharmacies, refill centers, and other pharmaceutical retail entities now use bar codes to manage inventory and ensure correct dispensing.

In the mid-1990s, hospitals in search of quality improvement began to reassess the value of bar-code technology for reducing errors associated with point-of-care drug administration, blood transfusion verification, and laboratory specimen identification. These new clinical applications, known collectively as bar-code-enabled point-of-care (BPOC) systems, were cited in a 1999 Institute of Medicine report noting that bar coding is "an effective remedy" for medication errors, "a simple way to ensure that the identity and dose of the drug are as prescribed, that it is being given to the right patient, and that all of the steps in the dispensing and administration processes are checked for timeliness and accuracy."[8] Indeed, bar coding has been proven to deliver fundamental advantages to health care. Most important, through bar coding of patient identification bands, caregiver badges, and medications, BPOC systems are able to reduce medication errors by 65–86%.[9-11]

The medication-use process is complicated and rife with "failure points," where unintended and sometimes undetected human error can introduce serious risk to patient safety. Mental lapses can happen to any caregiver, no matter how experienced or well trained. The only defense against these unpredictable human factors is to acknowledge that they are inevitable and to use methods to detect errors and prevent serious harm.

Studies show that manual redundancies, such as having two nurses perform independent dosage calculations before administration, can detect about 95% of errors.[12] The concern is for the 5% of errors that get through human detection systems. To safely address this margin, technological solutions have the potential to identify and intercept an otherwise undetectable error before it reaches a patient.

Using machine-readable labeling and scanning is one such technology for error detection that safeguards the medication administration process from inevitable human error. The most ubiquitous machine-readable identifier, the bar code, offers exceptional accuracy and speed of information collection. Tests have shown that bar-code scanning has an error rate of 1 error in 10,000,000 characters, compared with keyboard-entry error rates of 1 error in 100 characters.[13] In the hospital environment, where keyboard transcription is generally one step removed from manual record keeping, the use of bar-code scanning of medications at the point of care not only decreases errors but increases the accuracy of charting.

Bar-code scanning at the bedside enables medication administration data to be collected in a fraction of the time required for manual documentation. A BPOC system capable of generating an electronic medication administration record (MAR) automatically records all pertinent administration data in a highly legible format, including the exact time of administration, the caregiver's identification, and the dosage and route of administration, in the patient's MAR. Properly designed and implemented bar-code technology offers exceptional ease of use. A nurse can be trained to use a scanner in a matter of minutes. However, as has been documented by the Veterans Health Administration, poor design and inadequate training can compromise the efficacy of the system and may even introduce error into the medication-use process.[14]

The real and perceived challenges of bar coding and the reluctance of many pharmaceutical manufacturers to use this value-added feature on all immediate containers (not just bulk containers) have constrained the adoption of BPOC technology. Surveys of hospitals in 2000 found that 43% had discussed the possibility of using a BPOC system but that only 2.5% used this technology institutionwide.[15,16]

This article provides an overview of bar coding for patient medication safety.

Impetus for change

Many health care provider organizations have asserted that pharmaceutical manufacturers have the systems, controls, and economies of scale to place bar codes on package labels. National hospital, pharmacy, technology, patient safety, and ac-

crediting organizations have issued public statements encouraging the Food and Drug Administration (FDA) to mandate manufacturer-applied machine-readable coding to all pharmaceutical packaging down to the smallest immediate container.[17-19] In response, FDA is proposing a rule in 2003 that would require bar-code labels on all human drug and biological products.[20]

Spurred on by this announcement, drug companies, led by American Pharmaceutical Partners, Pfizer, Abbott Laboratories, and Baxter, have announced that they will soon begin applying bar codes to all medication packages. Simultaneously, group purchasing organizations Premier and Novation have announced plans to require bar coding on all pharmaceutical products covered under new and renewed contracts.[21,22] The resolve behind these buying-preference decisions will not be tested until late 2003, but it may encourage more rapid compliance from the drug manufacturers.

Delays in manufacturer bar coding

Even with an FDA mandate, universal manufacturer bar coding of immediate containers is likely to be several years off. Because of printing-space constraints, labeling of immediate containers (e.g., single-tablet and single-capsule packages, prefilled syringes, ampuls, and vials) may require changes in label design, production line retooling, and, in some cases, increased package size. The government estimates that compliance will cost the pharmaceutical industry between $500 million and $1.4 billion over a 10-year period.[23] In light of these costs, FDA has acknowledged that some manufacturers and repackagers might eliminate their unit-dose-packaged drugs rather than incur the retooling expense. A survey has validated this concern.[24] Three quarters of respondents reported a waning of unit dose packaging for both new and well-established products on the market.

FDA delays, manufacturer procrastination, and possible shifts in product availability are likely to slow progress but should not preclude health systems from adopting BPOC technology to achieve gains in patient safety. Undeniably, bar-coded medications are a prerequisite for effective implementation of BPOC technology. In the absence of widespread manufacturer bar coding, hospitals should become familiar with available bar-code printing and repackaging options so that they can institute BPOC systems as soon as possible. Successful use of BPOC systems is reliant on comprehensive bar coding of virtually all medications. Early-adopter hospitals found that sporadic bar coding of medications inevitably leads to user noncompliance.

In light of current shortages of nurses and pharmacists, the growing complexity of drug products, and the increased acuity of illness of hospitalized patients, the clinical application of bar coding is among the host of technologies that are long overdue and can provide an appreciable reduction in medication errors. Failure to act on the grounds that bar coding of medications is not feasible is unwarranted. The experience of early-adopter hospitals has been that patient safety can be enhanced by bar-code-enabled verification at the point of care with manageable effort and expense.

The anatomy of a bar code

Bar-code technology is a replacement for traditional keyboard data entry. It requires that an identifier be converted to a symbolic representation—a machine-readable identifier—that can be printed on or affixed to an item, read by a scanner or imager, and fed into a computer.

