HIBCC, Hospitals & Patient Safety

Preventing Hospital Errors:
LEVERAGING INDUSTRY STANDARDS FOR PATIENTS, PRODUCTS & PROCUREMENT

Exclusive LINES Provider Edition brought to you by: Health Industry Business Communications Council
PATIENT SAFETY

Safer Medication Administration: Lessons From Mass General
In 2004 MGH embarked on a project to define and develop a safer system for the administration of medication to its patients. The success of their efforts led the organization to seek formal standardization of their processes, in order that they could be easily and uniformly implemented by other providers.

PROCUREMENT

HIN: Healthcare’s Facility ID for Providers
The Health Industry Number (HIN) System has been the industry standard for facility and organizational identification for 20 years. Here’s how the HIN works to get the right product to the right location for the right price…and at no-cost to providers.

TECHNOLOGY

RFID: The Next Wave in Healthcare?
Much has been promised about the revolutionary potential of RFID. While the trade literature and RFID advocates emphasize its promise of improving patient safety and efficiency, others express concern about whether it can be cost beneficial in light of proven and less expensive alternatives such as bar-coding. LINES takes a look at the myths and the realities of this new technology.

PRODUCT TRACKING

HIBC: The Preferred Standard for Safer ID
Bar coding has proven itself as an effective tool for enabling more efficient and more accurate processes. In healthcare, the potential is even greater. Here’s what you need to know about healthcare’s bar code standard for product tracking.
And — In 2004, the FDA began regulating bar code labeling of human drug products — now it considers medical device labeling.
HIBCC will shortly celebrate its twenty-fifth year of service to the healthcare community, continuing the mandate given to us in 1983 by the American Hospital Association (AHA). In ’83 the AHA created HIBCC by calling together a task force of supplier organizations — representing manufacturers and distributors of both pharmaceuticals and medical devices — to develop a labeling standard to meet the unique requirements of healthcare providers. Although retail labeling standards were already in use, provider organizations like the AHA knew that medical care would need standards incorporating more stringent patient safety considerations not available in the generic bar code standards commonly used in warehouses and grocery stores. Today, HIBCC continues to apply these same principals — enhanced standards for patient safety — as newer technologies for labeling and identification are developed and standards applied.

HIBCC thus became healthcare’s supply chain standards organization. Through the years, we have continued to emphasize “safety first” as our scope has expanded beyond labeling. Now more than ever, thanks to the advent of electronic and Internet commerce, healthcare institutions can benefit from applying error-reducing standards to automated practices. Logistics management, cost containment measures and system integrity can enhance the safety of the people entrusted to healthcare institutions only if they adhere to standards that keep error reduction, traceability and medical-specific requirements at the forefront.

Over the years many individuals from the provider community have served on our Board of Directors and various operating committees, thereby keeping our focus on the real customer — their patients. Hospital CEOs, CIOs, purchasing managers, pharmacy directors and others have been key contributors to HIBCC.

Currently our Board includes individuals representing hospital groups, such as HCA, as well as individuals who can speak to the needs of individual facilities. An excellent example is our newest AHA-appointed Board member — Claude Ritman, Executive Director of Coler-Goldwater Specialty Hospital and Nursing Facility on Roosevelt Island in New York City. Coler-Goldwater is a 2,000-bed, comprehensive care center that provides high quality medical, rehabilitative and long-term care to New York City residents as part of The New York City Health and Hospitals Corporation (HHC). Claude’s facility-specific perspectives compliment those of our Board members who work in the larger management and buying organizations that are by necessity more distant from direct patient care. Both perspectives are crucial to our work.

We invite you to join our efforts by participating in our governance process, whether it is at the Board or Committee level. For additional information please email info@hibcc.org.
In 2006, HIBCC and Partners HealthCare Systems began a joint effort to develop a standard to enhance patient safety through automated medication administration systems. The standard, entitled, “Positive Identification for Patient Safety; Part 1: Medication Delivery” defines the processes and technologies involved with safe medication management.

The standard is being developed from work initiated by Massachusetts General Hospital (MGH), a hospital within the Partners HealthCare System. In 2004, MGH embarked on a project to define and develop a safer system for the administration of medication to its patients. The success of their efforts led the organization to seek formal standardization of their processes, in order that they could be easily and uniformly implemented by other providers.

It all started with two models of outpatient IV pumps and a bar code.

Two outpatient chemotherapy IV pumps looked very similar, but operated very differently. One required input of the amount of drug per hour; the other — the amount of drug for the duration of therapy — (which can be multiple days.) The probability for error (and death) was staggering. The Sims Lab at the hospital had already seen the need almost 10 years before and had the vision to design the concept of IV pump libraries for IV ‘smart’ pumps. (The Sims Lab holds the patent for it. That patent is licensed by virtually every IV ‘smart pump’ manufacturer.) These libraries contain information about drugs, their uses and safe dose limits. The dosing instructions the clinician enters into the pump are checked against the hospital-defined drug library limits for safety. Although the use of drug libraries can certainly reduce medication errors, a clinician could still select a wrong drug or concentration which could potentially harm the patient.

“Since that time, not one medication error has occurred using the bar codes to program the IV pumps.”
The Sims Lab and the MGH Department of Pharmacy were also early promoters of Patient Safety measures. The IV pump situation was a prime candidate for a safety initiative. They decided that any Ambulatory pump to be programmed for the duration of therapy would be programmed ONLY by a bar code. And only by a bar code produced from their Pharmacy system. They found a suitable ambulatory infusion pump and modifications were made to their inhouse Pharmacy system to produce a custom linear bar code on the IV medication labels — from orders that had been reviewed and approved by Pharmacists. This initiative was a resounding success. Since that time, not one medication error has occurred using the bar codes to program the IV pumps.

In 2003, The Sims Lab at the hospital began a dialogue with IV pump manufacturers to explore the possibilities of embedding a bar code reader in IV pumps. The bar code reader would read drug information from a bar code on a medication label and use that information to validate against the ‘onboard drug library’. Workflow models for the pumps were developed.

