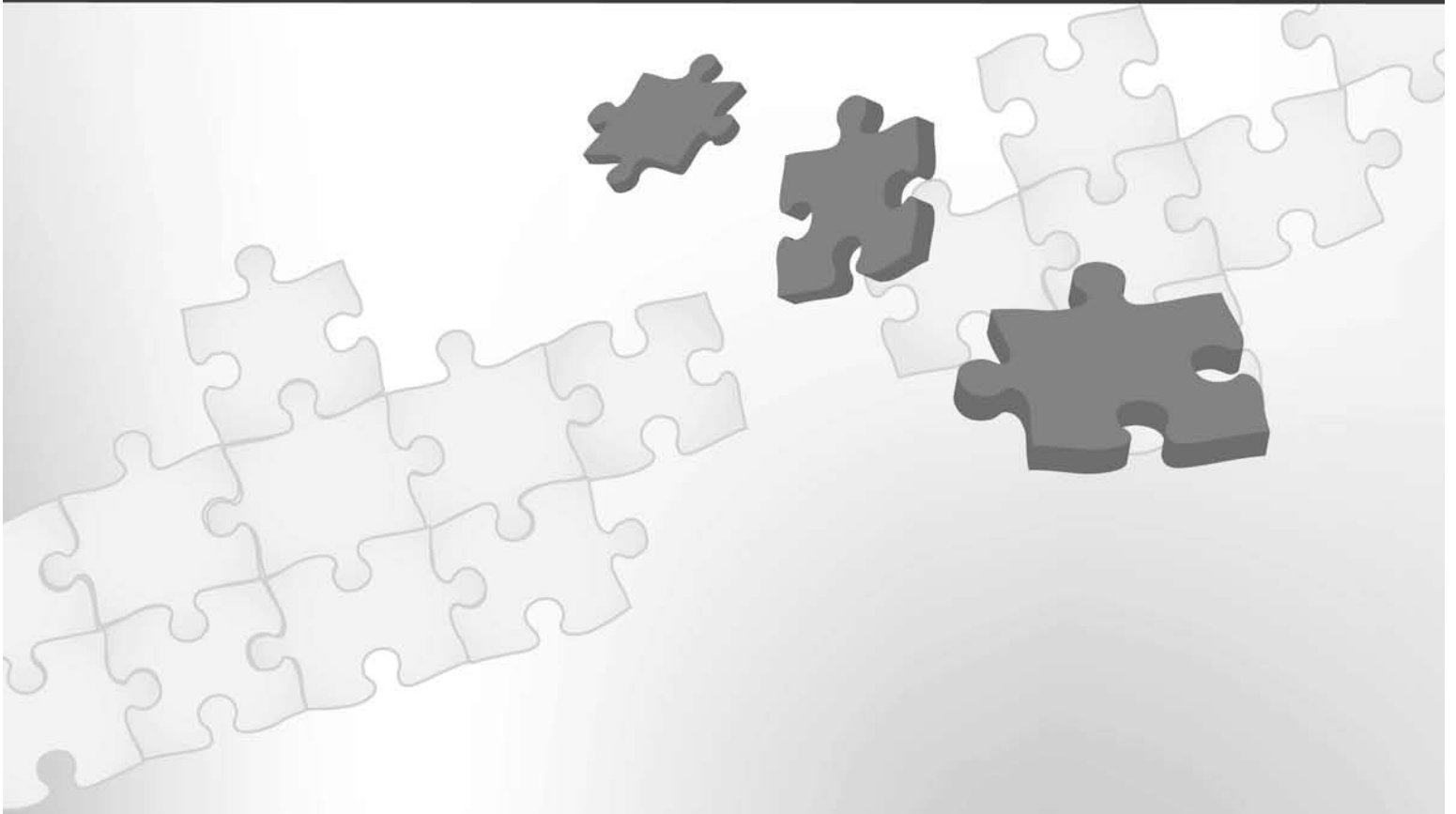


WORKING THE PUZZLE

Data Standards: Heading Toward Sunrise?



Spring 2010 IDN Summit and Expo Peer-to-Peer Learning Exchange Research Report

Data Standards: Heading Toward Sunrise?

WHAT'S INSIDE

Setting the Stage	2
Not Everyone's on Board	3
Unique Device Identification	3
The GS1 Healthcare US System of Standards	4
Steps toward Implementation	5
A Case Study in Success	5
Session Follow-up	6
Information Resources	7

SETTING THE STAGE

This is an important year in efforts to reach agreement on a unique system for identifying healthcare products from the point of manufacture to the point of care.