The language surrounding bar coding is unnecessarily cryptic and can discourage health care practitioners who are not technologically savvy. That need not be the case. The fundamental elements of bar coding are analogous to those of any written language. For both a bar-code identifier and a sentence, content determines the meaning. An identifier's data format is equivalent to sentence structure. Finally, symbology is to bar coding what font is to the written word. Hence, a sentence may be printed to read, "The nurse administered the medication" or handwritten as "*the medication was administered by the nurse*." In either case, the content, or meaning, is the same, although the data format (sentence structure) and symbology (font) differ.

Content. Ultimately, the content of a bar-code standard may be influenced by the expected FDA rule, but most stakeholders anticipate that all medication package bar codes will encode at a minimum the national drug code (NDC) (primary data) and, most likely, the expiration date and lot number (secondary data). The NDC alone represents three pieces of data: (1) the labeler (L) (the drug company or packaging house that labeled the package), (2) the drug, form, and strength (D), and (3) a package code that identifies package size and type (P) (e.g., ampul, bag, blister pack, bottle, dial pack, inhaler).

Data format. Data format refers to the data embedded within the bar code. For medications, standard formatting generally includes a 10-digit NDC plus a single "check digit" necessary for ascertaining data integrity. These data elements work in concert to give each bar code a unique, item-specific reference, such that the receiving system can delineate a patient identifier from a medication identifier or one medication from another, and so forth.

The complications of uniquely identifying each medication can be illustrated with the most commonly used identifier in the United States, the NDC. When represented in a bar code, formatting is removed, yielding a 10-digit number. Since the format of NDC identifiers is not consistent and

FDA delegates the generation of drug and package codes to the vendors, multiple NDC formats are permitted. An unformatted NDC of 1234567890 could therefore be 1234-5678-90, 12345-678-90, or 12345-6789-0.

To guard against the possibility of two drugs from two manufacturers or packagers having the same identifier, database vendors force NDCs into an unformatted 11-digit number in a 5-4-2 sequence (LLLLL-DDDD-PP) to obtain uniqueness. To further guard against misreading, a check digit is computed by using a mathematic equation. For example the equation may be to multiply the odd digits by 3, add all the digits, and divide by 10. Each time a code is scanned, the computer automatically performs this calculation. If the user manually enters the code incorrectly or the scanner misreads the symbology, the calculation will fail, and the user is notified that the code entered is invalid.

While manufacturers are given some liberties, health care is not without bar-code format standards. Currently, there are two established format standards in health care, one put forth by HIBCC and the other by the Uniform Code Council (UCC). Ultimately, the market will probably accept one of these standards over the other, but a single standard is not necessary for medication bar coding to improve patient safety. Regardless of the consensus, scanning devices can be programmed to read both formats, and BPOC systems can receive either one.

Symbology. Any investigation of existing bar-code technology will quickly lead to a discussion of which symbology is appropriate for a given application. "Symbology" is the term used to describe the "font" in which a machine-readable code is written. For bar codes, symbology refers to the number of printed bars and intervening spaces that constitute the identifier (Figure 1). The type and number of characters encoded, the print quality, and the amount of space available for the bar code are some of the factors that determine which symbology is most appropriate.

There are two major classifications of machine-readable identifiers in health care: linear and two-dimensional symbologies.

Linear symbologies. Linear symbologies, commonly known as bar codes, are the most common machine-readable identifiers used in health care (Figure 2). Two specific symbologies have prevailed. The first is code 39, a symbology commonly used because all bar-code equipment can read and print the code. However, code 39 produces relatively long bar codes requiring more space on the package it identifies. The second, code 128, is able to produce dense bar codes that allow more data in a smaller identifier. Code 128 is the preferred symbology for patient wristbands, caregiver identification badges, pharmacy-repackaged medications, blood products, and laboratory specimens. Code 128 is readable by all readily available scanning equipment.

Recently, a new linear Reduced Space Symbology (RSS) (Uniform Code Council, Lawrenceville, NJ) has been introduced to address the special limitations of small medication packages. RSS is leading the way in labeling small medication packages, largely because existing mid- to high-quality scanners are upgradable to read the symbology with only minor software modifications. To protect the investment in bar-code-scanning equipment, hospitals should insist on guarantees from their hardware vendor that the scanners they purchase today will support RSS or will be easily upgradable to support the smaller symbology in the near future.

Figure 1. Typical bar code. A = The numeric translation of the bar code (human readable code).

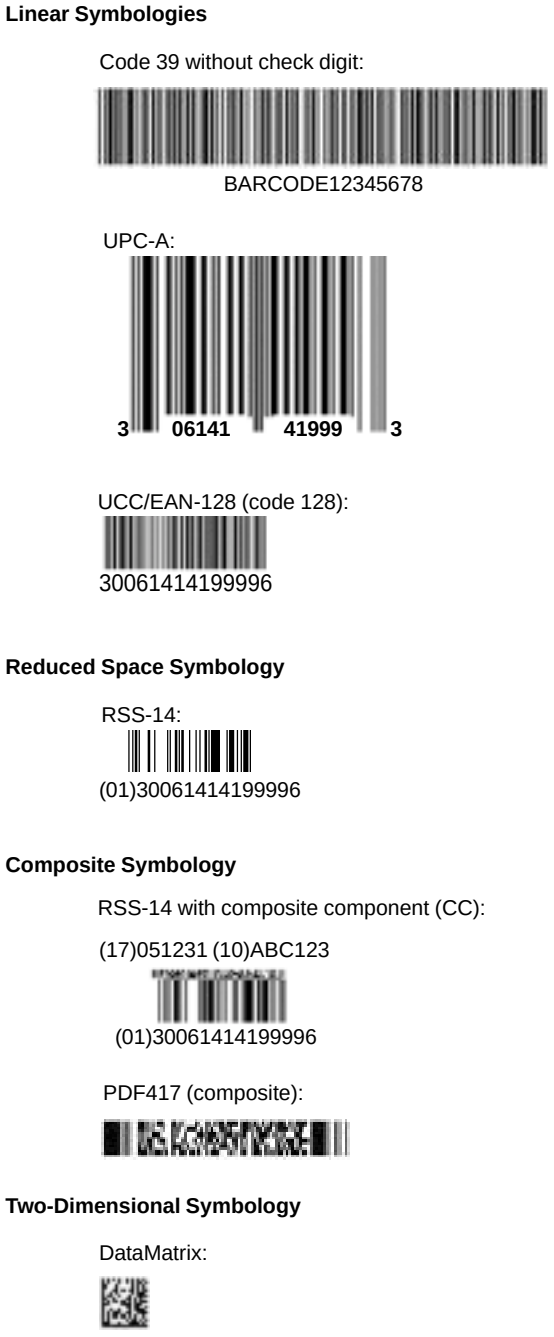
Because RSS is capable of handling only primary data (labeler, drug, and package), a new Composite Symbology (Uniform Code Council) has been developed to handle secondary data (lot number and expiration date). Composite Symbology includes a portable data file (PDF) code stacked on top of an RSS. The PDF consists of a number of thinly sliced linear RSS bar codes stacked on top of each other. Primary data reside in the RSS and secondary data in the PDF.