When the hospital migrated to a new Pharmacy System, they decided they did not want to delay their implementation by requiring vendor customization for their chemotherapy IV pump barcodes. To solve the problem, software was created on Intermec programmable printers to construct properly formatted bar codes for the IV chemotherapy pumps from the pharmacy system label data.

This lead to demonstrations in April 2004 with leading pump manufacturers that showed how a 2D symbol could program a smart infusion pump. An Intermec bar code printer received (existing legacy) pharmacy system label data and produced 2D symbols containing patient, drug and order information. The pump was a virtual infusion pump on a PC that contained a drug library. Scenarios for wrong patient, unknown drug and overdosing dose were demonstrated. The workflow of the pump followed the model previously developed.

Massachusetts General Hospital then asked that a formal smart infusion pump auto-id specification be developed. Upon completion of this specification, the Partners Healthcare High Performance Medicine Committee for patient medication safety worked to help expand the standards to include several key areas.

Previous good work done by many Partners groups was reviewed. Interviews were conducted with several member hospitals in the Partners system along with pump manufacturers. Analysis was done to determine both the practicality and reality of what data was needed by both the clinicians and the devices. The resulting work includes standards for employee badges, patient wristbands and other patient labeled items, IV and non-IV medications, and device license plates.

Although prior work has been done in each of these areas by various organizations, most of the focus has been on simple identification, asset management, and/or supply chain needs. This design was from a “patient safety first” perspective, and incorporated the ‘five rights’ (patient, medication, route, dose, time).

KEY DESIGN POINTS

The design goals included extensibility, versioning, a building blocks approach, clear discrimination from other information, issuing provider identification and a compact symbol size.

The resulting standards define records that are defined by three letter codes similar to the format of HL7 records and XML/HTML style tags to encapsulate the overall message and contextual groups. The design is further optimized by ordering the fields in each record from mandatory to least significant. (cont. on page 12)
A Procurement Dilemma
The materials management process is a fundamental but complicated activity for all healthcare organizations, regardless of size. Managers and administrators are burdened with the task of establishing and maintaining multiple identifiers for each of their suppliers, as well as for each facility and ship-to location at which they receive products.

Given the number of suppliers and delivery locations, there are potentially thousands of proprietary numbers to maintain. The task can be overwhelming in complexity and a significant drain on both human and financial resources.

The Solution
In 1988, the healthcare industry undertook an effort to address the issue and streamline the process. The Health Industry Number (HIN®) System is the result.

During the past fifteen years HIN has been successfully deployed within the supply chain to streamline manufacturer-supplier/distributor-GPO processes, and has now been expanded to allow providers to directly use it and benefit as well.

Provider organizations will now be better able to manage their procurement functions when interacting with their trading partners, GPOs and others.

What is the HIN?
The HIN is a nine-character, alphanumeric identifier that is assigned to every facility, delivery location and business activity in the healthcare supply chain. Each HIN is consistent, unique, and flexible enough to represent a facility as well as the numerous ship-to locations within its organization.

The first seven positions of the HIN comprise the “base HIN” which identifies a health care entity at a particular location. The seventh position of a base HIN is a check-digit for verifying the first six positions.

The last two positions of the HIN comprise the suffix that uniquely identifies a specific ship-to location, alternative location or a functional affiliation with the entity.

Why use the HIN?
Many participants in the healthcare supply chain have already realized the benefits of the HIN System. Further benefits can now be derived by provider organizations, including:

Reduce Administrative Resources
By using the HIN when communicating orders or talking to suppliers, an organization can eliminate the maintenance of supplier assigned customer numbers. Staff no longer needs to look up and/or remember potentially thousands of supplier assigned customer identification numbers, resulting in a reduction in many manual operations.

Providers Control Definition
Through use of the HIN and communication with HIBCC, provider organizations can define who they are and how their trading partners view them in a consistent framework.

Facilitate Accurate Pricing And Reporting
By providing a common and consistent identification to its suppliers, organizations can eliminate the confusion of disparate identifiers and ensure that all its trading partners are using the same accurate view. This is a critical function when communicating membership for contracting and sales reporting.

How Does the Industry Use HIN?
HIN has become an integral component of many supply chain processes, including:

- membership and pricing eligibility;
- drug pricing;
- sales reporting;
- drop shipments;
- contract administration;
- rebate reconciliation.

Through a centralized and standardized repository, the HIN System provides consistency and accuracy of
customer identification for hundreds of major manufacturers, distributors and provider organizations, as well as US government agencies such as Department of Defense, US Public Health Service, VA Hospital System and the Centers for Disease Control.

HIN has been endorsed by the Efficient Healthcare Consumer Response (EHCR) initiative as a key tactical enabler for reducing supply chain costs, and is also endorsed by the Healthcare Distribution Management Association (HDMA) and the Health Industry Distributors Association (HIDA) for customer identification in their contract administration guidelines.

Who Maintains the HIN?
The HIN System is maintained in a common, centralized database that is administered by the Health Industry Business Communications Council (HIBCC). HIBCC is an industry sponsored, non-profit standards development organization (SDO) that was founded by major healthcare associations in 1983 and is accredited by the American National Standards Institute (ANSI). In addition to HIN, HIBCC also maintains many industry standards in support of efficient e-commerce applications, including: Health Industry Bar Code (HIBC) Standards, Universal Product Numbers (UPN) and the Labeler Identification Code (LIC).

To secure the integrity of the HIN System, HIBCC applies a uniform identification standard to all entities submitted for HIN enumeration. The standardization process includes a review to ensure that duplication does not occur in the database, as well as phone verification of all information about the entity. Since inception, the number of records in the HIN Database has grown from 7,000 hospitals to over 1.5 million facility records.

