More than 90% of the manufacturer-produced pharmaceutical packages arriving at the central pharmacies at Geisinger Health System's two Pennsylvania hospitals boast linear bar codes. That is pretty much true at hospital pharmacies throughout the U.S. David W. Jungst, RPh, PharmD, BCPS, Director of Pharmaceutical Care Services at Sarasota Memorial Hospital, confirms the omnipresence of linear bar codes on drugs reaching his central pharmacy. But Sarasota, again, like most hospitals, repackages a small number of non–bar-coded, unit-of-use packages—in Sarasota's case, at a co-op facility 60 miles away.

Manufacturers slap linear bar codes on most of their drug packages because of a 2004 FDA rule that went into effect in 2006. The 2004 FDA final rule said that drug manufacturers had to put the National Drug Code (NDC) via a linear bar code on all drug packages, with some exceptions. A report from the Institute of Medicine (IOM) 5 years earlier spurred the FDA's action. Its report, To Err is Human, said that preventable adverse events caused "at least 44,000 and perhaps as many as 98,000 deaths in hospitals each year." The report cited hospitalized patients receiving the wrong drug, sometimes because of confusion when two drugs had similar names, sometimes because of flawed systems and procedures and sometimes for various other reasons.

Over the past 6 years, hospitals have reduced those kinds of medication errors thanks to bar codes that pharmacists scan as the drug comes into the central pharmacy from the wholesaler. The bar codes are often scanned again when the floor nurses take the drugs out of automated dispensing cabinets on the way to the patient's bed, and sometimes once again at bedside, where the bar code on the drug package is reconciled with the bar code on the patient's wrist.

So, the 2004 FDA rule has been a rousing success, right? In one sense, yes—if we consider compliance by manufacturers and a reduction-in-errors yardstick—although "rousing" might be too strong a term. Bar codes have clearly helped reduce medication errors in hospitals, but the drop has been less than precipitous. Moreover, approximately 30% of hospitals do not have linear or any other type of bar-code scanners. Even pharmacy directors who appreciate scanner technology are quick to point out the shortcomings of linear bar codes.

"Are we satisfied? No," says Deborah Templeton, RPh, MHA, Vice President of Supply Chain Services at Geisinger, referring to the quality of bar codes reaching her facilities. She says that the pharmacy staff spends too much time determining whether the bar codes printed on the drug packages are readable. Unreadable bar codes are common on suppositories and intravenous (IV) solution bags, for example. Bar codes printed on the bottom of ointments become unreadable as the tube is rolled up when a dose is administered. Bar codes on inhalation drugs become covered up when the drug is inserted into a device for administration. Geisinger pharmacies, like other hospital pharmacies, must do a considerable amount of repackaging to overcome those problems.

Those drawbacks, and more, are in no way confined to Geisinger's two hospitals. "Those are all true stories," confirms Sarasota Memorial's Dave Jungst.

Almost every hospital in the U.S. has a drug-repackaging operation, either in-house or in a separate location, or it contracts with an outside repacker. Jon Lakamp, PharmD, BCPS, Executive Director of Mercy Clinical Support Services and Vice President of Pharmacy for Mercy Health System in St. Louis, which owns 31 hospitals in four states, says his company owns its own repackaging subsidiary, ROi Systems. Many liquids sold by manufacturers do not come in unit doses, for example, and are repackaged at ROi. In other instances, Mercy might want to purchase a drug that is bar-coded at the unit-dose level, but that drug would be considerably more expensive than a competing product without a bar code. Mercy therefore buys the less costly product and adds the bar codes to the unit doses at ROi.

Dr. Lakamp says about 65% of drugs purchased systemwide have linear bar codes. To the extent that Mercy must repack and reapply bar codes for the other 35%, extra costs are obviously involved. Moreover, the drugs bar-coded by ROi typically have a shelf life of 6 months to 1 year. That is considerably less than the 3- to 4-year shelf life of manufacturer bar-coded drugs, which require the manufacturer to meet longer FDA shelf-life requirements.