These multitiered bar codes may be read by infrared scanners available today, but they require software upgrades. They also may be read by newer imaging devices.

Two-dimensional symbologies. Two-dimensional (2-D) identifiers are an up-and-coming technology. These are not considered bar codes but rather are referred to as digital identifiers. 2-D identifiers have the greatest data-density potential for labeling small items, with Data Matrix being a leading example (Figure 2).

2-D identifiers cannot be read with conventional linear charge-coupled-device (CCD) scanners; they require an investment in newer imaging devices. Unlike CCD scanners that use a linear beam of light to read the symbology, imagers read the code much like a camera takes a picture. There is no need to swipe the scanner across the identifier, as with CCD devices. In addition to 2-D symbologies, imagers may read linear identifiers and even accommodate future applications, such as face-recognition verification of photo identification. This function comes at a cost, but, expense aside, 2-D identifiers hold the promise of providing health care with a compact, data-rich symbology ideal for medication bar-code labeling. It will be at least five years before 2-D coding is

Figure 2. Symbologies used in bar codes. Each bar code or identifier is encoded with the same data and has the same narrow bar width. Symbols are illustrated to represent the comparative size difference among the symbologies.



readily available for drug packages.

Currently, several drug manufacturers encode the NDC on some of their container labeling by using code 39, code 128, or UPC bar codes. Others have announced plans to use RSS in all future labeling. Many manufacturers use a three-digit code encoded in Pharmacode, a bar-code symbology readable only with highly specialized equipment. This code is designed for inventory management purposes and cannot be read by point-of-care verification systems. Hence, it is not enough to have a machine-readable identifier on the container; it must contain unique information to reliably identify the right drug if patient safety is to be served.

Bar-coding basics

Every nurse is taught to guard against medication error by applying the "five rights" of drug administration: the right medication, the right patient, the right dose, the right route, and the right time.[25] While this seems simple, all too often one or more of these checks are subject to human error that can result in an adverse drug event. Requiring a second nurse to review the dose and using checklists can reduce administration errors but do not remove the opportunity for lapses, interruptions, and other human factors that may compromise safety. As long as the nurse follows the established steps of bedside bar-code verification, a BPOC can eliminate the human errors that affect medication administration.

The importance of adequately preparing the organization for any interdepartmental initiative, such as bar-code verification at the bedside, cannot be overstated. Hospital preparedness is dependent on the organization's understanding of the complexities and challenges associated with a hospitalwide bar-coding effort. The guidelines presented here were collected through experience with implementing and using BPOC systems. They offer practical insight into the failure points and critical factors for success in bar coding for improved medication safety.

For a BPOC system to deliver this level of patient protection, the hospital must first establish reliable processes for a patient identification band, caregiver badge, and medication bar coding.

Patients. The content of the patient bar-code identifier should follow an established standard that uses a marker to delineate the type of entity (object or individual) the bar code

is meant to identify, in addition to the specifics (e.g., patient account number for that entity and check digit) (Figure 3). For example, if a nurse scans a patient wristband when the BPOC system is to identify a medication, the system would recognize the error and could alert the user. This is particularly important if that patient's identification number in the bar code happens to match a drug product number.

From a technical perspective, adding a bar code to the patient wristband is not difficult, and hospitals have numerous options for facilitating the process. A common approach is to purchase a thermal-transfer or direct thermal bar-code printer. The hospital must then work with the vendor of the hospital's registration (admission, discharge, and transfer [ADT]) system to add control codes for printing bar codes to the existing system that generates text wristbands. If the ADT system vendor is unable to accommodate this requirement, there are third-party vendors that offer solutions. Their hardware and software applications can enable the registration system to produce bar-code labels.

A critical, but often underestimated, factor in successful patient bar coding is the paper on which the identification wristbands are printed. The paper stock must be manufactured for thermal-transfer printing or direct thermal printing. Even then, paper specified for direct thermal use can "fog" when exposed to prolonged heat, such as when a patient lies on his or her forearm. In addition, materials must be fluid resistant and designed to withstand 10 or more days of use in a hospital setting without loss of the integrity of the bar code.

To verify the durability of a paper, it is highly recommended that new patient wristband stock be tested before making the final selection. This can be accomplished by asking a nurse or another individual in the patient care environment to wear a sample patient wristband with bar code for 10 or more days. At the end of the test period, the bar code should still be readable with a scanner.

In some cases, particularly for psychiatric services, pediatric care, and long-term stays, maintenance of the wristband or other patient identifier can be difficult. Likewise, errors during admission can result in the issuance of an incorrect wristband for a given patient. For these reasons, biometric identification methods may one day replace the "right patient" scanning check of current BPOC systems. Devices for scanning irises or fingerprints will provide even greater assurance that the patient is accurately identified.