How do Hospitals Communicate with HIBCC?
HIN information about their respective facilities is available to providers without charge, as the system is largely underwritten through the participation of manufacturers and distributors. Hospitals are encouraged to periodically review and update their HIN assignments, as well as to request additional assignments for locations that have not yet been enumerated with a HIN. The process can be initiated by:

Phone: 1.877.GETHINS (1.877.438.4467)
Fax: 1.602.381.1093
E-Mail: gethins@hibcc.org
Web: www.hibcc.org

Without a HIN
1 Hospital, 1 Buying Location
Has a unique Customer Number with each supplier

Without the HIN: Multiple suppliers delivering to multiple locations requires the maintenance of thousands of proprietary numbers and continual maintenance — a time and resource consuming task.

Without a HIN
1 Hospital, Multiple Buying Locations
Has many Customer Numbers with the same or different suppliers

Without the HIN: Each hospital must establish and maintain different customer identification numbers for each supplier (above) and for each ship-to location within their facility.

With a HIN
1 Hospital, Multiple Buying Locations
Uses the same customer identification number with every supplier

With the HIN: Utilizing the HIN, a hospital and its many suppliers communicate using a common and consistent view — streamlining the administrative process.
HIBCC Addresses Questions on the FDA’s Proposal for Unique ID for Medical Devices

HIBCC was developed by the healthcare industry, and our efforts reflect the stated needs and interests of our constituents — the suppliers of medical goods and the providers of medical care. Our proposals are the product of these efforts which have already been implemented on a global scale.

In 2006, the US Food and Drug Administration (FDA) began deliberations on a proposed regulation for labeling of medical devices. The regulation was a follow-up to their 2004 mandate which required the use of bar codes on all pharmaceutical products.

After circulation of a draft proposal during which the industry was asked to comment, the FDA is continuing its review of current processes and technologies. A final proposal is anticipated sometime during 2007.

The following was prepared to assist the industry as it considers forthcoming legislation.

WHY IS UNIQUE MEDICAL IDENTIFICATION NECESSARY?

Automated processes, such as standardized product identification, have proven highly effective for reducing error and improving efficiencies in many industries. In healthcare, the potential benefits have even greater significance. A standardized system for unique device identification (UDI) such as that being considered by the FDA, has tremendous potential for supporting cost containment and patient safety practices.

For suppliers, UDI will enable consistency and efficiency of processes, enhance full-cycle supply chain management from manufacturing to end-user delivery, and improve track and trace protocols in the event of product recall.

The benefits to providers include improved patient safety through secure product identification and efficient traceability, and greater ability for monitoring expenditures and reimbursements.

ARE THE CURRENT SYSTEMS BEING USED FOR MEDICAL DEVICE ID APPROPRIATE?

Absolutely. In the mid-1980’s, the healthcare industry recognized the need for developing a system of standards that would address the unique security concerns of medical product identification. Existing retail standards were considered by some to be inadequate as they are based on all-numeric, point-of-sale transactions, and thus failed to allow millions of alphanumeric identifiers. This limitation required costly and risky translation processes. HIBCC standards were thus developed based upon an alphanumeric format that allows for direct and literal encodation of product information. For medical devices this is especially critical as many product identifiers and serial numbers contain both alpha and numeric identifiers.

The healthcare industry was not unique in its concern. Many industries where considerations for consumer safety and sensitivity to error are essential, such as aviation, automotive and blood banking, also rely upon alphanumeric based standards.

WHAT TECHNOLOGIES ARE VIABLE?

There are many technologies that can accommodate serial numbers, including traditional linear bar codes, two dimensional (2D) symbols such as Data Matrix, and of course radio frequency identification (RFID).

SHOULD THE PHARMACEUTICAL INDUSTRY SERVE AS A MODEL?

The guidelines set forth by the FDA regarding identification of pharmaceutical products are important for several reasons. First, they provide clear direction and guidance to the industry and set in motion incentive for the industry to adopt important technology and practices. Second, the requirements provide continuity by specifying existing and internationally recognized standards for product
identification. And third, within this framework, they allow for flexibility of choice of identifiers. The FDA recognized the importance of the alphanumeric HIBC standards to the industry in its regulation.

**SHOULD THE IDENTIFICATION SYSTEMS AND STANDARDS BEING DEVELOPED BE THE SAME FOR BOTH?**
It is absolutely critical that government regulations support existing healthcare standards. These standards have been long established, are proven and are in practical use by healthcare participants. What is important now is developing incentive for further integration by all parties in the supply chain.

**WHAT CHALLENGES DO HOSPITALS FACE?**
There are no significant technical or practical barriers to implementation provided that existing international standards are required.

Regulations should be relatively straightforward and should not be made overly complex as a consequence of onerous requirements. Technology creep, as in any industry, can overly complicate what can be very simple processes. Any regulation should define current capabilities, consider what are likely to be needs in the future and weigh the cost benefit of complex processes such as serialization.

**IS THIS A GLOBAL ISSUE? IS ONE REGION OR COUNTRY AHEAD OF THE REST?**
Patient safety and cost containment are critical issues in any language, and product identification goes a long way toward reducing these risks. The efforts of international standards organizations such as ISO and ISBT have already addressed issues related to global harmonization for identification and the FDA should be building upon these successful efforts.

**WHAT IS HIBCC PROPOSING?**
HIBCC was developed by the healthcare industry, and our efforts reflect the stated needs and interests of our constituents — the suppliers of medical goods and the providers of medical care. Our proposals are the product of these efforts which have already been implemented on a global scale.

**HOW HAVE THESE IDEAS BEEN RECEIVED AROUND THE WORLD?**
The HIBC standards have been implemented by thousands of companies from every region of the world, representing small manufacturers to multi-nationals. Many of the largest US exporters that supply a vast percentage of total product worldwide have implemented HIBC. The success of the HIBC standards is based upon two critical factors: first, the preference by these companies for alphanumeric identifiers, and second, the global consistency of the HIBC standards. The HIBC data structure is standardized no matter what region of the world it is applied.

