

Advocacy White Paper

Bar Coding for Patient Safety

INTRODUCTION:

The Institute of Medicine's Quality Chasm report has crystallized attention on the human and economic cost of medical errors. Causes and thus remediation of medical errors is complex. Elimination of reliance on oral and handwritten communication along with minimizing transcription, translation, and interpretation are common elements of remediation.

Bar codes to enable self, or auto identification of medical items, patients, and staff are integral to many of solutions to the medical errors problem. In August 2001, the Federation of American Hospitals (FAH) announced their resolution on patient safety and reduction of medical errors that included a specific call for standardized machine readable bar coding on single unit dose packaging. The National Coordinating Council for Medication Error Reporting (NCCMERP) and the American Society of Health-System Pharmacists (ASHP) publicly called for the FDA to mandate bar codes down to the immediate unit-of-use package on all medication packages. In May, HHS Secretary Tommy Thompson testified to the benefits of bar coding as a "simple technology ... everyone has seen at the grocery store." His estimate of the benefit from broad use of bar coding was \$11 billion dollars in supply chain costs alone.

With apparent consensus on a shared vision for the use of bar coding in health care, it's worth considering why this "simple technology" that has been part of everyday life for nearly four decades has not already become commonplace in health care. In fact, bar coding is quite common in health care materials management. It is at the point of care that bar coding is rarely used.

The lack of everyday point of care use of bar codes is a chicken-and-egg problem. Manufacturers are not labeling (each) units-of-use with bar codes because they are not required to do so by regulation or market forces. Health care software vendors haven't built point-of-care bar code systems for lack of market incentives. Providers haven't invested in point-of-care bar code technologies because of limited software vendor products and not enough unit-of-use labeled products and medications.

HIMSS members are key players in many aspects of this issue. This paper was prepared to provide an overview of the topic of bar coding, discuss the issues related to achieving the vision and recommend subsequent initiatives. The "Description of the Issue" section provides a brief overview of other organizations involved in bar coding, pertinent standards and data sets, and the current use of bar coding in health care. Discussion of the economic, market and political dynamics of getting widespread bar-code use as a key element in medical error reduction is provided in the "Discussion/Analysis" section. Finally, recommendations for HIMSS initiatives are presented.

DESCRIPTION OF THE ISSUE

Requisite for the vision of bar coding being able to resolve patient safety problems are standards and code sets that are acceptable across the supply chain. Fortunately with a few exceptions, standards are complete and mature.

BAR-CODE STANDARDS ORGANIZATIONS

The Health Industry Business Communications Council® (HIBCC®, www.hibcc.org) is an industry-sponsored and supported nonprofit organization. As an ANSI-accredited organization, its primary function is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners. HIBCC is active in a number of critical areas, including electronic data interchange message formats in ASC X12 approved message formats, bar code labeling data standards Health Industry Bar Code (HIBC), universal numbering systems for manufacturer, customer, and product identification codes, including Universal Product Number (UPN®), the Labeler Identification Code (LIC), and Health Industry Number (HIN®), and the provision of databases which assure common identifiers.

Uniform Code Council, Inc. (UCC) and EAN International are voluntary standards organizations charged by their respective Boards with the management of the UCC/EAN system. EAN International has a decentralized structure with a membership of Member Organizations (MOs) that manage the EAN system in a country or economic region. The UCC manages the numbering system for the U.S. and Canada. Many consider the UCC as the point of origination for the automated identification and data capture (AIDC), more commonly known as bar coding, industry. The bar coding used in grocery stores is UCC.

Standards governing the physical and technical appearance of bar codes are managed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) through the SC 31 a Subcommittee of Joint Technical Committee 1 (JTC 1) on Information Technology.

SYMBOLGY STANDARDS

Three types of code representations are available: the familiar bar codes, two-dimensional codes, collectively known as symbologies, and wireless codes. Advances in hardware have made it possible for "scanners" to understand multiple symbologies including those that are used for small-packages and unit-of-use labeling. For health care applications, HIBC standards specify Code 39 or Code 128 bar codes, examples of which are shown below. Where there is insufficient label area to allow the use of Code 128 or Code 39, either the Code 16K or Code 49 symbology can be used. HIBC Standards specify the use of 2-dimensional symbologies, such as Data Matrix and PDF-417. The two dimensional symbologies can be produced and read in very small sizes such as unit of use medication packages.