The greatest challenge to patient bar coding is preparing the organization to alter current processes with the intent of improving patient safety. When launching a facilitywide bar-code initiative for positive patient identification, many hospitals seize the opportunity to reformat the standard content of the patient wristband. While this is a logical and efficient use of retooling, making radical changes may extend the time needed to implement a bar-coded patient wristband and may affect departments throughout the organization. Interdepartmental consensus on the proposed changes is an important part of successful deployment.

Ultimately, the success or failure of patient-identification bar coding will be judged by the nurses who use BPOC systems reliant on accurate and easily read bar codes. Two independent studies have shown that, because of cumbersome scanning procedures and concern for the patient's comfort, the safety check of scanning wristbands to identify patients is circumvented more often than scanning medication bar codes.[14,26] There is work to be done, both in system design and in user training, to rectify this problem.

Caregivers. Like patient bar coding, machine-readable caregiver identification is not technically difficult. However, challenges may arise. Caregiver identification is very similar in design to the patient bar code (Figure 4). One of the first things to consider when bar coding the caregiver's name badge or other identification tag is selecting an identifier that will not change during the caregiver's tenure with the organization. Inconsistencies in caregiver identifiers compromise the electronic MAR, since most BPOC systems cannot combine the records or history of a single caregiver who records administrations under more than one identifier. Therefore, a badge number is typically a poor choice; badges are often lost, and a replacement badge will have a different number. A recommended identifier is the caregiver's employee number.

Complications may emerge in the management of nonhospital-employee caregivers, such as agency nurses, students, and instructors. Nearly all hospitals utilize the services of nonhospital employees and may be challenged with how to identify these individuals in their BPOC system. The issuance of temporary badges that are not tied to the nurse's name can lead to ambiguous administration data. It is recommended that the hospitals devise a means for issuing contract nurses unique bar-code identifiers. Ideally, an agency nurse ought to be assigned a standard hospital identification badge with a unique identifier, once he or

Figure 3. Patient bar code compliant with Health Industry Barcode standard. A signifies the marker for an identifying device affixed to a patient (e.g., a wristband), C is a prefix signifying that the patient identification number follows, 0123455 indicates that the data portion is hospital specific but that a patient identification will be 15 characters or fewer, and the % symbol is the check digit.

AC0123455%

Figure 4. Caregiver bar code compliant with Health Industry Barcode standard. I signifies the marker to flag the identification card as the bar-code carrier, E flags the personnel identification number, 999999999 indicates that the data portion is hospital specific but that a clinician identification will be 15 characters or fewer, and R is the check digit.

IE999999999R

she has completed the credentialing process. In lieu of this practice, contract nurses may be instructed to enter their professional license number into the computer with each administration or therapy.

Medications. Pharmacists and nurses have long agreed that dispensing patient-specific medications in the exact dose prescribed is among the best ways of reducing medication administration errors and enhancing patient safety. However, the tenets of the unit dose system devised in the 1960s have been altered over the years to accommodate less than ideal dispensing practices. From the unit dose concept of all medications dispensed in the precise patient-specific ordered dose was born the less labor-intensive unit-of-use dispensing process. Many medications are sent to the point of care in quantities that do not match the ordered dose. In these instances, the nurse is expected to prepare the correct dose and administer it. For example, the pharmacy may dispense a 10-mL manufacturer-packaged immediate injectable vial from which the patient is to receive a 2.5-mL dose. This practice, although common, increases the risk of an administration error.

BPOC systems require that bar codes be provided on the immediate container of all medications administered at the bedside. In the case of injectable medications, as long as the immediate container—whether a prescribed unit dose or unit-of-use package—includes a bar code, the BPOC system will verify the correct medication, strength, and form and direct the nurse to appropriately draw the ordered dose from the vial. Hence, complete bar coding at the prescribed unit dose level is not necessary to make use of the safety benefits offered by bar-code verification systems. Still, a manufacturer-bar-coded syringe or an exact dose prepared by the pharmacy offers the greatest level of patient safety. Since all medications are not dispensed in a prescribed unit dose package, however, further preparation by the nurse at the bedside is commonplace.

At present, only about 35% of medications in a typical hospital have labels containing a bar code at the unit dose level.[27] Automating the point of care would require hospital pharmacies to apply bar-coded labels (or to arrange for them to be applied by a repackager) to roughly two thirds of their inventory.

While bar-code labeling is a challenge, it is not insurmountable when approached methodically, with a thorough understanding of the existing options. Hospitals may choose to make elective changes in purchasing patterns, use pharmacy repackaging methods, or pursue outsourcing alternatives.

The efficacy of bar-code scanning at the bedside relies in no small measure on the accuracy of medication bar-code labels. How these labels are applied to the immediate containers may affect labeling accuracy. Acquiring manufacturer-bar-coded immediate containers down to the single tablet or capsule blisters, prefilled syringes, and smallest ampuls and vials is the assumed best practice. When drugs are not available in these forms, controlled use of repackaging equipment under strict quality assurance is the best alternative.

Medication- and patient-specific bar codes. Medications can have either medication-specific or patient-specific bar codes. Both varieties result in the desired machine-readable code that supports the five rights of drug administration. Medication-specific bar codes are unique to one drug, dose, and dosage form. They generally consist of the NDC identifying the manufacturer, drug product, strength, and dosage form, although other unique identifiers may be used.

There are several approaches to attaining medication-specific bar codes on medications. First, the pharmacy should maximize the purchase of products with manufacturer-applied bar coding on immediate containers. Second, the hospital may elect to purchase drugs in bulk and to repackage these into immediate containers by using automated equipment capable of printing a bar code on the label. Alternatively, the hospital may elect to contract with repackaging firms or overwrapping services or to set up medication-overwrapping processes inhouse that include the bar code on the overwrap label. Finally, some portion of the bar-code-labeling work may be accomplished by manually applying labels to extemporaneously prepared unit doses or immediate containers (ampuls, vials, syringes, etc.) with a bar-code-label-generating software program. In most pharmacies, a combination of these options will be used because of manufacturer product availability, existing group purchasing agreements, equipment and staff availability, and outsourcing options.