**WHAT DO YOU PREDICT WILL HAPPEN IN THE NEXT TWO YEARS? FIVE YEARS? TEN YEARS?**
There is no doubt that technology integration has been recognized by the industry as a powerful tool. The extent to which new technologies are integrated depends largely on how the marketplace learns to leverage them. Over the next two years, there will be an increasing use of 2D symbols, particularly for small packages at the unit-of-use, and also etched onto metal surfaces for some medical devices, such as surgical instruments. Within five years, there will likely be increased use of RFID within “closed loop” (internal) systems. And over a period of ten years, barcoding and 2D symbols will co-exist as alternative technology options for healthcare participants to choose. Barcodes and 2D will continue to represent a low cost option that delivers significant ROI for many applications.
What is RFID?
Radio Frequency Identification (RFID) is a technology that uses electronic chips embedded on tags to transmit radio waves. These tags can identify products, assets, medical records, and even individuals with embedded security cards or wristbands.

RFID may thus have the potential to help healthcare facilities improve patient safety and reduce costs. Early adopters of RFID are utilizing it to track medical devices, drugs, staff, and patients.

A tag may contain information about products or people, their physical location in real time, and other information such as lot number and expiration date for medical supplies and drugs, patient allergies or blood type, and much more. When transmitted to a “reader” within the facility, the information can be stored in a database or used by staff.

In the past, most healthcare facilities have kept track of their various resources and patients manually, or through the use of barcoding. RFID is a tool that can further enhance and augment these efforts.

What Benefits Can it Deliver?
Proponents of RFID cite many potential advantages over existing and conventional Auto-ID technologies, such as barcoding, that can improve supply chain and other processes. For example:

- Barcode labels are “read only,” while RFID tags can have both read and write capability, making them more versatile.
- Unlike barcode scanning, which requires that labels be individually read, groups of RFID tags can be read simultaneously, thereby enhancing productivity.
- Using “smart shelves,” which have RFID readers embed-
ded within them, it will be possible to obtain real-time inventory status by using RFID tags.
- The U.S. Food and Drug Administration (FDA) is evaluating the use of RFID tags for verifying product pedigree. This can be accomplished by encrypting information in the tag to eliminate counterfeiting of products, such as drugs and high-cost medical devices.
- Critical data, such as temperature monitoring for sensitive products like blood, can be automatically logged using RFID tags.
- RFID tags allow for invisible and resistant marking for special applications, such as wristbands.
- Unlike barcoding, there is no line of sight required to read an RFID tag.
- The use of RFID tags permits reading orientation directly through materials like boxes and textiles.

Some proponents have suggested extremely broad possibilities for RFID, such as the creation of an “Internet of things,” in which “every single object would be connected to the Internet through a wireless address and unique identifier.”

Given the well-established track record of barcoding, a more realistic perspective for RFID is that its potential for productivity improvement will be greatest in those areas in which barcode technology has limitations.

Will RFID Live up to Expectations?
Although there are potential longterm benefits of RFID, it appears that widespread adoption of the technology for supply chain applications is still a long way off. This may even be true in the retail industry, where large companies, such as Wal-Mart, have already invested considerable capital in RFID projects.

Several industry wide investments will be necessary prior to wide-scale implementation. These include systems design and engineering, systems integration, business process redesign, and logical IT data management integration. Furthermore, given the current costs of the tags themselves, adequate return on investment is indicated in only select applications.
Nevertheless, there are some promising short-term applications for RFID, and successful implementation with business benefits is likely where certain conditions are met. For example:

• “Closed-system” applications where productivity and working capital improvements for an individual company’s internal processes can result.
• Specialized, high-cost equipment, where reduced loss and obsolescence may lead to significant financial benefits.
• High-cost items or applications that require a high degree of traceability. These items include medical devices such as pacemakers, defibrillators, and other implanted prostheses.

**Limitations of RFID**

There are a number of challenges posed by RFID implementation in healthcare:

**COST.** RFID is still expensive, not plug-and-play, and has not yet proven its reliability in large-scale implementations.

**ENVIRONMENTAL CONDITIONS.** Tag reliability can be impacted by humidity, metal surfaces, and more. Current RFID tags cannot withstand extreme temperatures without temperature resistant housing. For that reason, using them for items like surgical instruments is complicated.

**LIMITED APPLICATION.** It is difficult to apply and read RFID tags on metal and fluids. This currently limits tag application to cardboard, paper and plastic packaging.

**TECHNOLOGY INCOMPATIBILITIES.** Interoperability between different RFID standards—for example, the ability for a single reader to read tags from multiple frequencies—is not available at this stage, and will be technologically difficult to achieve.

**Applications in Healthcare**

RFID applications in healthcare could include:

• Supply chain applications. This includes high-cost items like pacemakers, defibrillators, and artificial joints. The supply chain for these items is complex, and they are often supplied on consignment. They also require a high degree of traceability from the supplier to the patient.
• Patient safety applications. This may include improved patient identification using RFID tags in patient wristbands.
• Quality assurance applications. This may include improved instrument tracking for infection control purposes. Some vendors supply RFID-enabled trays that can be tracked through central sterilizing departments.

**Will RFID Supersede Barcoding?**

Barcoding will continue to be used in the future, and will co-exist with RFID. As with all technologies, each will be utilized in the functions for which it offers the highest benefit/cost ratio and comparative advantage.

Consideration of the following will help determine which technology is used:

• The marginal cost of including a barcode on a product label. For low-cost items sold in high volumes, barcoding is still a viable and cost-effective option.
• There will always be applications that do not require many items to be read simultaneously. In these cases, RFID offers only a small benefit over barcoding.
• Barcoding is a mature technology, and its scanning reliability is well proven in broadscale implementations. By contrast, RFID is relatively immature, and is yet to be proven in widespread usage.
• Because some members of the supply chain may not have the capability to implement RFID, a second means of identification would need to be applied to all RFID-tagged products. This is not necessary for barcoding or other 2D options.

