BY ELISABETH PENA

As the FDA proposes a rule to require bar coding on almost all medications and blood products, the pharmaceutical and hospital industries are **moving forward with efforts to incorporate bar codes on unit-dose packages of drugs as a way to prevent hospital medication errors**. But challenges — including a lack of standards and questions about technology — need to be overcome before complete point-of-care automation can be realized.

SCANNING To Save Lives

Almost four years ago, a report by the Institute of Medicine made headlines by calling attention to the need to address medical errors in the U.S. healthcare system. The report found that between 44,000 people and 98,000 people die in hospitals each year as a result of preventable medical errors. The issue is no less critical today, especially when one considers the highly publicized incident in February when a 17-year-old girl died two weeks after she mistakenly received organs with a different blood type during a heart-lung transplant operation at Duke University Hospital.

Deaths from medication errors that take place both in and out of hospitals — more than 7,000 annually — alone exceed those from workplace injuries, according to the IOM report. The majority of medical errors do not result from individual recklessness, the IOM report found, but

John Combes

A BARRIER TO USING BAR CODING AT THE POINT OF CARE IS THE ABSENCE OF THE BAR CODE ON THE UNIT-DOSE PRODUCT. ONLY ABOUT 30% OF THE PRODUCTS RIGHT NOW HAVE BAR CODES ON THEM THAT ARE USEABLE AT THE POINT OF CARE.

from basic flaws in the way the health system is organized. Stocking patient-care units in hospitals, for example, with certain full-strength drugs — even though they are toxic unless diluted — has resulted in deadly mistakes. And illegible writing in medical records has resulted in administration of a drug for which the patient has a known allergy.

Four years ago, the report's recommendation was that hospitals and healthcare organizations should implement proven medication safety practices, such as using automated drug-ordering and bar-coding systems.

The Food and Drug Administration also has recognized this critical situation, and as this issue went to press, issued a proposed requirement for bar codes on all pharmaceutical products, excluding samples, to reduce the number of medication errors in hospitals and other healthcare settings.

Of the IOM's estimates for medical errors, agency officials believe that 30% to 50% of those deaths are associated with errors involving the use of FDA-regulated medical products, drugs, vaccines, blood and blood products, and medical devices. The agency held a public meeting July 26, 2002, to solicit comments about developing a regulation requiring bar-code labeling for human drug and biologic products. The purpose of the proposed regulation is to reduce the number of adverse drug events, including deaths that occur every year because of medication errors. The FDA has released its proposed regulation for comment and will issue a final rule by the end of the year.

The benefits that the use of bar coded unit-dose products could bring to the healthcare system in the United States are virtually undisputed. A small number of hospitals and purchasing groups already require that the pharmaceuticals they buy and administer be bar coded, and others have plans to make this a requirement. Manufacturers also are recognizing the need for bar codes and are beginning to put bar codes on their unit-dose packaging. But to effect a change across all sectors will require significant investments in technology and staff training, and perhaps a push from the FDA.

Industry experts agree that the problems surrounding medication administration could be greatly reduced with the inclusion of a bar code on the product package that is opened at a patient's bedside.

"If one looks at the medication administration system, it is made up of prescribing, dispensing, and administering," says John R. Combes, M.D., chairman of the National Coordinating Council for Medication Error Reporting and Prevention and senior medical advisor of the Hospital & Healthsystem Association of Pennsylvania.

"And 39% of the medication errors occur in the prescribing phase, 11% in the dispensing phase, and 38% in the administering phase," he says. "Another 12% of errors are due to verification and transcription errors, which are in the dispensing phase but would not be affected by bar codes. So clearly, almost 50% of medication errors could be avoided with bar coding."

Dr. Combes believes that in an ideal situation, a health practitioner can scan the medication, scan a bar code on the patient's wristband, and even scan a bar code assigned to the person giving the medication to make sure that the right drug is given to the right patient at the right time through the right administration route and in the right amount.