Patient-specific bar codes are those placed on packages of intravenous solutions with patient-specific additives, partial doses of medications, pediatric doses, extemporaneous preparations, and so forth. For these products prepared or compounded by the hospital, ambulatory care site, or outside vendor, the provider uses an identifier to enable the identification of the ingredients or dose of the medication. Patient-specific bar codes, like a license plate number, do not contain descriptive information but rather provide a ref-

erence number that a computer uses to look up associated descriptive data. These bar-code labels generated by the pharmacy information system utilize the patient account number and order number as a reference to the specific product and dose entered into the information system for the prescribed order. Since it is not possible to generate medication-specific bar codes for multiple-ingredient items, such as pharmacy-compounded i.v.'s, small-volume injections, total parenteral nutrient (TPN) solutions, and extemporaneous preparations, patient-specific bar codes are used. Because this type of bar code does not protect against preparation or dispensing errors, it should be limited to multiple-ingredient or patient-customized items and subject to standard quality assurance procedures, including a pharmacist's final review of the preparation. Currently available technologies, such as TPN compounders and syringe fillers, also use bar codes to provide in-process checks and reduce the risk of compounding errors.

If the pharmacy information system cannot produce a patient-specific bar code on the label for i.v. and other extemporaneous preparations, software programs are available for printing standard bar-code symbology. Control characters can be sent and recognized by these printers to enable bar coding without interference with human-readable printing.

Manufacturer-applied bar codes. It is generally agreed that manufacturer-applied bar codes, generated under good manufacturing practices (GMPs), have the highest degree of accuracy and the best guarantee of patient safety. Therefore, purchasing drug products with manufacturer-applied bar codes, when available, contributes to medication safety. A thorough inspection of a hospital's formulary items for a bar code is likely to yield opportunities to purchase manufacturer-bar-coded medications. Besides encouraging the expansion of manufacturer-bar-coded product offerings, altering a hospital's purchasing to favor manufacturer-bar-coded drugs will greatly reduce the resources required for inhouse bar coding.

This is an arena in which group purchasing organizations may exercise their buying clout to effectively drive manufacturer bar coding and bring greater value to member hospitals that do not independently search out the existing bar-coded medications on the market. The cost of acquiring manufacturer-bar-coded unit dose medications is negligible in relation to the patient safety benefits inherent in their use. Up to 84% of pharmacists believe that a slight increase in cost would not deter them from purchasing a specific vendor's unit dose medication with a bar code.[18]

When medications are not available from the manufacturer in immediate-container-bar-coded packaging, other means must be devised to apply a bar code for use at the point of care.

Repackaging equipment. As a first step, hospitals should investigate the "bar-code readiness" of any existing packaging equipment in the pharmacy. Most oral solid and liquid packaging devices have the ability to print bar-coded labels. If not, a software upgrade can usually enable bar-code printing. The bar code is printed on the label, along with all the usual human-readable medication identification information.

The least sophisticated automated repackaging and labeling devices are inexpensive and easily operated, although they may require resource-intensive manual intervention. More sophisticated equipment provides rapid automated repackaging that requires very little human intervention. Similarly, more expensive high-end systems can provide bar-code verification between the manufacturer bulk container and the drug-dispensing canister in the device, as well as an interface with the pharmacy information system.

Among the most commonly used options are hopper-based automated devices that repackage bulk oral solids into immediate containers. To operate these machines, the user fills the device's hopper with tablets or capsules from the manufacturer bulk container; the device then repackages the individual tablets or capsules. Likewise, liquid packaging equipment pumps the liquid medication directly from manufacturer bulk containers into immediate containers. Repackaging devices for both oral solids and liquids apply a bar-coded label to the medication packages.

As a bar-coding option, oral solid and liquid repackaging equipment is relatively inexpensive and easy to install. It also enables bulk purchasing of medications that may be less costly on a per dose basis than medications bar-code labeled by the manufacturer or repackaged by a distributor. However, the acquisition expense is a tradeoff for the pharmacy labor required to repackage and the potential safety gains inherent in packaging with manufacturer-applied bar codes.

The disadvantages of this option are few but significant. Inhouse repackaging requires a trained operator, as well as attention to a critical quality assurance process. Also, according to USP 26 minimum standards for unit dose repackaging, when hospitals repackage manufacturer bulk medications, the expiration or beyond-use date decreases. With the latest set of standards, the beyond-use dating of oral solids is one year or the manufacturer's expiration date, whichever is less, if the highest-quality packaging materials (class A) are used. Class B packaging requires six-month dating or one fourth of the manufacturer's expiration date, whichever is less.

Overwrapping. Automated overwrapping systems place a manufacturer immediate container into a bar-code-labeled pouch or bag. This

option is typically used more with vials, syringes, and ampuls than with tablets and capsules.

Only a few devices are commercially available for overwrapping medications, and the process is fairly cumbersome for the individual hospital. When one pharmacy in an integrated delivery network repackages medications for all hospitals in the system, overwrapping may be an effective solution. However, the ability to do multifacility packaging may depend on the board of pharmacy regulations in each state. Some states frown on this practice and classify repackaging for multiple sites as manufacturing, which requires a special license and adherence to federal manufacturing regulations.

Disadvantages of automated overwrapping systems are the space-consuming footprint of the equipment and the substantial up-front capital expense. Also, overwrapping can cause problems with unit-based dispensing cabinets, as the size of the overwrap may make it difficult to store the medication in certain types of drawers and pockets. Some overwrapping is necessary with robotic dispensing, although the packaging is often outsourced.

Manual bar coding. The more manual the repackaging process, the more vulnerable it is to human error. To reduce the risk of introducing error into labeling, the pharmacy should study and adapt sound quality assurance practices for repackaging. Hospitals should extract best practices from current GMP standards to safeguard their processes. Furthermore, manual labeling ought to be limited to medications that cannot be addressed by the aforementioned methods. There are several software applications on the market that make it possible to print and manually affix bar-coded labels to packages that cannot be bar coded by other means. This method works well for vials, syringes, ampuls, multidose containers, i.v. solutions and any other extemporaneously prepared medications.