**Current RFID Standards**

RFID is a complex technology that includes many components, each requiring standardization to achieve interoperability. And, because there are numerous standards that are related to RFID, they can be confusing. However, they all fall into two broad categories:

• Standards that relate to the air interface, or transmission frequencies and parameters for communication between the RFID reader and tag; and
• Standards that relate to data and applications for RFID systems.

The leading worldwide organization that oversees these standards is the ISO/IEC (International Organization for Standardization/International Eurotechnical Commission).

HIBCC RFID standards and recommendations are designed to be consistent with ISO/IEC standards.

**RFID Resources**

HIBCC provides an RFID Resource Center from its web site available at www.hibcc.org. Included in the RFID Resource Center:

Using HIBC Standards with RFID: An Implementation Guideline, detailing the requirements for utilizing the HIBC Supplier Labeling Standard with RFID technology;

Understanding RFID in Healthcare: Benefits, Limitations and Recommendations, a comprehensive and practical guide to RFID technology, its potential in healthcare and the cost implications of implementation;

Articles and announcements from other industries regarding trends in RFID.

Requests for publication copies of materials can be made to the HIBCC office at: 602.381.1091 or via email at: info@HIBCC.ORG.
Records may be truncated after the last field that is implemented to reduce symbol size.

By using the tag structure, the messages are ‘embeddable’. The messages must be human readable. Although most implementations are likely to use 2D symbols, the standards focus on the data, not the media. 2D symbols, RFID chips, wired and wireless media may be used to convey the data.

The goal of having an “electronic label” is attainable using the standards. A patient wristband can contain only a patient id number; or it can contain name, age, physician, and other information. The photo of an insulin vial accompanying this article shows a set of symbols for drug identification that contains the full drug name, NDC number, drug amount and total volume, lot number and expiration date.

Infusion pump medication administration can fully involve all areas of the standard. The employee badge identifies the employee to the pump.
The patient wristband associates the patient to the pump. The IV medication symbol communicates patient information, drug information and dosing instructions to the pump. A device license plate on the pump enables workflow devices such as PDA’s to link to the pump to download log information. It is important to remember, however, that no matter how much information is communicated to the infusion pumps via the data, it is still ‘best clinical practice’ to require clinician review and positive acknowledgement before the medication is administered.

The implementation of wireless networks is growing in healthcare. This provides opportunities for infusion pumps to verify against the ordering systems that medication orders are still active/appropriate. A “bar code” system provides a backup system for caregiver validation when the network is down. It can also provide a low-cost alternative to a wireless implementation, or the ability to pilot use of the ‘smart pumps’ for a safety initiative before an expensive wireless infrastructure is available. Non-network connected devices can read and redisplay information in an easier to read format, and perform checks such as matching a patient to a patient-specific medication.

Although patient wristbands and employee badges are fairly simple, medication identification and their administration instructions are not. It is most significant that the data in the symbol can convey an NDC number, private drug alias, the drug name, strength or concentration, dose form and route information. If you scan the AZTEC symbol on the cover, you can see an example of an IV medication order.

**SPECIFICATION TO STANDARD**

Upon completion of the standards and review with early stakeholders, Partners Healthcare conveyed the standards to HIBCC in recognition of HIBCC as a focal point for creation of healthcare data interchange standards. The Auto ID Technical Committee (AITC) members and HIBCC staff worked together to revise and re-format the documents in preparation for public review and ANSI approval.

**IMPROVED SAFETY AND THE ‘BOTTOM LINE’**

Implementing the standards can expedite and facilitate implementation of patient safety initiatives for safe medication delivery. This will make hospital patients more satisfied customers and the hospital caregivers more confident that they are providing safer care.

Payors are increasingly looking at safety initiatives, and rewarding institutions as they implement them. Medication safety initiatives seem to be most favored by payors at this time.

**EARLY ADOPTERS**

Sigma embraced the standards early in the development process and is expected to ship their IV bar code ‘smart’ pumps later this year. Smiths Medical allowed modifications of their pump management software to read both the original chemotherapy pump bar code and the 2D symbols of the standards and this software is in use today. A few other large pump manufacturers have developed bar code pump systems but their symbol content is not as advanced as the HIBCC standards. Intermec added the Aztec symbology to their printer line as a result of our work on this project.

Two drug repackagers are in the process of implementing 2D symbols on IV and unit dose medications.
In 1983 the healthcare industry determined that existing bar code standards were inadequate for the specific applications and needs of a healthcare environment. The existing standards were based upon the point-of-sale, “cash register” needs of retailers who did not have patient/consumer safety concerns.

HIBCC’s mission was to design a specialized, yet fully interoperable, bar code labeling standard based upon the critical requirements of a health care environment.

The Health Industry Bar Code (HIBC) System is a result of these efforts. Here’s what makes it the preferred standard for healthcare—

+ **Alphanumeric Character Set** — The HIBC Standards utilize an alphanumeric character set. This allows for literal encryption of a manufacturer’s existing product identifiers into a bar code data structure, eliminating the need for translation of alpha characters into numeric signifiers.

+ **Variable Length Data Structure** — The variable length data structure allows the manufacturer to incorporate current product identifiers without having to truncate or pad digits.

+ **No Risk of Duplication** — The 36 alpha and numeric characters combined with the flexibility of a 1–13 digit variable length format, provide an almost infinite set of identifiers — over 75 quintillion (mathematically defined as 75 million trillion). This virtually eliminates the possibility of duplicate identifiers in the same database.

+ **Consistent on All Packaging Levels** — The HIBC data structure is consistent for every package level of a product, whether it is a unit-of-use or a pallet load. Different levels of product are specified within the ‘level of packaging indicator’ field with manufacturer assigned characters. This simplifies and reduces the risks in building software systems to scan the bar codes. When tracking and traceability for the purposes of recall are at issue, this streamlining is both critical and essential.