In 2004, the FDA admitted that its linear bar-code requirement was a compromise and a placeholder of sorts until more sophisticated technology and industry standards evolved. Technology and standards have now evolved, which is why the FDA announced last October 26 that it was considering updating the pharmaceutical standard for bar codes.

In its Federal Register notice to that effect, the agency cited President Barack Obama's Executive Order No. 13563, "Improving Regulation and Regulatory Review." The order, signed on February 2, 2011, requires federal regulatory agencies to consider strengthening, complementing, or modernizing rules when necessary. The FDA said it chose the bar-code rule as the first one to address. The agency plans to reassess the costs and benefits of the 2004 rule to determine whether it should be modified to take into account the availability of new technology.

A number of developments beyond the forward march of bar-code printing and scanning technology, as well as changes

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in standards at international organizations such as GS1, have also forced the FDA to blow the dust off the 2004 rule. Manufacturers will not be able to use linear bar codes, for example, because in 2015 they must start complying with a California rule that 50% of drugs must have e-Pedigrees on their unit-of-use labels. (The other 50% will be required in the following year.) An e-Pedigree must include the manufacturer, the drug’s trade or generic name, the quantity in the package, the container’s size, the expiration date, the lot number, the companies that handled the drug after it was produced, and other information. Pharmacies must be able to scan e-Pedigrees starting in 2017.

The California requirement has reverberated at the national level. The Prescription Drug User Fee Act (PDUFA) of 2007 required the FDA to develop standards for identifying, validating, authenticating, tracking, and tracing prescription drugs. Like the California e-Pedigree rule, the PDUFA requirement—which mandates standards, not compliance with those standards—goes beyond patient bedside safety objectives to the broader goal of improving the security of the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Although the PDUFA provision lacked a national mandate for compliance, drug manufacturers particularly are eager for either Congress or the FDA to establish a nationwide requirement so that they aren’t forced to package one way in California and another way in other states.

Manufacturers have been particularly outspoken about the need for the FDA to update the 2004 bar-code rule. Mark J. Goldberger, MD, MPH, Divisional Vice President of Regulatory Policy and Intelligence at Abbott Laboratories, says: “Abbott recommends that FDA not require one specific bar code type but instead select GS1’s approved data carriers. Using GS1 standards, manufacturers could choose the appropriate data carrier type for the package size and market.”

The drug-packaging standard at GS1 allows a linear, two-dimensional (2-D) bar code or a radiofrequency identification (RFID) tag.

Kendra Martello, Assistant General Counsel for Pharmaceutical Research and Manufacturers of America, argues that the FDA should drop the linear requirement entirely by 2016. “After 2016, only 2-D bar codes should be used, consistent with manufacturers’ migration to the use of 2-D bar codes for other applications,” she claims.

Manufacturers would like to print only 2-D bar codes on drug packages (i.e., probably Data Matrix Code) because they satisfy California’s requirement and those in some foreign countries. Aztec is another 2-D bar code that is used mostly in Europe, typically on airline and train tickets.

Dirk Rodgers, author of the blog RxTrace.com, says manufacturers of drugs that are marketed in countries such as France and Brazil will need to encode some data in 2-D bar codes, such as the global trade item number, lot number, and expiration date. Those companies are already in the process of adding that capability to all of their foreign packaging lines.

Therefore, imperatives from both foreign places and California are pushing the FDA to drop its linear requirement. Over the past few years, the agency has laid some tentative groundwork. It produced guidance in 2010 on a Standardized Numeric Identifier (SNI), which was also required by the 2007 PDUFA. The SNI, a unique combination of two numbers printed on a package label, identifies the drug inside the package. The FDA’s final guidance says that half of the SNI is the NDC, which is essentially unique for each drug made by each manufacturer. The second half is a unique serial number, generated by the manufacturer or repackager for each individual package. Although manufacturers viewed the voluntary SNI guidance as a step in the right direction, even having the SNI in a bar code would fail to meet California’s e-Pedigree requirement.