A label-generating application capable of bar coding can be used in conjunction with either laser-quality or thermal-transfer printers. Thermal-transfer printers may be preferred, since label stock can be purchased in rolls rather than as the sheets required by a laser printer. However, the most appropriate print option will be determined by the label size needed by the item to be repackaged. Pharmacists may find that they have to use both types of labels. It is important that the pharmacy closely monitor printer ink level; faint bar codes pose scanning problems at the bedside.

Labels should contain medication names (both generic and trade names when appropriate), strength and volume, container size, expiration date, lot number, and manufacturer, in addition to the bar code that will contain the NDC. Careful attention should be given to ensuring that important elements of the manufacturer label are not concealed when the bar-code label is affixed to the immediate container.

Batch bar coding—generating large batches of labels and manually applying them to medications—is easily and inexpensively implemented and may act as an interim solution that can be scaled back as the hospital procures more bar-coded immediate containers from manufacturers or until the pharmacy acquires repackaging equipment to automate labeling.

Manual bar coding is labor-intensive, but, when it is used in conjunction with a BPOC system, the need for additional labor may be offset by streamlined medication crediting. BPOC systems are able to interface with hospital billing systems to allow the pharmacy to charge at the time of drug administration. This feature reduces pharmacy reliance on the manual crediting of patient accounts for medications not administered, thereby eliminating labor dedicated to crediting.

Outsourcing. Hospitals can consider outsourcing bar-code-labeling activities. Drug wholesalers offer programs to overwrap medications that can reduce the cost of pharmacy repackaging, free up inventory, and help pharmacies avoid potential errors.

The advantage of outsourcing is obvious: Drugs are either repackaged before arriving at the pharmacy or repackaged and labeled onsite by contract personnel. Internal quality-control processes should be established when the pharmacy uses outsourcing of repackaging. Outsourcing of repackaging is not subject to GMP standards and may present a higher risk of error. Another tradeoff with outsourcing is added expense per dose.

Critical factors for successful bar coding

Universal bar coding. Patient safety is best achieved when virtually all medications are bar coded. The scarcity of manufacturer-applied bar codes on immediate containers requires the pharmacy to affix bar-code labels to up to 65% of doses. Repackaging and labeling of solutions may present challenges for some medications. A small percentage of infrequently used medications may not be candidates for repackaging (e.g., oral antineoplastic agents may be incompatible or unsafe when used with the packaging material). Nonetheless, appreciable and immediate gains in patient safety can be realized by prioritizing the bar-coding effort by medication. Hospitals are encouraged to begin with a review of high-risk and high-use medications so that a BPOC system can immediately address the most prominent threats to patient safety. Although the typical hospital pharmacy has a formulary consisting of 2000–3000 line items, the pharmacy can achieve immediate gains in patient safety by bar-code labeling its top 500 most commonly used drugs. Expansion of the bar-coding effort should contin-

ue from there to ensure that virtually all medications sent to the point of care are bar-code labeled.

Readability. From a technical standpoint, the success of bar-code identification is determined by the readability of the printed bar-code label on the object being scanned. Special attention should be given to the correct curvature, location, and orientation of the bar code once it is affixed to or printed on an object.

Curvature. The most important factor in readability is curvature. Curvature should be minimized whenever possible. If the curvature of the bar code is too great as it wraps around the patient's wrist, it may not be readable with the scanner. This is a common problem encountered when patient identification wristbands include bar codes that wrap around the wrist. Hence, the preferred orientation for the bar code is vertically on the identification band.

The same is true for cylindrical medication containers, such as ampuls, vials, and syringes. The bar code should be placed vertically on the cylinder. If a bar code wraps around the cylinder, the beginning or end of the bar code may not be scannable. RSS may yield the highest degree of readability when curved surfaces are involved.

Placement. The bar code should be located where it is most easily accessible. For example, locating a bar code on the back of a nurse's name badge is not advisable, since this requires the nurse to turn the name badge over every time he or she scans it. In addition, the nurse's hands are often filled with charts, medications, and the scanner itself, so the ease of scanning the identification tag is important. The more difficult it is for nurses to scan items, the more likely it is that they will work around the process.

Orientation. The orientation of the bar code also plays a role in usability. Placing a nurse's identification bar code vertically on the front of the name badge has proven to be more ergonomic, while improving targeting accuracy during scanning. Like patient identification, caregiver log-on and identification may be better served in the future by biometric identification devices.

Deliberate attention to these factors will greatly increase the effectiveness of the BPOC system and foster more rapid acceptance by nurses. When scanning becomes difficult or cumbersome for the nurse, "work-arounds" may evolve. For example, poor bar-code placement on the wristband may require the nurse to contort the patient's arm and make several attempts before successfully scanning the identification code. Caregivers have been known to carry a key-ring-like collection of patient-identifying bar codes that they scan as an alternative to disturbing patients. This work-around compromises a critical five-rights check—the right patient—and invalidates the system's data. Improper use can jeopardize patient safety and hinder quality improvement.

Bar-code mapping. Pharmacy computer systems have adopted the NDC as a primary identifier for drug products. This may result in the NDC remaining static even when the product changes; thus, the actual product stocked may no longer be represented. Furthermore, purchasing from wholesalers may result in periodic substitution of one vendor's product for another, further distancing the NDC of the actual drug used from the NDC recorded in and used by the pharmacy information system.

It is imperative that BPOC systems provide a rich mapping function that allows the system to recognize these changes. Part of BPOC system setup includes mapping each product bar code against the corresponding formulary item in the system. Once the initial mapping is completed, new items can be mapped as part of procurement. Robust BPOC systems provide an easy way to determine if a bar code has already been mapped and allow mapping multiple bar codes against the same formulary item to accommodate variations in product availability. In addition, there should be a process whereby a nurse who discovers a medication that has not been mapped during scanning can alert the pharmacy.