+ **Globally Compatible** — The HIBC data structures are the same everywhere in the world. There are no regional variances. This enables implementation of secure and efficient tracking processes in both domestic and international markets.

+ **Secure Link Characters** — For many medical and pharmaceutical products, especially implant devices, a primary bar code (product identifier) and a secondary bar code (serial number) are required. During the manufacturing process the primary symbol will be structured and labeled first, with the secondary symbol labeled at the end of the assembly.

  Only the HIBCs have a ‘link’ character to prevent the wrong serial number from being matched up with its product identifier. This is a critical feature for ensuring the security and reliability of tracking processes and their extension into the hospital environment.

+ **Embedded Data Check Characters** — All HIBCs have data check characters to verify the accuracy of the information encoded in the data structure. Check characters also guarantee that the data messages have not been corrupted during transmission. This prevents errors in the scanning of product identifiers and secures the process of product tracking.

+ **Achieves Interoperability** — The HIBC system of standards provides for the identification of medical products and for all health care applications, including the identification of: patients, clinicians, specimen/tissue samples, pharmacy prepared medications, X-Ray films, medical records, facility locations, transplant organs and surgical instruments. These standards enable consistent implementation of the data capture and verification process and facilitate complete interoperability in a networked hospital environment.

+ **Technologically Advanced** — HIBC Standards specify the use of 2-D symbologies, such as Data Matrix and PDF-417, for small device and instrument marking. Both small space symbols have been widely implemented and are supported by readily available technologies. Data Matrix is currently in use within the aerospace and automotive industries for critical parts identification and tracking.

  Health care products have unique requirements that are especially well suited to the use of small space symbols. Data Matrix is the only symbol that can be etched directly onto a device and read reliably. It is currently used for marking implantable devices and surgical instruments, providing a more durable and less costly alternative to traditional labeling.
The following manufacturers and distributors have implemented the HIBC Labeling standards for their products.

These organizations have demonstrated their support of HIBCC’s goal of implementing auto-ID technology and achieving health care improvement.

We applaud these organizations for their commitment to their customers, the industry, and patient safety.
China
Johnson & Johnson Medical

Denmark
Coloplast A/S
Contura International A/S
Radiometer Medical A/S

Finland
Bionix Implants OY
Kolmi-Set OY
Mediata OY
Sataside OY
Tyke-Tuote

France
ATF-Vitatech
Becton Dickinson France
Benoist Girard et Cie S.A.
Bioland
Biomatlante
Biomatex S.A.
Corneal Industries
Dentsply France SAS
Ethicon SAS France
Ethnor S.A.
Group Lepine
Hexacath SARL
Helioscopie-Ceerdil
Hospal International
Ilottech Laboratories
Johnson & Johnson Medical
Landanger-Landos
LDK Medical
Medicea
Micro-Mega S.A.
New Deal
Pierre Rolland
Sarl Biomatlane
Satelec
Sofradim Production
Surfix
Tornier

Germany
Abbott Vascular Instruments
Aesculap A.G.
B. Braun Melsungen A.G.
B. Braun Surgical GmbH
BEGO GmbH & Co.
Beiersdorf Inc.
Bosch & Sohn GmbH & Co.
Chem. Pharmazeutische Dentaurum J P Winkelstroet
Dentsply GmbH
Dr. Jean Bausch KG
E. Hahnenkratt GmbH
ESPE Dental-Medizin GmbH
Estheident GmbH
Ethicon GmbH Germany
Fotocochmeische Werke GmbH
Girrbach Dental GmbH
Heraeus Kulzer GmbH
Howmedica GmbH
Howmedica Leibinger GmbH
Johnson & Johnson Medical
Karl Storz - Endoskope
Lohmann GMBH & Co.
Merz + Co.
Merk Dental
Noba Berbandmittel Danz
GmbH
Orochemie Durr + Pfug GmbH
PVB Medizintechnik GmbH
Renfert GmbH
Resorba Chirurgisches Naht
Richter & Hoffman Harvard
ROEKO GmbH + Co.
Scheu-Dental
Serag-Weissner GmbH
Tiolex Implants GmbH
Vita Zahnfabrik

Ireland
Abbott Vascular Devices
Abbott Ireland Limited
Allergan
Howmedica International Ltd.
Howmedica International Inc.
Fujisawa GmbH
Johnson & Johnson Prof.
Products
Mednova
Proxy Biomedical Ltd.

India
Johnson & Johnson Ltd.
Ethicon Division

Israel
Medinol Ltd.

Italy
Biotek SRL
Critikon—Johnson & Johnson
DiaSorin S.R.L.
Dideco SpA
Gambro SpA
Johnson & Johnson Medical Holdings, SpA
Kerr Italia SpA
LIMA-LTO SPA
MD & I SRL
MedicalPlastic S.R.L.
RS Medica SRL
Sorin Biomedica Cardio SpA

Japan
GC Corporation
Fuji Photo Film Company Ltd.
Konica Corporation
Terumo Corporation

Korea
U & I Corporation

Hungary
De-Puy Sanatmetal Mfg.

Mexico
Mallinckrodt Medical Inc.
Mallinckrodt Medical TPI

The Netherlands
Abbott B.V.
Academisch Zkh. Maastricht
Alcon Pharmaceutical Ltd.
Astra Pharmaceutical Products Inc.
Bayer Nederland B.V.
Bipharm B.V.
Boehringer Ingelheim B.V.
Boots Pharmaceuticals B.V.
Bourneville-pharma B.V.
Brocacef B.V.
Brocacef B.V.
Bufa - Chemie B.V.
Byk Nederland B.V.
Centrafarm
Central Lab V.d.
Bleodtransfusiedienst
Christiaens B.V.
Dg Lederle Nederland B.V.
Demex B.V.
Duphar Nederland B.V.
E Merck Nederland B.V.
Eli Lilly Nederland B.V.
Farmaceutische Ond.
Lansbergrotterdam
Gefarma
Gist Brocades
Glaxo B.V.
Guerbet Nederland B.V.
Handelsonderneming Tempus B.V.
Hoehst-holland N.V.
Ici-Farma
Inpharzam/Zambon Nederland B.V.
Interpharm B.V.
Janssen Pharmaceutica B.V.
Johnson & Johnson Medical B.V.
Kabi Pharmacia B.V.
Kativik Farma B.V.
Knmp
Knoll B.V.
Koninklijke Utermohlen N.V.
Lundbeck B.V.
Magnafarma B.V.

