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Promoting and Standardizing Bar Coding on Medication Packaging: Reducing Errors and Improving Care

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Errors resulting in patient injury and death are occurring in hospitals at significantly high and unacceptable numbers. In 1999, the Institute of Medicine (IOM) published a report, *To Err Is Human: Building a Safer Health System*, calling public attention to the important issue of patient safety. According to the IOM, as many as 98,000 Americans may die annually because of medical mistakes made by health care professionals. A significant number of these deaths can be attributed to medication errors. The diversity of causes of errors will require many solutions. The most immediate and far-reaching may be in the area of technology implementation.

One way patient safety can be improved by information technology is through the use of machine-readable codes such as bar codes in a standardized format on all medication packages and containers. A scannable bar code can help guarantee that the right drug and dose are being administered to the correct patient.^{1,2,3} Technology developments allow for increased information to be imbedded within a bar code and makes coding of smaller packages possible.

The National Coordinating Council for Medication Error Reporting and Prevention organized a one-day conference on August 7, 2000, and invited individuals representing end users, the pharmaceutical industry, information systems vendors, regulators, and electronic standards-setting organizations. Four expert panels were organized to address specific areas relative to Bar Coding Technology: Needs Assessment, Current Standards, Equipment Manufacturers, and Cost Implications. While the Council's conference and literature review focused on the application and use of bar codes in institutional settings, the Council believes these recommendations may have broader applicability to other settings.

The Council proposes the expeditious implementation of the following recommendations:

1. FDA and USP should collaborate with pharmaceutical manufacturers and other appropriate stakeholders to establish and implement uniform bar code standards down to the immediate unit-of-use package* that are consistent with the critical elements listed in Recommendation Number Two below.

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2. The data elements of a bar code should include:

- National Drug Code (NDC)
The unique product identifier in the bar code should be a uniform NDC number. This number has regulatory standing with the Food and Drug Administration (21 CFR Section 207.20) and is currently used by the pharmaceutical industry and by health care organizations in automated tracking of drug products. The Council understands that both 11-digit and 10-digit NDC number formats exist today and strongly encourages key stakeholders to come to agreement on a single uniform format for the NDC number.
- Lot/control/batch number and expiration date
The bar code should contain two secondary identifiers: the lot number and the expiration date. A unique lot number that is used in the event of a recall identifies each manufacturing batch. Inclusion of this lot number within the bar code will ensure that those lots subject to a recall can be readily identified. Inclusion of the expiration date within the bar code will ensure that the patient does not receive a medication that is beyond its expiration date.

3. Format parameters for the bar code should include:

- The three data elements of a bar code (i.e., NDC, lot number, expiration date) should be uniformly ordered
- The three data elements should be bar coded using existing symbologies, such as reduced space symbology in the form of a composite bar code. For example, the NDC number can be encoded by a linear bar code with the lot number and expiration dates in the two-dimensional code.
- The bar code print density should be sufficiently consistent to allow an accurate scan each time.

4. Labeling parameters should include:

- Standardized location of the bar code on the label
- Only one bar code per label
- Human readable drug name, strength/concentration, lot and expiration date per existing FDA regulation

5. The standard bar code should be included on:

- Immediate container labels of all commercially available prescription and non-prescription medications, in any dosage form (e.g., oral solids, oral liquids, injectables inhalers, nasal sprays, topicals, and other forms of specialized drug-product packaging)
- Intermediate container or carton
- Shelf Keeping Unit (SKU)

6. Bar code down to the unit-of-use package

The standard bar code should be included on all immediate unit-of-use packaging which may include single-unit, single dose, unit-dose, unit-of-use, multiple-unit, and multiple dose containers.*

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7. Professional associations should develop relevant standards of practice including, but not limited to:
- repackaging and labeling of extemporaneous preparations
 - educating practitioners on the proper and optimal use of bar codes
 - avoiding “work-around” processes

The recommendations contained in this report should not be seen as a mandate to health care providers but as a first step to the ultimate use of bar codes in the medication-use process. Before health care practitioners and organizations can benefit from machine-readable codes, the codes must be physically present in a standard format on unit-of-use medication packaging.

These recommendations will allow the development of systems to take advantage of the bar code; however, the Council recognizes that the development and implementation of such systems will be complex, costly, and will take a significant amount of time. All stakeholders in health care need to recognize these barriers and address how they will be overcome.

Further research is needed to quantify the safety and cost-effectiveness of bar coding in the medication-use process and should be undertaken before their universal incorporation into these processes. The use of bar coding technology as a mechanism to improve medication safety should be implemented incrementally with careful planning and given thoughtful deliberation for cost, cultural, and implementation issues.

* Terms as defined in General Notices, pg. 11, The *United States Pharmacopeia* and the *National Formulary*

Single-Unit Container – A single-unit container is one that is designed to hold a quantity of drug product intended for administration as a single dose or a single finished device intended for use promptly after the container is opened. Preferably, the immediate container and/or the outer container or protective packaging shall be so designed as to show evidence of any tampering with the contents. Each single-unit container shall be labeled to indicate the identity, quantity and/or strength, name of the manufacturer, lot number, and expiration date of the article.

Single-Dose Container – A single-dose container is a single-unit container for articles intended for parenteral administration only. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

Unit-Dose Container – A unit-dose container is a single-unit container for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

Unit-of-Use Container – A unit-of-use container is one that contains a specific quantity of a drug product and that is intended to be dispensed as such without further modification except for the addition of appropriate labeling. A unit-of-use container is labeled as such.

Multiple-Unit Container – A multiple-unit container is a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

Multiple-Dose Container -- A multiple-dose container is a multiple-unit container for articles intended for parenteral administration only.

1. Meyer GE, Brandell R, Smith JE, et al. Use of bar codes in inpatient drug distribution. *Am J Hosp Pharm.* 1991; 48; 953-66.
2. Hokanson JA, Keith MR, Guernsey BG, et al. Potential use of bar codes to implement automated dispensing quality assurance programs. *Hosp Pharm.* 1985; 20:327-37.
3. Puckett F. Medication-management component of a point-of-care information system. *Am J Health-Syst Pharm.* 1995; 52:1305-9.