Bar-coding policies and procedures. Internal bar-coding efforts require that appropriate policies, procedures, checks, and controls be in place to reduce the opportunity for error to be introduced into the medication-use system. The staff must be involved and adequately trained in all bar-coding processes. To ensure labeling accuracy, a step of scanning the medication bar code to test the bar code label should be added to the standard pharmacy checks. Bar-code verification should be the last step in repackaging and labeling to confirm that the correct bar code has been placed on each immediate container. Access to a bar-code scanner and the BPOC software program in the repackaging area is critical to ensuring that this step occurs without fail.

Cost-effectiveness and return on investment

A tradeoff exists between the capital acquisition cost and the labor required to execute any of the bar-code-labeling solutions described in this article. Staffing costs associated with medication bar-code labeling vary with the extent of automation used by each pharmacy, but all processes require some amount of pharmacist and pharmacy technician time. Typically, pharmacy bar-coding operations require the addition of one full-time-equivalent pharmacy technician position, as well as 30 minutes per day for a pharmacist to check the repackaging work.[21] While more automated solutions require greater up-front investment, they can reduce ongoing labor costs. Other labor savings inherent in BPOC systems, such as the elimination of

clerical work to credit unused medications, can offset the additional labor needed to bar code medications.

A bar-coding system may yield financial gains as well. On average, a preventable adverse drug event lengthens a patient's stay by 2.2 days and costs $4685.[28] A simulation of the combined effect of BPOC systems, computerized physician order entry, automated dispensing technology, and clinical decision support systems in a large hospital reduced medication error rates and associated adverse drug events by over 26%, representing a saving of up to 1226 days of hospitalization and $1.4 million in associated costs annually.[29]

Discussion

In this era of heightened awareness of medical errors, health systems are recognizing the role of information technology in error avoidance and outcomes improvement. Health systems are carefully reviewing policies and procedures and implementing proven best practices. Through vigilant application of quality improvement programs, institutions are embracing technology as a critical component of their patient safety agenda.

Each organization must evaluate its own clinical performance to identify the source of risk factors in its medication-use process. Each technological option poses unique implementation, cultural, and change-management hurdles. For many health systems, analysis will reveal a potential for patient safety gains through the implementation of BPOC technology. For organizations that pursue this solution, bar-code labeling is the price of admission.

Affixing the bar code to patient identification bands and caregiver badges is relatively straightforward with the aid of software from a variety of vendors. Placing bar codes on the immediate-use medication container is more complex. Options to consider include type of bar code (medication specific or patient specific) and selection of the appropriate bar-code identifier (NDC or medication mnemonic or drug code) on the basis of the type of medication (unit dose tablet or capsule, vial, syringe, multiple-dose item, plain i.v. solution, or compounded i.v. solution). In addition, the placement of the bar-code identifier (on the unit dose tablet or capsule as it is repackaged, on the i.v. label as it prints, on the patient label as it prints, or on a small, auxiliary label printed from bar-code-generating software) plays an important role in the effective use of bar codes at the point of care.

The ultimate solution, which will vary by health system, will be a combination of these options on the basis of the bar-coding equipment available, pharmacy dispensing practices, the volume of unit dose medications sent to nursing, and patient safety considerations.

Conclusion

By bar coding patient identification tags, caregiver badges, and immediate-container medications, health systems can substantially increase patient safety during drug administration.

References

1. The effect of barcode-enabled point of care technology on patient safety. Solana Beach, CA: Bridge Medical; 2002 Sep.
2. Hokanson JA, Keith MR, Guernsey BG et al. Potential use of barcodes to implement automated dispensing quality assurance programs. *Hosp Pharm.* 1985; 20: 327-37.
3. Nold EG, Williams TC. Barcodes and their potential applications in hospital pharmacy. *Am J Hosp Pharm.* 1985; 42: 2722-32.
4. Barry GA, Bass GE, Eddlemon JK et al. Bar-code technology for documenting administration of large-volume intravenous solutions. *Am J Hosp Pharm.* 1989; 46:282-7.
5. Lefkowitz S, Cheiken H, Barhart MR. A trial of the use of bar code technology to restructure a drug distribution and administration system. *Hosp Pharm.* 1991; 26:239-42.
6. Meyer GE, Brandell R, Smith JE et al. Use of bar codes in inpatient drug distribution. *Am J Hosp Pharm.* 1991; 48:953-66.
7. Longe K. The status of barcodes in hospitals: a survey report. Hospital Technology Series. Chicago: American Hospital Association; 1989:8.
8. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer health care system. Washington, DC: National Academy Press; 1999:195.
9. Malcom B, Carlson RA, Tucker CL et al. U.S. Department of Veterans Affairs: eliminating medication errors through point of care devices. Paper presented at 2000 Healthcare Information and Management Systems Society Conference. Dallas, TX; 2000 Apr.
10. Puckett F. Medication management component of a point of care information system. *Am J Health-Syst Pharm.* 1995; 52: 1305-9.
11. Johnson CL, Carlson RA, Tucker CL et al. Using BCMA software to improve patient safety in Veterans Administration medical centers. *J Healthc Inf Manage.* 2002; 16 (1):46-51.
12. Grasha AF. Psychosocial factors, workload and risk of medication errors. *US Pharm.* 2002; 26:HS52-71.
13. SNX: the barcode mechanics. www.snx.com/mechanics.html (accessed 2001 Apr 28).
14. Patterson ES, Cook RI, Render ML. Improving patient safety by identifying side effects of introducing bar coding in medication administration. *J Am Med Inform Assoc.* 2002; 9(5):540-53.
15. Medication safety self-assessment, 2000. Huntington Valley, PA: Institute for Safe Medication Practices.
16. American Society of Health-System Pharmacists. National survey of pharmacy practice in acute care settings: dispensing and administration—1999. *Am J Health-Syst Pharm.* 2000; 57:1759-75.
17. Machine-readable coding. In: Deffenbaugh JH, ed. Best practices for health-system pharmacy. 2002–2003 ed. Bethesda, MD: American Society of Health-System Pharmacists; 2003:4.
18. National Coordinating Council for Medication Error Reporting and Prevention. Promoting and standardizing bar coding on medication packaging: reducing errors and improving care. Adopted June 27, 2001. www.nccmerp.org/index.htm?http://www.nccmerp.org/rec_010627.htm (accessed 2001 Jul 10).
19. National Alliance for Health Information Technology. Prospectus. June 2002. www.nahit.org/content/prospectus.pdf (accessed 2002 Aug 12).
20. Food and Drug Administration. Barcode label requirements for human drug products. *Fed Regist.* 2001; 66:61173.
21. Premier to require barcoding for hospital pharmaceutical products offered under its group purchasing contracts. Premier, Inc., news release. Chicago, IL; 2001 Dec 20.
22. Novation releases guidelines regarding unit-of-use barcoding on contracted products. Novation news release. Solana Beach, CA; 2001 Dec 10.
23. Thompson CA. FDA to develop rules for mandatory bar-code labels. *Am J Health-Syst Pharm.* 2002; 59:107-12.