New Zealand
Enztec Limited

Norway
Nycomed Imaging AS

Portugal
Johnson & Johnson Produtos Prof.

Puerto Rico
Puerto Rico Hospital Supply Inc.

South Africa
Johnson & Johnson Medical
Ortho Sol (PTY) Ltd.
Spain
Howmedica Faimon S.A.
Howmedica-Iberica S.A.
Johnson & Johnson
Productos Prof.
Metalor Iberica

Sweden
Carmel Pharma AB
Gambro A.B.
LIC Hygien A.B.
Medscand Medical AB
NobelPharma

Switzerland
aBien-Air S.A.
Canduler AG.
Central Labs Blood
Transfusion Svs.
Coltene AG.
Degradable Solutions AG
Hamilton Medical AG
Hospal Ltd.
Jaquet Orthopedie S.A.
Maillefer Instruments S.A.
Metaux Precieux S.A.
Precimed S.A.
Metaux Precieux S.A.
Metalor Iberica
Johnson & Johnson

Turkey
Altera Tibbi Malzeme San. ve Tic. A/S

United Kingdom
3M Health Care Limited
B Braun Melsungen AG
Downs Surgical
BOC Health Care
Boc Health Care
Corin Ltd.
Critikon - Johnson & Johnson
Professional Products
Davis, Schottlander & Davis
Dentistry

United States
3M
3M Med/Surg
A-Dec Inc.
Aaron Medical Industries Inc.
Bovie Medical
Astrom Biosciences
Abbott Laboratories
Abco Dealers Inc.
Ability One Corporation
Absorbent Products
Company Inc.
Dentsply International Inc
Ash Instruments
C.M.W. Laboratories
Dentsply Ltd.
DePuy Dentsply Ltd.
Medical & Industrial Equip.
DePuy CMW
DePuy International Limited
Ethicon Ltd. United Kingdom
E-Z-EM Limited
Finsbury Orthopaedics
Howmedica (UK) Limited
Iolab Intracural (U&J)
John Poulten Ltd.
Johnson & Johnson Medical Ltd.
Johnson & Johnson
Orthopedics Ltd.
Johnson & Johnson Cardiff
Wales UK
Lidco Ltd.
Metalor Dental Products Ltd.
Neoligaments Ltd.
Ohmeda Inc.
Orthodontics
Plasma Surgical Limited
Portex
Portex Limited
Poulten & Graf Limited
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Sherwood Medical Int.
Smith & Nephew
Smith & Nephew plc
Sulzer Vascutek Ltd.
Summit Medical Ltd.
Synthes
Tissue Science Labs
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Limited