PROVEN RESULTS

Although the number of hospitals that have the capability to read bar codes at the site of patient care is low, hospitals that do have the system in place report measurable results. The Children's Medical Center of Dallas has been working for about six years to automate its medication process. In March 2001, the hospital began rolling out bar coding on point-of-care oral and injectable products and more recently installed a bar-coding system on its IV pumps.

"The program that was started in March 2001 has reduced our errors by a third," says John Tourville, Pharm.D., department director for pharmacy at Children's Medical Center of Dallas. "Through automation in the pharmacy with bar coding, robotics, and delivery improvement, we've been able to cut errors in half. We cut errors in half again with the point-of-care system. We believe the bar coding on the IV pumps will cut errors again in half."

The hospital's recent advance, bar-coded IV bags and corresponding bar-coded reading pumps, was a joint effort between the hospital and B. Braun Medical Inc.

With B. Braun's Outlook Safety Infusion System, the prescribed medications come from the pharmacy bar coded. Each patient has a bar-coded name band and the clinician who is administering the medication also has a bar-coded name badge. The clinician scans the three bar codes and the pump programs itself automatically.

Dan Thomas

ELIMINATING MEDICATION ERRORS CAN LEAD TO COST REDUCTIONS THROUGH THE ENTIRE SYSTEM. A SIDE BENEFIT OF BAR CODING COULD BE BETTER DATA CAPTURE OF BILLING INFORMATION.

"Through the use of the B. Braun Outlook Safety Infusion System's bar-code technology, the clinician ensures medication administration safety by matching the right medication to the right patient," says Louise Baran, marketing manager of nursing at B. Braun Medical Inc. "The Outlook's DoseScan technology further ensures safety by notifying the clinician when institution-defined dose limits are exceeded."

Dr. Tourville says this system also allows staff to download from the hospital's main system all the data that the pump needs to correctly load itself with infusion parameters. The pump then sends information back into the hospital system as it is infusing.

"Errors with IVs and IV pumps account for 35% of our big errors," Dr. Tourville says. "With this bar-coded pump system, we actually have an ongoing activity between the systems; it is that last great hurdle for our bar-coding project at the bedside."

Because only 35% of all drugs administered at the bedside contain a bar code, The Children's Medical Center of Dallas repackages many of the pharmaceuticals it receives and applies bar codes to the new packages for use by the hospital staff.

"We are still doing a bulk of the bar coding ourselves; we commit two pharmacists and a couple of technicians to putting bar codes on products," Dr. Tourville says.

"For example, when ampules of morphine come in we stick a bar code on each ampule and we use a good manufacturing process to double check and triple check everything," he says. "Once the bar code is put on the product, we rely on that code. I believe in the next two years, manufacturers will assume much of this responsibility."

A few buyers also have worked to support bar coding. Novation, a supply-chain management company serving VHA Inc. and the University HealthSystem Consortium, requires all pharmaceuticals under its private Novaplus label to be bar coded at the unit-of-use level. Additionally, effective with the 2004 pharmacy portfolio re-bid, all Novation contracted pharmaceuticals will be required to have bar coding on unit-of-use packaging.

"The good news is that all of our suppliers want to do this because they are getting the same input from their customers and they know that some form of regulation will be coming from the FDA so they are very in tune to adhering to our standards," says John H. Riddick, director of QA/RA and supplier certification at Novation.

He says the suppliers he deals with have not shown any resistance to Novation's bar-coding policy, but they do question what technology or symbology to use.

Mr. Riddick says Novation will wait until the FDA issues a final requirement before deciding what it will require on the products his group buys. Currently the group has told the suppliers to use any technologically readable bar code.

"This has worked out great in every area except for the pharmaceutical products with very small vials," he continues. "With the very small vials, the FDA requires human readability, where everything on the label must be able to be read. There is so much on the label already that its tough to have any space for even the smallest bar code."

The Veterans Health Administration, which provides federal benefits to veterans and their dependents, also established a mandate for the installation and implementation for bar-code medication administration at Department of Veterans Affairs' medical centers by November 2002.