24. ISMP survey shows drug companies providing fewer unit dose packaged medications. *Med Saf Alert.* 2002; Mar 6.
25. McGovern K. 10 Golden rules for administering drugs safely. In: Preventing medication errors. Springhouse, PA: Springhouse; 1994:2-3.
26. Puckett F. Medication-management component of a point-of-care information system. *Am J Health-Syst Pharm.* 1995; 51:1305-9.
27. U.S. Food and Drug Administration. Bar code label requirements for human drug products. Hearing record from a public meeting held on July 26, 2002. www.fda.gov/cder/drug/MedErrors/default.htm (accessed 2002 Aug 6).
28. Bates DW, Spell N, Cullen DJ et al. The costs of adverse drug events in hospitalized patients. *JAMA.* 1997; 277:307-11.
29. Anderson JG, Jay SJ, Anderson M et al. Evaluating the capability of information technology to prevent adverse drug events: a computer simulation approach. *J Am Med Inform Assoc.* 2002; 9:479-90.

Glossary

Packaging terms

Manufacturer bulk container: A manufacturer-packaged unit containing multiple tablets, capsules, or large-volume liquid medications.

Manufacturer immediate container: With respect to oral solid medications, the blister for single pills, pouch for multiple pills, or bottle for bulk oral solid pills; with respect to liquid medications, any size of bottle, ampul, vial, syringe, tube, or canister holding the liquid medication, whether a pharmacist prepared the dose to match the order exactly or the medication requires additional preparation by a nurse before administration.

Manufacturer unit dose package: For oral solid medications, generally a single tablet or capsule packaged in a pouch or blister; for liquid medications, the smallest-volume container that may or may not contain the exact dose for the patient; for injectable medications, the smallest-volume ampul, vial, or syringe dispensed by the pharmacy. *Preferred to "unit dose package."*

Ordered unit dose: A ready-to-administer patient-specific dose of medication that exactly matches the dose ordered by the prescriber. This may or may not correspond to the manufacturer unit dose package. *Preferred to "unit dose package."*

Patient-specific bar code: A bar code placed on intravenous solutions with patient-specific additives, partial doses of medications, pediatric doses, extemporaneous preparations, and so forth. Patient-specific bar codes, like license plate numbers, do not contain descriptive information but rather provide a reference number that a computer uses to look up associated descriptive data.

Unit-of-use package: A medication supply for a course of therapy, such as 21 tablets for 1 tablet three times a day for one week or 96 tablets for 1 tablet four times a day for 28 days. *Often confused with ordered unit dose.*

Identifier terms

Bar code: A machine-readable identifier utilizing a number of printed bars and spaces of various widths to encrypt and carry data.

Composite Symbology: A multitiered machine-readable code consisting of a micro portable data file (PDF) placed on top of a Reduced Space Symbology (RSS) bar code. The PDF consists of several thinly sliced RSS symbols stacked vertically. While RSS may be used as stand-alone identifiers, the PDF component cannot function independently. In the Composite Symbology bar code, the primary data (national drug code [NDC]) will reside in the RSS, and the secondary data (lot number and expiration date) will reside in the upper PDF portion. Composite Symbology codes can be read by current charge-coupled-device (CCD) scanners once software upgrades are applied.

Content: The information encoded in the identifier. For medications, this usually corresponds to NDC, expiration date, and lot number.

Data format: The order in which the data elements representing each content item are arranged within the identifier.

Linear bar code: A bar code that is read with an infrared beam in a linear fashion. A bar code has vertical redundancy such that a horizontal scan of the top portion of the code reads the same data as a scan along the bottom of the bars. This facilitates a consistent first read of the data. Code 39 and code 128 are representative and have been the most common bar codes used in health care.

Machine-readable identifier: Any encoded identifying mark representing data that can be read with a computerized reading device, such as a scanner or imager.

Reduced Space Symbology: A compact linear symbology designed for smaller items, including blisters, ampuls, vials, and syringes.

Symbology: The manner in which a machine-readable code is written. Scanners or imagers may be programmed to read multiple symbologies and data formats.

Two-dimensional (2-D) symbology: Identifiers that are able to encode high-density data in tight spaces. The most common 2-D symbology emerging in health care is DataMatrix; it is approximately 30 times smaller than a code 39 bar code representing the same data. 2-D identifiers are not bar codes. Their unique structure requires that they be read with imaging devices rather than linear CCD scanners.

Reader terms

Bar-code scanners: Commonly known as linear CCD scanners, these devices may be programmed to read any linear code. Software programs the scanners to read the multiple symbologies and formats necessary. Scanners may be tethered or wireless "guns" or embedded in wireless hand-held devices. With software upgrades, standard scanners may be programmed to read RSS and Composite Symbology. They are not upgradable to read 2-D codes.

Imagers: Devices required for reading 2-D identifiers and capable of reading linear bar codes. Unlike scanners, imagers do not require the user to pass the reader over the surface of the bar code. Instead, the imager reads the 2-D code similarly to how a camera would take a picture.