Code 39



EAH783G

Code 128



EAH783G

Data Matrix

PDF-417



Bar code images can be produced as bit-map images, vector images, or bar code fonts. Bar-code fonts, which are easiest to incorporate in software or desktop tools, are unfortunately rather problematic because of the non-standard way fonts are treated in word processing and other applications.

CONTENT STANDARDS

The Health Industry Bar Code (HIBC) Standard is composed of two parts:

- ⚡ Part One, the HIBC Supplier Labeling Standard, covering the formats used by suppliers of products and
- ⚡ Part Two, the HIBC Provider Standard, covering the formats used for internal labeling by health care providers themselves. For point-of-care systems both parts are pertinent.

The Health Industry Bar Code (HIBC) Provider Applications Standard describes how to encapsulate a wide spectrum of healthcare information into an automatic identification data carrier ('data carrier'). This includes information such as patient identification.

Patient Identifiers are typically assigned by care giving institutions. Their scope tends to be local. The patient ID at one hospital will be different from another hospital's patient ID for the same person. However, patients will travel from one care giving entity to another, increasing the possibility that the scope could be enlarged. With the use of the method described in this specification, a patient ID could be captured, interpreted and used by another hospital to ensure the correct patient identity.

The HIBC Provider Applications Standard specifies a data carrier and a compatible data structure in which patient identification can be reliably encoded and captured. For example, patient identification, printed as a bar code or other form of automatic identification, could be found on a patient wristband, on medical record jackets, specimen containers, etc.

DATA SETS

In order to transmit business information electronically, trading partners must be able to quickly and efficiently identify the three most common elements in every transaction: the "item", "seller", and "buyer". Each of the HIBCC database system services, including UPN, LIC, and HIN, provide subscribers the unique identifiers that allow this to occur.

Item Identification

Health care organizations may see items with a variety of identification codes. Items that are commonly available in retail outlets may have UCC codes. UCC coding which is all numeric can be differentiated from HIBC coding that is alpha numeric. For quality and safety reasons, there are two item identification systems that are pertinent to healthcare: UPN and NDC. The Universal Product Number (UPN) is a unique identifier of medical-surgical (non-pharmaceutical) products ("items"). Each item will have a single UPN, which can consist of either the HIBCC-LIC primary data structure or the UCC/EAN primary data structure. UPN combines one of these different structures with manufacturer-assigned product numbers to create a unique identifier for cross-referencing and electronic data interchange (EDI) purposes.

The UPN Database is a repository of individual company product catalogs containing not only the UPN but also product descriptions and packaging-level information. For products distributed via both retail and health care channels, UCC code mapping can be found in the UPN Database

NDC (National Drug Code) is a 10-digit number administered by the FDA, typically for pharmaceuticals. NDC codes are accommodated in the HIBC structure.

Seller Identification

HIBCC's Labeler Identification Code (LIC) identifies individual manufacturers and independent-label distributors ("sellers") via a unique, four character LIC. Because LIC codes are part of both the Health Industry Bar Code Labeling Standard and the Universal Product Number (UPN), LIC Services are used within the industry for dual purposes - uniform product labeling and electronic contract administration.

Buyer Identification

Provider identification through the HIBCC HIN System originally concentrated on market segments that were of immediate concern to the supply side of the US health care system - hospitals, nursing homes, buying groups, retail pharmacies, manufacturers and distributors - for the buying and selling of health care products. However, in recent years attention has shifted to the provider segment of the industry and the HIN has been recommended for application in payer-provider transactions. The HIN Database now comprises approximately 500,000 individual practitioners. The element that sets the HIN System apart from other numbering systems is that it can accommodate the unique attributes of health care entities - such as the identification of multiple locations within hospitals and multiple practices of individual practitioners.

