Thank You FDA for the Bar Codes

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The Food and Drug Administration (FDA) took a bold step with its proposed rule on bar codes. Tasked with protecting the public from medication harm, this proposed rule, if adopted, will do as much as anything in this agency's history to enhance patient safety through the safe administration of medications.

The FDA should be cheered for its effort, and all clinicians, providers and vendors must strongly support this proposal. If our goal is to provide the best and safest health care possible to patients, it is clear that this proposal is a great step forward.

For years, the use of bar codes on products has provided manufacturers, retailers and consumers with numerous benefits. These benefits are so obvious and universally recognized that it would be superfluous to review them in detail here.

Applying bar codes to medications offers the healthcare industry similar benefits in both efficiency and accuracy. Inventory management, shipping, packaging and tracking improve dramatically due to the simplicity and accuracy that applied bar codes provide.

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As proposed by the FDA, bar codes will be required on all prescriptions, some over-the-counter drugs and vaccines. According to the FDA, each bar code would, "at a minimum, contain the drug's National Drug Code number, which uniquely identifies the drug, its strength, and its dosage form" (2003). This delivers a means to accurately check medications before they are actually administered.

Although some organizations purchase medications that are bar coded by independent third-parties, this rule extends this capability to all hospitals and their patients, allowing for efficient bar coding of the medications at the point of manufacture, and before distribution.

The FDA estimates that bar codes will result in a 50 percent increase in the interception of medication errors, resulting in approximately 413,000 fewer adverse events over the next 20 years. This is probably a conservative number and does not include benefits from applying them in ambulatory settings and retail pharmacies. Linkage to a computerized provider order entry system further enhances this medication safety net.

The optimal system for safe medication management includes:

Computerized physician order entry with clinical decision support - Provides clinical advice to the physician at the time of medication ordering, performs drug checking using comprehensive medication databases, and accurately routes the medication order directly to the pharmacy for verification.

Computerized pharmacy information system and automated dispensing - As the medication order is received electronically, pharmacists focus on reviewing the order rather than interpreting and transcribing a handwritten, sometimes illegible, medication order. In turn, the electronic order can direct dispensing robots and cabinets that "read" the bar code to prepare and route the medication to the proper patient.

Bedside medication administration - Using bar-code scanning technology at the patient's bedside, nurses ensure the 'five rights' of medication administration: right patient, right drug, right dose, right route, and right time. In addition, care is automatically and accurately documented allowing for improved patient monitoring.

Such a complete system simplifies and automates processes while greatly reducing the potential for human error. These systems are inherently more reliable, and therefore safer.

As with any new rule there are associated implementation costs, including the cost of new bar code scanning equipment, pharmacy systems, dispensing units, medical databases, clinical data repositories and training. These additional costs are partially offset by the reduction in avoidable morbidity and decreased days in the hospital.

The FDA estimates savings of $41 billion over the next 20 years. Each organization will achieve its own level of savings, while many of the benefits, such as increased staff efficiencies, improved staff retention or more efficient use of infrastructure, will be difficult to quantify.
Even with these potential savings, healthcare organizations, especially in this era of declining revenue, need some financial assistance, possibly in the form of various reimbursement incentives.

Recently, the Institute of Medicine in their November 2002 report Fostering Advances in Health Care supported the government funding of demonstration projects to help identify best practices for implementing information technology systems. This new FDA rule offers a timely demonstration project that promises great benefits in the area of patient safety.

For those of us committed to patient safety and quality, we can only consider this a step forward. Thank you FDA.

More...

REFERENCES

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BIOGRAPHICAL SKETCH

Barry P. Chaiken, MD, MPH, Vice President of Medical Affairs, McKesson Information Solutions, has more than 16 years of experience in medical research, epidemiology, continuous quality improvement, utilization management, risk management, healthcare consulting and public health. Dr. Chaiken is currently on the Board of Directors of ABQAURP.