Driving standards nationally and internationally are a number of legislative acts. In the United States the law is H.R. 3580, which calls for the creation of the Unique Device Identification. It was signed into law by President George W. Bush in 2007. The law creates a mandate for the Food and Drug Administration to establish a unique way to identify each medical product. Those regulations were expected to be released for public comment last year and a final rule issued in 2010. So far, no rule has been issued.

There was also a flurry of activity within the healthcare reform debate over whether to mandate that the FDA come up with regulations for UDI within six months of the reform bill taking effect. The provision in House legislation did not make it into the final law signed by President Obama.

However, the most prominent voluntary effort on product IDs is moving forward. In just seven months what is known as the GS1 Global Location Number Sunrise will be reached. Dec. 31 marks the first milestone in an effort to improve the supply chain's ability to ensure that every medical product reaches its destination and intended user. These common global standards hold out the hope of reducing costs, medical errors and counterfeit products, in the process streamlining what remains a chaotic supply chain.

Most IDNs, their purchasing partners and healthcare suppliers still do business the old-fashioned way: Each uses its own identification system to track products, often manually. That means that trading partners can't properly follow drugs and devices as they move through the supply chain. Products arrive at the wrong locations, and staff members waste countless hours trying to locate them. There is no chain of custody for sensitive materials. Healthcare products are supplied through complex, multi-echelon global supply chains that are vulnerable to infiltration by counterfeit products at too many points in the process. Counterfeit healthcare products are almost impossible for dispensing healthcare professionals to spot.

The end result of all this: Wasted time, wasted money, misuse of valuable employee time and effort, and last, but hardly least, harm to patients.

Standardized automatic identification and traceability systems will simplify and improve accuracy in a multitude of supply chain processes from the point of manufacture to the point of care. Using a unique identification for every individual package enables traceability and authentication systems with readily available technology.

For quite some time there has been evidence of the value of automatic identification systems. For example, the Veterans Affairs Medical Center in Topeka, Kan, has reported that bar coding reduced its medication error rate by 86% over a nine-year period.

The need for standardization on a global scale has been addressed. Major stakeholders around the world, including healthcare providers, purchasing partners, distributors and manufacturers, have signed on to the GS1 system of standards and protocols. Although many have yet to adopt the first step, the Global Location Number (GLN), the vast majority of stakeholders believes this is the system to use. Many other industries have been using these standards and enjoying the many benefits for years.

GS1 are open standards, meaning they are not linked to any proprietary technology. They allow for full interoperability and compatibility, proponents say. Those who adopt them quickly find they can turn their attention and resources to other problems in the supply chain.

NOT EVERYONE'S ON BOARD

Although 93% of respondents to IDN Summit and Expo's Healthcare Supply Chain Survey last fall said that data standardization was "extremely important," an earlier survey found that progress toward GS1 adoption by healthcare providers was lagging.

Conducted by researchers from the Center for Innovation in Healthcare Logistics at the University of Arkansas, Fayetteville, and published in March 2009, the Cost and Quality in Healthcare Logistics Survey of 1,381 health care providers revealed that 31% of respondents were moving toward the adoption of a data standards system, with 85% of those respondents going with the GS1 system. However, 53% of respondents said they did not know if their organization was moving toward the adoption of data standards. "This lack of knowledge is a clear indication that there remains a need for educational efforts to increase the awareness of data standards throughout the health care industry," said the authors of the survey report, Heather Nachtmann and Edward Pohl, professors at the university and leaders of the Center for Innovation in Healthcare Logistics.

Some 27% of the 328 health care provider respondents that are planned adopters of data standards believe that their organization is "ready" or "very ready" to adopt a data standards system. When asked about their timeline for adoption, a small percentage of these respondents (7%) had already adopted a location identification standard such as the Global Location Number (GLN) in the GS1 system, while even fewer (4%) had adopted a product location identification standard such as GS1's Global Trade Identification Number (GTIN). However, an additional 23% of planned adopters expected to adopt both of these standards within one year, in time for the first "sunrise."

With the GLN Sunrise on the near horizon, it may be that significant progress has been made since the center's survey.