The use of a bar-code system has been reported to enable a North Chicago VA Medical Center to reduce the occurrence of medication errors by 86%. The group's bar-coding initiatives earned it the 2002 Pinnacle Award for the Institutional category from The American Pharmaceutical Association Foundation, and the Health Care Quality Alliance. The Institute of Medicine also recognized the Veterans Health Administration's efforts in a report titled Leadership by Example.

DRUG ERROR REPORTING

MedMARx, a national database for hospital medication error reporting, studied reported medication errors in 56 hospitals from January 1999 to December 1999. Here are some of their findings:

- **97%** of errors **DID NOT RESULT IN PATIENT HARM**, although **67%** of these errors **REACHED THE PATIENT**. Errors occurred most often at the **POINT OF ADMINISTRATION** (**40%**), rather than during prescribing (**11%**).
- **INSULIN AND ANTICOAGULANTS**, such as warfarin and heparin, were the drugs most likely to be **INVOLVED IN AN ERROR**.
- **OMISSION**, **IMPROPER DOSE**, and **UNAUTHORIZED DRUGS** were the three most frequently reported types of errors.
- **PERFORMANCE DEFICITS**, **FAILURE TO FOLLOW PROCEDURES** or **PROTOCOLS**, and **KNOWLEDGE DEFICITS** were the most frequent causes identified. Distractions, work load, and inexperience were cited as contributing factors.

Source: U.S. Pharmacopeia, Rockville, Md., "Summary of 1999 Information Submitted to MedMARx."

BARRIERS TO BAR CODING

Despite proven results and industry agreement that bar coding systems can benefit patients by increasing safety, transforming the medication packaging process of the industry's manufacturers and the medication distribution system of every hospital is not simple.

"Cost is the biggest barrier," says Dan Thomas, director of information technology, at RxCrossroads and MDI. "And manufacturers typically package drugs in a variety of facilities and we often don't see corporate standards for bar codes or even answers to the basic question of what the format should be and what information should be included. People are struggling with such questions as whether the lot number and expiration date should be included."

Additionally, the incompatibility of current information systems with bar-coding technology is a significant hurdle.

The team at the Children's Medical Center of Dallas knows the barriers to implementation through first-hand experience.

"One of the biggest barriers is the mentality that 'we've always done it that way' and 'we can't afford it,'" Dr. Tourville says. "We found that if we work on this piece by piece, each piece saves money and then we roll that money into the next piece."

In addition to cost concerns and working past a traditional mindset, once a decision is made to implement a bar-coding system, changes must be made by the hospital's nursing and physician staff as well.

"There has to be a tremendous change in mentality and work flow," Dr. Tourville says. "Point of care means that nurses now must document as they are going along instead of whenever they have time. Money wasn't the biggest issue for us — the biggest challenges were people changing and process changing."

SETTING STANDARDS

Once the decision to implement a bar-coding system is made, additional issues to be considered include what information the bar code will contain. The National Drug Code (NDC), which serves as a universal product identifier for human drugs, is the standard piece of information all groups agree should be included.

Each drug product listed under Section 510 of the Federal Food, Drug, and Cosmetic Act is assigned a unique 10-digit, 3-segment number. This number — the NDC — identifies the labeler/vendor, product, and trade package size. The first segment, the labeler code, is assigned by the FDA.

A labeler is any firm that manufactures, repacks, or distributes a drug product. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code identifies package sizes.

Before the FDA issued its proposed rule, only requiring the NDC number, many in the industry were concerned about what information should be included other than the NDC. Many believe the lot number and expiration date also are important pieces of information that should be included, especially for use in tracking recalled and out-of-date products.

But adding the lot and expiration numbers to the bar code can be a costly venture, which some say should be implemented at a later date.

Groups such as the American Society of Health-System Pharmacists (ASHP) advocate that the NDC, lot number, and expiration be included on all bar coded unit-dose pharmaceutical product packages used in hospitals.

"We have great expectations that the FDA will come out with a workable rule that mandates that pharmaceutical companies take this very seriously and provide all pharmaceutical products used in hospitals in unit-dose packages with bar codes containing NDC, lot number, and expiration date," says Kasey K. Thompson, Pharm.D., director of the Center on Patient Safety for ASHP. "This will show a great commitment to patient safety by the pharmaceutical industry."