The FDA has made life a little easier for hospital pharmacies too. In the only change it has made so far to the 2004 bar-code rule, the FDA announced in 2011 that vaccine manufacturers could print 2-D Data Matrix bar codes instead of linear bar codes on their unit-of-use packages. Vaccines are a special case because of the National Childhood Vaccine Injury Act of 1986, which requires health care providers to report certain childhood vaccine-related adverse events to the Vaccine Adverse Event Reporting System.

To do that, says Mercy’s Jon Lakamp, pharmacies must manually record the lot number and expiration date on the package, where it is printed near (but not encoded in) the linear bar code. The 2011 FDA guidance that allowed 2-D bar codes on vaccines permits pharmacies to automate the recording of lot numbers and expiration dates. However, the published guidelines did not address the underlying shortcomings of linear bar codes, much less those of the NDC itself.

A host of problems is undermining the utility of the NDC. For example, when a manufacturer markets a new drug with a new NDC number, that number does not always get placed into the NDC database that is available via a pharmacy’s software. This omission causes problems for the hospital pharmacy, which cannot identify the new drug without performing some time-consuming software gymnastics.

Nancy Payne, RN, MA, Director of Compliance and Regulatory Affairs at Allina (which includes 11 hospitals and 80 clinics) explains:

Our electronic health record [EHR] vendor provided three symbologies that allow recognition of the majority of NDC bar codes. Approximately 20% of our product stock had a bar code that did not correspond to a standard symbology and could not be interpreted by our EHR system as a valid NDC. This required custom programming by our information systems support to interpret and validate the bar code back to its corresponding NDC.

Mark Neuenschwander, President of The Neuenschwander Company in Bellevue, Washington, adds:

It is crucial that the FDA revisit the NDC registry. Health care urgently needs a single, reliable, up-to-date, unambiguous database of all NDCs currently in the supply chain. It is equally important that no NDC be reissued after a drug manufacturer has discontinued its use. It is also imperative that this database be open and free. RxNorm is an example of such a database.

Linear bar codes also suffer from legibility problems. Robert Rack, President of BarCodeAmerica.com and Rack Design
Group, Inc., explains that a linear code can be made unreadable by a single line or a scratch through the code. “Due to the error correction built into Data Matrix, as much as 25% of the code might be wiped out before it becomes unreadable. Linear codes require large contrast differences between the bars and spaces. Data Matrix codes require only about a 25% contrast difference,” he adds.

A few hospitals already print 2-D bar codes in-house or send drugs to repackers for 2-D bar coding. That includes Brigham and Women’s Hospital in Boston, which helps develop the Health Industry Business Communications Council standard for 2-D encoding in health care. In fact, in 2003, the hospital adopted 2-D bar codes, using the Data Matrix symbology, even before the FDA issued its 2004 rule. Since that time, Brigham and Women’s has seen the increasing use of Reduced Space Symbology (RSS) by several of the generic manufacturers. RSS includes the lot number, expiration date, and NDC number. Stacked RSS symbology for the NDC number can be read by a linear scanner, and a 2-D scanner can be used for all three components.

Bill Churchill, MS, RPh, Chief of Service in the Department of Pharmacy at Brigham and Women’s Hospital, says the facility prints 2-D bar codes in-house on about 500,000 IV admixtures a year and sends another 180,000 oral medication doses annually to either SafeCor Health (in Massachusetts and Ohio) or Shamrock Medical (in Ohio), two contract repackers who also provide 2-D bar-code symbology. Those 180,000 doses include medications in fluid cups, droppers, oral syringes, overbags, pouch packs, and other containers. Brigham and Women’s Hospital dispenses about 7.5 million doses each year, most of them still having only linear bar codes. Interestingly, Mr. Churchill says that generic companies are more likely than brand-name companies to place 2-D bar codes on their drug packages.

Most of the hospitals that have bar-code scanners use laser-based readers, which work only with linear bar codes. If any player in the drug distribution chain opposes an FDA switch based readers, which work only with linear bar codes. If any player in the drug distribution chain opposes an FDA switch to 2-D bar codes, the use of the Data Matrix symbology, even before the FDA issued its 2004 rule. Since that time, Brigham and Women’s has seen the increasing use of Reduced Space Symbology (RSS) by several of the generic manufacturers. RSS includes the lot number, expiration date, and NDC number. Stacked RSS symbology for the NDC number can be read by a linear scanner, and a 2-D scanner can be used for all three components.