CURRENT USE OF BAR-CODES IN HEALTHCARE

Customer demand brought bar codes to the retail industry. When Safeway and Wal-Mart told manufacturers they would refuse to buy products without bar codes, bar coding at every level became the standard in the retail industry. Manufacturers and distributors couldn't afford to ignore retailers of that size. Because products were taken to a small number of reader stations (check-out lanes) the cost of scanners and related equipment at the retail level was minimized. In the much more fragmented healthcare industry, those unified market forces simply don't exist. A notable exception is the Department of Defense, which has told its suppliers that it won't accept any products without bar codes

Shipping, warehouse, and distributor bar code applications are widely used for health care supplies. The benefits of bar coding accrued to manufacturers drove its acceptance. Since bar codes on cases or shipping cartons were most useful to manufacturers, it is no wonder that 85% of shipping cartons had bar coded packages according to a recent HIDA survey. Unit-of-use bar coding was less than 60% in that same survey of medical/surgical supplies. Bar coding of unit-of-use pharmaceuticals is virtually nonexistent.

Another obstacle that limits the use of bar coding in healthcare is the consequence of an error in marking or scanning. A Miss-read in a patient care setting can have vastly greater consequences than misreading a can of peas.

Costs and Benefits Across the Supply Chain

Questions of market adaptation generally boil down to economics. The table below depicts a basic alignment of incentives for the use of bar coding on shipping and warehouse units, but a major skewing of cost and benefit for unit-of-use. Understanding the challenges to the vision described by Secretary Thompson, FAH, NCCMERP, and others, requires viewing the issue from multiple sector perspectives.

Constituent	Shipping		Unit-of-Use	
	Implementation Cost	Expected Benefits	Implementation Cost	Expected Benefits
Manufacture	\$\$\$	\$\$\$\$	\$\$\$\$\$\$	
Distributor	\$\$	\$\$\$\$	\$\$	
Provider	\$\$	\$\$\$\$	\$\$\$\$	\$\$\$\$\$\$
Software vendor	\$	\$\$	\$	\$\$\$

DISCUSSION/ANALYSIS

FROM THE MANUFACTURER'S PERSPECTIVE

Converting to bar coding at a unit-of-use level can be a very costly transition for manufacturers. Instead of considering a product as the entity, each unit-of-use is treated as a separate entity. This can require changes to nearly every system. Tiny checkerboard bar codes can now be put on the smallest of products, such as unit-dose medications, but at a price. The cost of labeling at the smallest level is very, very high, even though the technology now exists to do it. Graphics, printing and quality control carries substantial start-up costs and is operationally challenging.

FROM THE PROVIDER'S PERSPECTIVE

Scanners that read bar codes are still quite expensive and even for hospitals with point of care devices, there is very little commercial software that uses bar code auto identification. Very few hospitals have invested in expensive reading equipment and systems. As a result, they're not asking for bar coded products. Very few manufacturers are going to pay to print these miniscule tiny labels until the market demand justifies using them.

ALTERNATIVES TO ACCELERATING UNIT-OF-USE BAR-CODING

As is the case with other technology applications in health care, adoption of bar coding is inhibited by a disparity between those that must invest and those that benefit along with a gap between the timing of investment and the lag in realizing benefits. Market incentives are not sufficiently aligned for rapid adoption of unit-of-use bar coding. The leverage point seems to be the manufacturer. Initiatives are needed to get unit-of-use bar codes applied at manufacturing.

Government Mandate Alternative:

Under this alternative, federal legislation and regulation would be sought requiring manufacturers to imprint bar codes and specify point of use standards. This is being actively pursued by organizations such as NCCMERP and ASHP. Leveraging federal purchasing power is another opportunity. The DOD already requires unit-of-use supply bar codes. If both the DOD and the

Veterans Administration required unit-of-use on medications, this would have a formidable impact. The Centers for Medicare and Medicaid Services (CMS) is the largest purchaser of health care. Suggestions have been made that CMS should limit reimbursement to unit-of-use bar coded items.