Dr. Combes agrees that while the lot and expiration date are important pieces of information, their inclusion could be put off to begin the work necessary to get bar codes on unit-dose pharmaceuticals.

"Other groups have recognized that it will be a little more difficult to get the lot number and expiration date on the product since those have to be printed late in the manufacturing process and they require more dynamic printing, which is of concern in terms of the quality of the bar code," Dr. Combes says. "Most organizations recognize that the NDC should be included in the bar code immediately."

GETTING A HEAD START

Even as some hospitals and buyers have begun to work with using and requiring bar coding systems, pharmaceutical companies are not sitting idle. Pfizer is leading the way among pharmaceutical manufacturers with its initiative to use bar-code technology on its hospital unit-dose products. The new bar-code system identifies each Pfizer unit dose of product by its NDC, expiration date, and lot number in both machine and human readable format.

Richard Hollander

BECAUSE THERE IS NOT A LARGE CRITICAL MASS OF PHARMA COMPANIES PUTTING THIS INFORMATION INTO BAR-CODE FORMAT, THE HOSPITAL SETTING HAS NOT DEVELOPED THE COMPUTER SYSTEMS TO UTILIZE THE DATA.

The miniaturized bar code is applied to product containers at the time of packaging by Pfizer.

The bar-code technology used for Pfizer's products was developed in accordance with the Reduced Space Symbology (RSS) and composite code standards established by the Uniform Code Council (UCC). RSS bar codes are two-dimensional and significantly smaller than conventional linear bar codes.

"The issue, which prevented many drug manufacturers from putting bar codes on our blister packages, was that there was no widely accepted or utilized standard for bar-code symbology or data structure; we had a very difficult time trying to understand what direction to go because there was no standard established by

John Tourville

THE BIGGEST BARRIER TO BAR CODING IS THAT THERE ARE SO MANY CHALLENGES — EVERYBODY IS LOOKING FOR THAT ONE SILVER BULLET THAT WILL RESOLVE ALL THEIR PROBLEMS, AND THERE ISN'T ONE.

either manufacturing companies or by the hospital side of the business," says Richard Hollander, senior director and team leader of packaging services and global manufacturing at Pfizer.

"The challenge was how to fit all the information, not just the NDC, but also the lot number and expiration date, on our very small packages," Mr. Hollander says.

To address this challenge, Pfizer turned to the work that the UCC had been doing to develop RSS and composite code bar-code symbology, which seemed to work well with relatively small packages.

Another manufacturer that is working to begin unit-dose bar coding is Abbott Laboratories, which pledged in July 2002 to affix unit-of-use bar codes to all of its hospital injectable pharmaceuticals and IV solutions product lines by early 2003.

While Pfizer and Abbott are pioneers in the field of bar coding unit-dose products, Dr. Combes believes many pharmaceutical companies haven't begun to include bar codes because the hospital side of the business does not require them to do so.

"Manufacturers haven't gone to bar coding because there has been no demand to do so nor is there any requirement to do it," he says. "To prompt change, we believe that the best route would be to require manufacturers to include bar codes through FDA regulation and then encourage the use of them by hospitals and other providers."

READY OR NOT

Demand for change is low, many industry experts say, because most hospitals in the United States are not ready to use bar-coding technology.

A 1999 ASHP survey revealed that only 1.1% of U.S. hospitals use bar-code technology to scan a patient's identification wristband, a nurse's badge, and a prescribed drug at the bedside.

Pfizer executives recognize that the majority of hospitals were not prepared to use the bar codes on its products at this time.

"Because there is not a large critical mass of pharma companies putting this information into bar-code format, the hospital setting has not developed the computer systems to utilize the data," Mr. Hollander says. "And the hospitals can't really prepare, in terms of developing a database, until they understand what data they are going to get and in what format the information will be received."

Mr. Hollander says Pfizer was very focused on developing a standard for the industry for others to consider using.