UNIQUE DEVICE IDENTIFICATION

The 2007 UDI law signed by President Bush contained the following language: "The (HHS) Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

And yet, nearly three years later, there are no regulations. Various industry groups are lobbying the FDA to explain its position. The FDA is on record outlining the need for device data standards and encouraging industry adoption and implementation of standards, but it says that its charter and the climate of what the agency can and cannot regulate, it cannot mandate a single standard or acceptable multiple standards.

Some in the industry believe FDA is quietly hoping GS1 is adopted voluntarily, while others vehemently disagree.

FDA did hold a public workshop on Feb. 12, 2009, where it discussed developing standardized UDIs, technology for their adoption, creation and maintenance of a UDI database; and implementation/adoption of UDIs by relevant stakeholders. Additionally, FDA sought industry input regarding what information to include in a UDI, which devices to exempt from the requirement, and how to address reprocessed, single-use devices.

A national UDI system would create a common vocabulary for reporting and enhancing electronic tracking abilities. In the most basic format, the UDI would be a coded number registered with standards organizations, and would incorporate a variety of information, including (but not limited to) the manufacturer of the device, expiration dates, the make and model of the device, and any special attributes that the device may possess.

THE GS1 HEALTHCARE US SYSTEM OF STANDARDS

It is no overstatement to say that the U.S. healthcare industry and global suppliers have coalesced around the global standards established by GS1. The supplier community list of endorsers includes Abbott, Amgen, Baxter, B. Braun, Boston Scientific, Bristol-Myers Squibb, Cook, Covidien, Edwards Lifesciences, Fresenius Kabi AG, GlaxoSmithKline, Johnson & Johnson, King Pharmaceutical, Medtronic, Merck & Co., Novartis Pharma, Pall Medical, Pfizer, Purdue Pharma, Sakura Seiki, Schering-Plough, and Smiths Medical.

The Association for Healthcare Resource & Materials Management of the American Hospital Association, which has more than 4,000 supply chain professional members, is also on board with GS-1. Among group purchasing organizations, Amerinet, Novation and Premier are members. Also involved is the Strategic Marketplace Initiative and its 32 healthcare provider members, including Duke University Health System, Johns Hopkins Health System, Mayo Clinic, Sisters of Mercy-ROi, SSM Health Care, University of Kentucky HealthCare, and Yale New Haven Health System.

Taken together, GS1 Healthcare US represents the vast majority of the healthcare supply chain.

The GS1 System of Standards includes a set of identification keys. These are numbers identifying products and services and providing access to information held in computer files. These numbers are:

- Unique: every variant of an item is allocated a separate, unique number.
- Non-significant: they identify an item but contain no information about it.
- International: GS1 identification keys are unique across all countries and all sectors.
- Secure: GS1 IDs are fixed length, numeric and include a standard check digit.

At the heart of the GS1 System are the GTINs. These numbers are allocated by the manufacturer according to published allocation rules. They include a GS1 company prefix assigned to a company by GS1, an item reference assigned by the company and an automatically generated check digit.

The GS1 System also incorporates a number of other identification keys, including the GLN, the Serial Shipping Container Code and the Global Returnable Asset Identifier.

GS1 Identification Keys can be carried on any type of data carrier—a GS1 bar code or a global Radio Frequency Identification (RFID) tag—on the specific product or packaging.

The GS1 Global Data Synchronization Network (GDSN), built around the Global Registry and GDSN-certified data pools, provides secure and continuous synchronization of accurate product and location data.

To push the envelope on GS1 in the United States, there are two sunrise dates for voluntary implementation. The goal of the 2010 GLN Sunrise is to use the numbers on all packages by Dec. 31, 2010. Each GLN identifier is a unique, 13-digit number for a specific location. By the end of this year that would mean:

- GLNs are assigned by location owners.
- GLNs are used in appropriate business transactions and processes between trading partners.
- GLN hierarchy is defined and maintained by location owners.
- The GLN Registry for Healthcare is used to facilitate correct location identification.

A second target date is the 2012 GTIN Sunrise. By Dec. 31, 2012 standardized GTINs would be:

- Assigned to healthcare products.
- Used in business transactions.
- Marked on appropriate packaging levels.
- Scanned at points-of-delivery to enhance clinical process.
- Use in product returns and recalls.
- Registered in a GS1 GDSN-certified data pool.

A number of groups have lobbied the FDA to issue UDI regulations that include the GS1 Healthcare US supply chain standards.

