Health Industry Business Communications Council

Bar Code Scanner and Related Technology Issues for Hospitals to Consider When Evaluating How to Implement or Improve Bedside Scanning Using FDA-mandated Bar Codes on Medications

Introduction:

The FDA has published regulations requiring that certain human drugs and biological product labels contain the FDA-administered National Drug Code (NDC) in a standardized linear bar code. FDA noted that "this rule will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time" [1].

There is general agreement that the use of automatic identification technology can provide hospitals with improved levels of error prevention similar to those found in other industries (e.g. parcel delivery, automotive manufacturers, retailing, etc.) and that the new FDA rule will encourage providers to adopt bar coding technology. It is estimated that less than 10% of hospitals currently use bedside bar code scanning technology. The deployment of bedside scanning-enabled clinical systems will allow hospitals to more accurately help identify patients and match them to their medications and treatments. The Health Industry Business Communications Council (HIBCC) is an industry-sponsored, non-profit standards development organization (SDO), established in 1983 by major national healthcare associations to develop and maintain information technology standards for healthcare applications. Its mission is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners. HIBCC extends its mission globally via IHIBCC, an international network of HIBCC offices. HIBCC and the Health Industry Bar Code Standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization (CEN). HIBCC has prepared this guide to assist hospitals in making an informed decision on the selection of bar code scanning equipment for point of care use such as in medication administration, specimen tracking and OR consumables use.

The Challenge:

While scanning applications in the hospital environment have many components similar to other industries, there are also important differences and idiosyncrasies that significantly differentiate hospitals in a number of ways:

[1] Federal Register: February 26, 2004 (Volume 69, Number 38) [Federal Register Docket No. 2002N-0204] Bar Code Label Requirement for Human Drug Products and Biological Products www.fda.gov/OHRMS/DOCKETS/98fr/04-4249.htm

- Unlike UPS or FedEx applications, bar code labels will have to be sized to the dose, rather than the dose package sized to the label – and most of these packages will be extremely small by logistical channel standards (For example, at UPS a "small" size is considered to be anything that fits within the opening of a coat hanger).
- Unlike a pharmaceutical manufacturing line, where single dose items "in bulk" can pass through a fixed scanner at high speed, in hospitals unit-doses will be scanned in a hand-held environment at human speed.
- Unlike supermarkets and other retail stores, all items will not be combined and brought to a centralized checkout; rather, they will have to be scanned while being dispensed at or near the bedside.
- Interactions with patients are likely to be occurring at the same time as scanning.

In short, scanning at a hospital or pharmacy will require that personnel – at both fixed and mobile workstations – be able to read a variety of bar codes in various formats and sizes, and be able to do so both quickly and with minimal effect on their other duties. Furthermore, this activity must be linked with the rest of the hospital IT infrastructure.

Issues to consider:

Today the major scanning technologies capable of reading the linear bar codes specified by the FDA regulation are: lasers, linear imagers, and area imagers. The FDA states that it specified a linear bar code so that hospitals already possessing linear scanners may not have to acquire new equipment because of this rule. Since most hospitals have yet to acquire scanning equipment, most will therefore be able to select from all of the above options. Furthermore, the likely presence of additional bar coded information desirable for patient safety – in particular Lot Number and Expiration date – but not mandated in the current FDA regulation will have a bearing on both the type of scanner selected and the nature of bar code symbols that will be used in the near future.

While at this time the FDA has not required that Lot Number and Expiration Date be included on unit dose or other levels of packaging, FDA stated that it is not opposed to this information being included *voluntarily. The FDA will reconsider whether to require Lot Number and Expiration Date in a future ruling as newer technologies become more mature and established*. Including this information in the limited available space – something which has obvious patient safety benefits- would require more than a linear bar code format as currently specified.

Due to space constraints on drug labels, a bar code representation of the required NDC number plus Lot Number and Expiration Date will need a more space efficient symbol. These symbols use both the vertical and horizontal dimension to represent their data. These symbols are said to be two dimensional or "2D". There are two classes of 2D symbols, stacked linear and matrix. Stacked linear symbols can be scanned by some classes of traditional linear scanners, while matrix symbols require an area imaging scanner.