Besides dedicated data-capture devices and mobile computers, many of your standard phones, like the iPhone and Droids and others of that ilk, can become bar code readers for both 1-D and 2-D codes by a simple software download. Virtually any reasonably recent smart phone could be turned into a reading and mobile data-collection device. Perhaps even better, since virtually all of these devices are Bluetooth-enabled, a separate Bluetooth reading imager device could be linked to your smart phone. More importantly, since imagers have no moving parts like lasers do, they are likely to last at least three times as long before replacement is required.

Nord would the added cost to manufacturers be astronomical. “Small 2-D bar codes could readily be added to virtually any pharmaceutical or medical device by printing of static or unique [identifications] via either thermal transfer printing, laser ablation, or inkjet printing,” he adds.

Drug wholesalers probably represent the most skeptical sector in the distribution chain when it comes to 2-D bar codes. The Healthcare Distribution Management Association (HDMA), which represents the wholesalers, opposes any changes unless and until the FDA simultaneously requires application of the SNI in lieu of the NDC, as defined in the final SNI Guidance.

“HDMA is concerned that any change to the bar-code rule or guidance as a result of the current reassessment could have unintended and incongruent consequences on stakeholders’ interpretation of, and ongoing efforts to implement, FDA’s March 2010 Final SNI Guidance,” says Anita T. Ducca, Vice President of Regulatory Affairs at HDMA. The connection between the older use of 2-D bar codes and a reduction in hospital medication errors seems as certain as a slam dunk. Bill Churchill says that the bar-code verification system at Brigham and Women’s Hospital prevents nearly 7,500 medication errors each month.

He explains: “This is with the limited use of 2-D bar codes. With full implementation of this technology, we would expect the intercept number to be significantly higher.”

The use of 2-D bar codes on that hospital’s IV admixtures results in the interception of approximately 400 attempts by nurses who try to administer an expired drug each month. Certainly, in the 13 years since the IOM’s To Err Is Human report was published, too many medication errors are still occurring in hospitals. In November 2010, the Office of the Inspector General (OIG) released a report based on data from almost one million Medicare beneficiaries who were discharged from acute-care hospitals during October 2008. Of that group, 780 beneficiaries had experienced 128 adverse events. Of the 128 events, 40 (31%) were attributed to medication errors, 36 (28%) to patient-care errors, 33 (26%) to surgical errors, and 19 (15%) to hospital-acquired infections. Twelve adverse events (9%) were found to have contributed to the patients’ deaths. Seven of the 12 deaths were related to medical treatment, either the result of a wrong drug or a wrong dosage or inadequate treatment of known side effects. The most common type of medication-related death (in five patients) involved excessive bleeding from anticoagulants. Half of the medication-related deaths were deemed preventable, based on reviews of the data by physicians.

The 13.5% adverse-event rate projected that an estimated 134,000 Medicare beneficiaries experienced at least one event in hospitals during the 1-month study period. Some individuals had experienced more than one event.

In light of these findings, the 2004 bar-code rule probably has room for improvement in patient safety. A move to 2-D bar codes would also increase the operational efficiency of hospital pharmacies. Pharmacies today have no idea which patients have received recalled drugs or the locations of those recalled drugs in the hospital—because linear bar codes do not contain information about lot numbers. Bill Churchill says:

The ability to capture lot and expiration information as part of a normal scan would permit the now-impossible task of knowing what recalled lots of drugs may have been used on what patients. It will also help to locate expired medications in our 120 automated..."
dispensing cabinets and will likely reduce the incidence of expired medications, thus reducing the cost to the hospital. It would also make it very easy to implement electronic IV compounding record keeping by easily scanning and recording the lot and expiration dates as well as the product, diluents, and IV bag names, sizes, and concentrations in one bar code scan.

Could I make the argument we could pay for the capital investment in 2-D scanners with the savings from new staff efficiencies, reducing drug waste, better patient safety, and other improvements? Yes, I believe that I could make the case.

REFERENCES