STEPS TOWARD IMPLEMENTATION

Geisinger Health System, Danville, PA., which participates in the Premier healthcare alliance's GLN transaction program, found that the process was relatively smooth and quick to roll out. Starting the process in August 2009, it was using GLNs for every order by October, Deborah Templeton, Geisinger's vice president of supply chain services, writes in an article in *Modern Healthcare* magazine (See Information Resources). "Geisinger currently has 625 GLNs at the 'ship to' level—the point at which the supplier leaves their shipment, and we distribute the products within our own walls. As we get further along, we may assign GLNs to nurses' stations, bins and other internal delivery points for our own control purposes," Templeton writes.

She recommends that to prepare for GLN Sunrise, providers should take immediate steps:

- Work with your GPO to cleanse your listings in the GLN Registry for Healthcare, a directory of U.S. healthcare facilities with corresponding GLNs (gs1.org/healthcare). "The major GPOs have registered for GLNs on behalf of members, yet no one knows your hospital better than you," she writes.
- Take maintenance control of registry information. As hospitals open and close, and new affiliations are added, GLNs must be updated. "Assign someone responsible for maintaining your registry information, since it serves as the single source of truth for location identification for your hospital. Once you have GLNs assigned at the highest level, you should establish the proper hierarchy of locations in the registry, including functional organizations and physical locations."
- Communicate your GLN hierarchy with your GPO to ensure alignment of information.
- Select supplier partners and begin transacting with the GLN.
- Leverage existing resources, including educational programs from your GPO, GS1 Healthcare US industry work groups and publications.

A CASE STUDY IN SUCCESS

In a white paper on its successful implementation of GLNs (see Information Resources), Mayo Clinic describe a relatively smooth, low-cost and swift adoption process.

In July 2008, Mayo Clinic and its distribution partner Cardinal Health collaborated with their mutual electronic business-to-business exchange partner, Global Healthcare Exchange (GHX) to implement the GS1 GLN as their sole account/location identifier for Mayo Clinic Foundation's Lawson Medicaid Management Information System. In October 2009, the three organizations accomplished the same task for Mayo Clinic Health Systems' Meditech information system.

The project was broken up into several phases:

- Phase 1: Pre-Implementation (planning and mapping)
- Phase 2: Cardinal Health Base System (standard order processing)
- Phase 3: Cardinal Health JIT System (value-added processing)
- Phase 4: New enterprise resource planning locations (because Mayo Clinic had an ERP implementation project running simultaneously)
- Phase 5: Wrap-up (resolve lower priority issues)

The test implementation process started with Mayo created 850 test purchase orders using the GLN ship-to locations. Mayo processed the orders and passed the transactions to GHX, which in turn did its own processing and forwarded the orders to Cardinal Health. Cardinal processed the orders and created 855 purchase order acknowledgments, 856 advance shipping notices and 810 invoice transactions, all of which were passed back to GHX. GHX processed those transactions, and then passed them to Mayo. Throughout the entire testing process, the joint GLN team monitored every step. Once each side was comfortable with the Mayo Clinic test results, the process moved to production.

"Internal training is necessary for buyers and customer support to have a successful implementation. It is necessary for end users to understand the changes so that they are able to transact via phone and fax if needed. Training was conducted with the Mayo Clinic procurement staff and a Cardinal Health sales representative," the white paper states.

The major cost of implementation on Mayo's end was devoting employee time to the project. Prior to implementation, it was estimated that 2.5 full-time-equivalent employees would be required over a period of six months. During execution of the project, actual FTEs needed were less than estimated. No incremental budget requests were made to staff the project or to make the minor system changes needed. In the end, the equivalent of just 1.1 full-time employee was devoted to the project.

Mayo Clinic/Cardinal Health price accuracy is currently 99.5%. All other suppliers average 95% accuracy. Superior price accuracy is attributed to not only GLN, but also to the commitment that both organizations make to price integrity and associated improvement efforts.

Mayo Clinic has stated that the GLN will be required by all suppliers by the end of 2010.

SESSION FOLLOW-UP

Introduction

The conclusion of the group was two-part: (1) many healthcare professionals have some understanding of data standardization but there exists a wide range of well informed to not well informed and (2) more broad communication is necessary.

Opening

P2P opened with reading H.R. 3580, Food and Drug Administration Amendments Act of 2007, Section 226, entitled "Unique Device Identification System." A summary follows:

"The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

This parlayed into a robust discussion on the issue of technology barriers. The consensus was: there are a number of items (or attributes) to identify. This important piece is currently being managed by GS1 and GS1US in an effort to drive international standardization. Agreeing on an international standard provides incentive for manufacturers to partner on a global basis to ensure they meet one set of attributes for distribution of product across the globe. Some of the discussion centered on any potential barriers whereby suppliers would be incentivized to create barriers for deployment internationally or domestically. The area of "how is this different from other industries?" seemed to allay concerns about supplier barriers, as other industries led efforts to standardize for the benefit of the industry as a whole.