Federal grants and subsidies would get to the heart of the issue: manufacturer's increased costs to bar code. Federal subsidies for an industry that already has an image problem are not likely.

HIPAA provides a striking reminder of the deficiencies of the federal mandate approach. HIPAA transaction standards were legislated due to heavy lobbying pressure from the health care industry. But when it came time to implement, the industry turned tail and attempted to delay, water-down or eliminate the requirement as too costly and onerous to implement.

Even with the purchasing power of the DOD and VA, the first organizations to mandate unit-of-use bar coding will face higher product costs. Taxpayers may not see the benefit.

Medicare and Medicaid provide reimbursement to providers not suppliers. To restrict payment to only bar-coded items would require the providers to enforce the requirement. Would providers buy more costly items for their Medicare/ Medicaid patients and less costly un-coded items for HMO patients? This would become an administrative nightmare.

Industry or Employer/Provider Consortium:

In this country, it is ultimately the market that prevails. Major players from across the supply chain could agree on methods and schedules to implement unit-of-use bar coding for the good of the industry. In this context, the DOD and VA would be part of a broader health care initiative that would active participation of some of the countries major Health Systems. The Group Purchasing Organizations (GPO) could have strong organizing and content influence. From the payor side active support from a group such as Leapfrog would be needed.

There is not yet a clear model for success of consortium influence making rapid national change. Since point-of-care, unit-of-use bar coding will require significant investment and a large, but lagged benefit, sustained industry support will be required.

CONCLUSIONS/RECOMMENDATIONS/POSITION STATEMENT

HIMSS should strongly support industry cooperation in achieving viable point-of-care, unit-of-use bar coding to reduce medical errors and improve productivity. The style for HIMSS advocacy of bar coding should be a hybrid approach of consortium and regulation. Those most closely involved in bar coding consistently site the lack of understanding and education as the first obstacle. HIMSS has strong and diverse capabilities to tackle the education problem. Most of the recommendations serve to educate members, constituents, and regulators.

HIMSS can accelerate adaptation of bar coding at the point-of-care through initiatives in four areas

- ☞☞ Internal HIMSS initiatives
- ☞☞ Education
- ☞☞ Washington advocacy

Internal HIMSS initiatives

1. Form a Supply Chain SIG to serve as SME (Subject Matter Experts) on this topic.
Possible activities include:
 - a. Review the issue of overlapping standards, standards ambiguity, and gaps in standards for the end-to-end process.
 - b. Prepare in coordination with other related SIGs, a function and feature description of an advanced point-of-care system that takes advantage of bar-code technology.
 - c. Collect case studies and ROI data on the use of bar coding.
 - d. Encourage HIMSS member's participation in HIBCC Committee meetings.
2. Add HIBCC bar coding information and links to the "Partnerships" page of the HIMSS web site

Education

1. Work with HIBCC through the Education Division to produce bar coding/patient safety educations offerings in the most appropriate format: including WebU tutorials, audio conferences, seminars, journal articles, white papers, books, chapter educational programs, and chapter newsletters.
2. Publish a Bar Coding book or CD comprised of reprints of recent Annual Conference sessions, material provided by HIBCC and re-prints from other HIBCC organizations such as HIDA (Health Industry Distributors Association)
3. Develop a patient safety track at the 2003 Annual Conference that includes sessions relative to HIBCC bar coding.

Washington advocacy

1. Continue to process bar coding legislative and regulatory issues through the Advocacy Committee.
2. Emphasize bar coding as a key element in our patient safety legislative agenda.
3. Work with Doug Peddicord, HIMSS/CHIP legislative advocate to identify, track, and respond to topic specific opportunities.
4. Identify positions taken on the issue by other organizations.
5. Provide content on the issue of bar coding to the HIMSS Board of Directors.
6. Develop a HIMSS position on use of bar coding technology

Demonstration efforts

1. Explore development of a research/survey project to identify the benefits of use of bar code technology at the bedside on reducing medication errors.

Key words

Patient safety, Medication errors, Bar-coding, Supply chain, and ROI

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