As technologies improve and the spotlight on medication errors continues to increase, hospitals will feel pressure to upgrade their systems to improve patient safety.

THE FDA SPEAKS ...

As the push for bar coding has been gaining momentum, the industry has waited for the FDA to issue a requirement. In March, the FDA issued a proposed rule to require bar codes on all prescription drugs, excluding physician samples, as well as over-the-counter drugs that are commonly used in hospitals and dispensed pursuant to an order. For blood and blood components, the proposal would require the use of machine-readable information in a format approved by the Director of the Center for Biologics Evaluation and Research.

The regulatory group's proposal requires the linear bar codes to

BARRIERS TO BAR CODING

The costs to the manufacturer to place the bar code on the unit-of-use label are not insignificant, but much larger expenditures will have to be made by healthcare organizations to take full advantage of a bar-coded medication delivery system that can draw information from other existing systems for dosage limits, drug-drug interactions, drug-food interactions, laboratory values, allergies, and decision support.

The incompatibility of current legacy information systems is a significant obstacle to use of a bar-coding system, according to the National Alliance for Health Information Technology. The perceived need for customization of every system by providers and the need to demonstrate differentiation from other products by developers and manufacturers are the primary barriers to the widespread use of standards in healthcare IT. Other barriers include:

- **LEADERSHIP** understanding and commitment
- A healthcare organizational and professional culture that **PREVIOUSLY STRESSED UNIQUENESS** and customization
- Difficulty in **GAINING WIDESPREAD CONSENSUS** across a fragmented healthcare continuum
- **LEGACY INFORMATION TECHNOLOGY SYSTEMS** and the challenge of integrating different vendor hardware and software
- **FINANCIAL COST** of change/sunk costs/lack of capital
- Meaningful measures/ability to demonstrate a **RETURN ON INVESTMENT**
- Perceived **TRACK RECORD** of information technology
- Competing organizational **PRIORITIES** demanding resources and attention

Source: National Alliance for Health Information Technology, Washington, D.C. For more information, visit nahit.org.

contain, at a minimum, the drug's NDC number. The FDA intends to issue a final ruling by the end of this year, which will become effective three years after it is published.

Before the FDA's ruling, the industry speculated about what the agency's role in issuing bar-coding requirements should be and whether the group's role should extend beyond the compliance requirement into the details of the bar-coding technology.

"I don't think the government should mandate a standard, because then we will be stuck with it for the next 20 years," Dr. Tourville says. "Technology is evolving so fast that we will have 2D bar codes in four or five years. The groups that should mandate a requirement are the group purchasing organizations."

Mr. Thomas agrees the FDA should not play a role in setting the standards for bar coding.

"There already are a number of standards bodies and this isn't an area where the FDA should be imposing any immediate regulation, but the agency could serve a role in setting a timetable for manufacturers to be compliant," he says. "The problem is that bar coding is not a static technology. Today, a simple linear bar code that has basic information may within a few years be two-dimensional or may even be an imbedded chip that transmits data. The FDA shouldn't jump in and say 'companies do this,' because bar codes on a product are not going to do any good until the hospitals have systems in place to take advantage of the data."

As the industry begins to prepare for unit-dose bar coding, a group has been formed to, among other goals, explore bar-coding standards. The National Alliance for Health Information Technology (NAHIT), a group of about 50 organizations representing providers, purchasers, manufacturers, and standard-setting organizations, has set its mission to improve quality and performance through standards-based information systems.

The group supports the implementation of bar-coding requirements for all prescription and nonprescription medications and believes that bar codes should be included on the labels of all unit-of-use pharmaceutical packaging.

The NAHIT supports the inclusion of the NDC as the initial data element included in the bar code, with the inclusion of the expiration date and lot number added to the bar code as soon as it is technically feasible and phased in over a longer period of time. Although the bar coding of unit-dose products is seen as a great improvement to the medication error problem in hospitals, Dr. Thompson warns that it will not fix all problems. "Technology is just a tool," he says. "If we assume that technology will solve all our problems, problems will definitely follow." ✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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