Another approach to increasing the information carried by a bar code when space is limited is Stacked or Composite presentations. This could be a stacked set of symbols such as shown at the right, or a combination of symbols such as Reduced Space Symbology (RSS) with a Composite Component. RSS-14 Stacked, notwithstanding its 2-row format, is not a '2D" bar code but is defined as a linear symbol. It is readily scanned with any linear scanner programmed to read the RSS family of symbologies.

Examples of secondary bar coded data such as Lot and Expiry information include the following:

- A separate and possibly linked linear symbol as per HIBCC or EAN.UCC standards
- A 2D Composite Component symbol printed in conjunction with current Reduced Space Symbology (RSS), U.P.C. or other EAN.UCC System symbols
- Some other form of 2D stacked linear symbology (such as microPDF, for example)
- A 2D matrix symbology (such as Data Matrix or Aztec code, for example)

The first two options described above are established and standardized. All but the first of these enhanced bar coded data elements would require at a minimum, different scanner optics (even with the linear scanners) or in the case of the 2D matrix symbols, 2-dimensional area imagers.

	Linear Bar Code (1-D)	Stacked Bar code (2-D)	Composite Bar code (2-D)	Matrix Code (2-D)
Laser	√	√	√ Will read Linear Portion	
Linear Imager	√	√	√ Will read Linear Portion	
Area Imager	√	√	√	√
	Linear Example	Stacked Linear Example	2D Stacked Example	2D Matrix Example
				

[3] Note: The addition of a 2D Composite Component with RSS or the use of a stand-alone microPDF symbol will likely require a different scanner optical package than that used in a scanner of the same family designed to read only linear symbols. This is a physical distinction, not merely a software upgrade.

The following applications and Auto-ID characteristics should be considered by hospitals acquiring scanning equipment:

Applications	**Data Structure and Symbology determined by**	**Standardized Data Structure and Symbology**	**Other possibilities**
1. Medication purchased with bar code on unit-of-use			
A. NDC Code	FDA Rule	EAN.UCC or HIBCC "Linear" Symbology • Code 128 • RSS Limited or RSS Stacked	• U.P.C. • UCC/EAN-128

B. Lot & Expiry	Pharma Choice	If EAN.UCC: 2D Composite Component If HIBCC: Separate Code 128 (microPDF and Data Matrix in process)	Manufacturer's unrestricted choice, including microPDF, Data Matrix, Aztec, etc.
2. Unit-of-use medication to which the hospital has attached a bar code	Hospital Choice	None	Hospital's unrestricted choice, by typically Code 128 or I2 of 5.
3. Blood and Blood products	FDA Rule	• Codabar • ISBT 128	
4. Hospital prepared IV mixes	Hospital Choice	HIBC PAS: - Code 128 (microPDF and Data Matrix in process)	Hospital's unrestricted choice.
5. Patient ID Band	Hospital Choice	HIBC PAS: - Code 128 (microPDF and Data Matrix in process)	Hospital's unrestricted choice.
6. Employee ID	Hospital Choice	HIBC PAS: Code 128	Hospital's unrestricted choice.
7. Specimen Container	Hospital Choice	NCCLS: - Code 128	Hospital's unrestricted choice.

HIBC PAS: Health Industry Bar Code Provider Application Standard, ANSI/HIBC1-1996 http://www.hibcc.org

NCCLS: Auto02-A - Laboratory Automation: Bar Codes for Specimen Container Identification http://www.nccls.org

An Exciting Future

When looking at new reader technology consideration should be given to the new technologies that are being developed and deployed, including 2D bar codes and RFID. There will be a convergence of technologies, for example, bar code for unit dose, RFID for patient and user identifications (as well as input to medical devices). EPC (also RFID) for tracking in the supply chain and active RTLS (real-time locating systems) RFID for local positioning (for asset tracking). The combinations of these Auto-ID technologies may require multi-functional devices that will be able to read the technology presented and allow the user to complete the required task. Similar to the combination of the cell phone with a PDA and a camera, these devices will impact the workflow and productivity of the users.