

Safe Medication Practices

Barbara Wells and Sylvia Hyland

Contributions to this column are prepared by the Institute for Safe Medication Practices Canada, a key partner in the Canadian Medication Incident Reporting and Prevention System.

BAR CODING — RAISING THE BAR ON MEDICATION SAFETY

On February 25, 2004, the US Food and Drug Administration (FDA) finalized a rule requiring bar codes on the labels of most prescription drugs and certain over-the-counter drugs.¹ The bar code, to be presented in linear format, must encode the drug's unique 10-digit National Drug Code (NDC) number and must appear on the drug's immediate container and the outside container or wrapper (unless the wrapper is transparent). This rule came into effect on April 26, 2004. New drug products must comply with the bar code requirement within 60 days after their approval date, and drug products that received approval before the effective date were given 2 years to comply.² The presence of machine-readable codes in a standardized format on all medication packages and containers can reduce medication dispensing errors and administration errors when used in conjunction with a bedside, point-of-care scanning system and a computerized database. According to the FDA, use of a bar code system is expected to reduce by 50% the occurrence of preventable adverse drug events that originate in the dispensing and administration stages of the medication-use process.²

The FDA considered other automatic identification technologies such as radiofrequency identification chips and 2-dimensional symbologies (such as DataMatrix). However, given that linear bar codes are a proven, established, and relatively user-friendly technology, one that is generally less expensive than newer emerging technologies, the FDA decided to support this particular technology. Mandating the use of a single technology (rather than allowing for flexibility) was also considered

necessary to encourage hospitals and others to implement bar code-based systems. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) has developed recommendations for promoting and standardizing bar coding on medication packaging.³ Although the US Institute for Safe Medication Practices and other organizations interested in patient safety advocated for inclusion of the lot number and expiry date in the product bar code, the FDA declined to mandate this information, stating that the additional safety benefits were insufficient to warrant the associated implementation costs.

Earlier this year, ISMP Canada was approached by several pharmaceutical companies seeking guidance on the inclusion of bar codes on labels for prescription drug products for the Canadian market. The feasibility and/or desirability of adopting or adapting the FDA requirements for Canadian guidelines warrant consideration. Is the framework developed for implementation in the United States relevant to the Canadian health care system and, further, does it adequately meet the needs of Canadian patient safety stakeholders? Similarly, what can Canada learn from pharmaceutical bar coding initiatives under way in other jurisdictions such as Japan?

ISMP Canada is leading an initiative to develop a guidance document for the automatic identification of pharmaceuticals in Canada. Sponsors for the project include Apotex, HealthPRO Procurement Services, MedBuy, Novopharm, Sandoz Canada, and Pfizer Canada. A discussion paper that is now in development will review current Canadian and international initiatives and will outline options for consideration. The discussion paper will be used to facilitate stakeholder discussions on determining automatic identification



guidelines to best meet the needs of Canadian health service organizations looking to implement medication dispensing and administration technologies to improve patient safety. Together with Health Canada and the Canadian Patient Safety Institute, an invitational Stakeholder Forum is planned for early 2007. Stakeholders will include end-users, the pharmaceutical industry, information systems vendors, regulators, electronic standards-setting organizations, and others.

Readers who are interested in reviewing the discussion paper or receiving project updates can contact Barbara Wells by e-mail at bwells@ismp-canada.org

References

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