Ace Medical
Acme United Corporation
Acumed Inc.
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Advance Medical Design Inc.
Advanced Medical Optics
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Advanced Meditech
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Matrix Division
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\textit{All-Pro Imaging Corporation}
Jelus International
Corporation
Akzo Pharmaceuticals
\textit{Organon Teknika}
Alba Health Products
Alcide Corporation
Alcon Laboratories
Allergan Inc.
Alliant Enterprises Inc.
Amcol International
Chemical Corp
American Australian ME
American Cyanamid Company
\textit{Davis & Geck}
American Dental Cooperative
American Dental Supply Inc.
American Home
Products Corp
\textit{Argyle Div of Sherwood Medical}
Dover Urologicals Div of
Sherwood
\textit{Monoject Div of Sherwood Medical}
Oxford Chemistry Div of
Sherwood Medical
Oxford Lab Supplies Div of
Sherwood Medical
Oxford Liquid Handling Div
Sherwood Medical
Sherwood, Davis & Geck
Veterinary Div of Sherwood Medical
US Clinical Products
Wyeth-Ayerst Laboratories
Amsensham Health
Amsino International Inc.
Anatomical Concepts Inc.
Angioscore Inc.
Anika Therapeutics Inc.
Anesthesia Medical
Specialties Inc.
Angiogenesis Corporation
Angiodynamics
E-Z-EM Inc.
Angioguard Inc.
A-Plus International
Applied Medical Resources
Applied Spine Technologies
Apotheus Laboratories Inc.
Armour Pharmaceutical Co.
USV Laboratories Division
USV Pharma Corporation
Arrow International Inc.
Arrow Precision Products
Arterial Vascular Eng Inc.
Arthrex Inc.
Arthrotek
Aspen Surgical Products Inc.
Astra USA
Athena Champion
Atrium Medical Corporation
ATS Medical Inc.
Audit Microcontrols Inc.
Auric Enterprises
Diack
Austenal Dental Inc.
Nobel Pharma USA
Automated Medical
Products Inc.
Automatic Liquid
Packaging Div
Healthcare Products Div
Avanti Systems Inc.
Avid Medical, Inc.
AXO Gen, Inc.
Bacchus Vascular
Bacharach Inc.
Bacterin International
Banta Healthcare
Baron Medical Corporation
Barriermed Inc.
Barriermed Glove Co.
Barnes Medical Inc.
Bausch & Lomb
Bayer Corporation
Agfa Division
Baxa Corporation
Baxter Healthcare Corporation
Midwest Textiles Inc.
B. Braun Interventional
Systems
B Braun Medical Inc.
Burron Mfg Div
B Braun Melsungen AG
Downs Surgical
Beckman Coulter Primary
Care Diagnostics
Beckman Coulter Inc.
Becton Dickinson & Company
Acucare Division
Diagnostic Instrument
Systems
Immunocytometry Systems
Infusion Systems
Labware Division
Medical Glove Division
Medical Technique Products
Microbiology Systems
Pharmaceutical Systems
Vacutainer Systems
Beiersdorf Inc.
Jobst Institute
Beiersdorf Medical
Bel-Art Products
Maddak Inc.
Belport Company
GingiPak
Bemis Health Care Inc.
Bemis Manufacturing
Company
Bergen Brunswig Corporation
Berkeley Medical Resources Inc.
B G Industries Inc.
Biddle & Crowther Company
Bionutrients
International PLC
Biocompatibles
International PLC
Biocompatibles
International PLC
Bio Compression Systems
BioDerm Inc.
BioForm Medical Inc.
BioGraft Medical Inc.
BioLab Diagnostica S/A
Manufacturers
3M-Minnesota Mining & Manufacturing Corp.
Abbott Laboratories
Abbott Laboratories Animal Health
Advanced Sterilization Products
Agilent Technologies
Aircast Inc.
Alaris Medical System
Alcon
Alliance Healthcare Corp.
Allergan Pharmaceuticals
Altana Inc.
American Pharmaceutical Partners Inc.
Amerigen Inc.
Ansell Perry Inc.
Aplicare Inc.
Apogent Technologies
Apotex Corporation
Arrow International Inc.
Astellas Pharma Inc.
AstraZeneca
Augustine Medical Inc.
Aventis
Aventis Pasteur
B. Braun Medical Inc.
Bausch & Lomb Inc.
Bausch & Lomb Surgical
Baxa Corporation
Baxter Healthcare
Baxter Pharmaceutical Products Inc.
Bayer Corporation
Bayer Corp Animal Health
Beckman Coulter, Inc.
Becton Dickinson & Company
Berlex
Bertek Pharmaceuticals
Biemerieux Inc.
BSN Medical, Inc.
Boehringer Ingelheim Pharmaceuticals
Boehringer Ingelheim Vetmedica
Bracco Diagnostics
Bristol-Myers Squibb U.S.
C R Bard Inc.
Cardinal CTS
Cardinal Health 414 Inc.
Carter-Wallace Inc.
Centocor
Cincinnati Sub-Zero
Colby Manufacturing Corp.
ComMed Corp.
Convatec
Cook Incorporated
Cordis Corporation
Dade Behring
Datascope Corp.
DePuy Orthopedics
Dey Laboratories, L.P.
Eastman Kodak Co.
Eisai Inc.
Elan Pharmaceuticals
Elanco Animal Health
Elekta Inc.
Eli Lilly & Co.
EndoPharmaceuticals
Energizer
Ethicon Endo-Surgery
Ethicon Inc.
E-Z-EM Inc.
Forest Pharmaceuticals Inc.
Fort Dodge Animal Health
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Galderma Laboratories
Gaymar Industries
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Getinge USA
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Glaxo SmithKline
Guidant Inc.
Gyrus Ent.
Heska Animal Health
Hiil-Rom
Hoffman-LaRoche
Hospira Inc.
ICU Medical
Impax
IDEXX Laboratories Inc.
Voland Corporation
Volcano Therapeutics
Vollrath Group Inc.
VQ Company
VWR International Company
W A Baum Company Inc.
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Wallach Surgical Device Inc.
Warner Lambert Company
Parke-Davis Division
Welch Allyn Inc.
Tyco Instrument Co
Diatek Instructions
Welcon Inc.
West Pharmaceutical Services
Westaim Biomedical, Inc.
Whatman PLC
Whatman International Ltd
Whatman Far East Pte Ltd
Whatman Lab Sales
Whatman Specialty Products
Whatman Inc.
Wheaton Industries
Whip Mix Corporation
Whitney Products Inc.
Ascent Medical Corp.
William A Cook
Australia Pty LTD
Winfield Industries
Wright Medical Technology Inc.
Wyant Health Care
Yellow Springs Instrument Co
Young Dental Manufacturing Co
Zassi Medical Evolutions
Zefon International
Zefon Medical Products
Zevex International
Zimmer Inc.
Zimmer Spine Inc.
Zirc Dental Products Inc.
Health Care Providers
Central Labs Blood Transfusion Services
(Bern, Switzerland)
The Cheshire Medical Center
(Keene, NH)
Children’s Hospital Medical Ctr
(Cincinnati, OH)
Cuyahoga Falls General Hospital
(Cuyahoga Falls, OH)
Grande Ronde Hospital
(La Grande, OR)
Geisinger System Services
Geisinger Foundation,
(Danville, PA)
Greenville Hospital System
(Greenville, SC)
Howard Young Medical Center
(Woodruff, WI)
Thomas Jefferson University
(Philadelphia, PA)
Lee Memorial Hospital
(Ft. Myers Hospital)
Methodist Hospital of Indiana
(Indianapolis, IN)
Riverside Community Hospital
(Riverside, CA)
St. Francis Regional Med.I Ctr
(Wichita, KS)
St. Francis-St George Hospital
(Cincinnati, OH)
St. Peter Hospital
(Olympia, WA)
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Advanced Medical Technology Association (AdvaMed)
American Hospital Association (AHA)
Federation of American Hospitals (FAH)
Healthcare Distribution and Management Association (HDMA)
Health Industry Distributors Association (HIDA)
Pharmaceutical Research and Manufacturers of America (PhRMA)

AT-LARGE SEATS

Seats are appointed on a rotating basis by the HIBCC Board to provide a balance of industry representation. Current and previous appointments have included:

- American Society for Automation in Pharmacy (ASAP)
- American Veterinary Distributors Association (AVDA)
- Association for Healthcare Resources and Materials Management (AHRMM)
- Healthcare Information and Management Systems Society (HIMSS)
- US Department of Defense (DoD)