A fair amount of discussion centered on whether data standardization was a patient safety issue or supply chain issue. The consensus of the group, which was an interesting perspective, was data standards is a supply chain issue. The reason why this is an interesting consensus is because the FDA's mission is patient safety, not supply chain. When asked "How can we move UDI to the finish line?" the consensus was focusing on patient safety.

Privacy was another issues garnering quite of bit of discussion. Concern was mentioned regarding use of data mining tools to surface patient type information that could be used or sold for other purposes.

Wal-Mart's name was mentioned as an industry trailblazer and the question was asked, "Is there a Healthcare Wal-Mart to drive this initiative?" The answer on the surface is: No! There is no Healthcare Wal-Mart. What does exist, though, is a strong group of providers, manufacturers, distributors, and MMIS companies that are a strong driving force under a non-profit organization called SMI (Strategic Marketplace Initiative). This group, along with GPO's, the Mayo Clinic, GS1 (and their subsidiary GS1US), AHRMM, Department of Defense and other associations are working in collaboration to ensure communication is available to all interested parties. The consensus, though, was providers will have to continue leading the industry while the FDA will continue driving compliance.

Transitional Concern

Some discussion centered on a transitional concern of the FDA's involvement. Basically, where is the FDA in all this? The group was informed that the FDA is providing strong leadership in this area, having worked with all players, especially SMI members, for the past couple of years to ensure sufficient insight was provided by providers and manufacturers on the issues related to a full implementation of data standards. Great progress has been made by the FDA to reach out to their counterparts in other countries around the world in an effort to standardize to one set of attributes.

Additionally, senior representatives from the FDA have been quite visible in the market and have spoken at numerous association meetings and summits providing understanding of the FDA's rationale for implementing the H.R. 3580. They are continually soliciting input from providers and manufacturers to ensure pending regulations forthcoming in a Federal register will essentially address how the healthcare industry will meet specific patient safety requirements.

Conclusion

For the most part, participants agree that data standardization will greatly approve healthcare safety and efficiency. There is a strong interest to ensure a robust communication continues throughout the industry so all parties (providers, manufacturers, distributors (especially private-label distributors, MMIS companies, applicable federal agencies, and patients) are well equipped to implement and efficiently drive standards and achieve patient safety results as each segment of data standardization is implemented.

The participants were informed of many locations (website or direct request) where GS1US data standards are being driven. Examples include ARHMM, Premier Inc., Novation, GS1US, and other upcoming locations as we move forward in time. Adding a link to the IDN Summit website would provide another location where advertisement could take place, while providing updated information and GS1US tools.

It is a fair request for all interested parties to search the web for more information by typing any of the following:

- GS1 Global Trade Item Numbers (GTIN)
- Standardized Location Identifiers or Global Locator Numbers (GLNs)
- Global Data Synchronization Network (GDSN)
- 2010 GLN Sunrise
- Mayo Clinic website
- DoD Data Synchronization Pilot
- AHRMM under Topics of Interest "Healthcare Supply Chain Data Standards"

INFORMATION RESOURCES

- Unique Device Identification law backgrounder, Wikipedia http://en.wikipedia.org/wiki/Unique_Device_Identification
- The State of Healthcare Logistics: Cost and Quality Improvements Opportunities, a survey by the Center for Innovation in Healthcare Logistics, University of Arkansas, and the Association for Healthcare Resources & Materials Management www.ahrmm.org/ahrmm_app/resources_and.../index.jsp
- Heather Nachtmann and Edward Pohl: "The industry's take on data standards: Survey reveals thoughts on standards, adoption timeline," *Materials Management in Healthcare*, March 2009 http://www.matmanmag.com/matmanmag_app/jsp/articledisplay.jsp?dcrpath=MATMANMAG/Article/data/03MAR2009/0903MMH_FEA_CoverStory&domain=MATMANMAG
- GS1 Healthcare Reference Book 2009/2010 http://www.gs1.org/docs/healthcare/GS1_Healthcare_Reference_Book_2009-2010.pdf
- Healthcare Provider Tool Kit: How-To Guides to Help Improve Patient Safety and Supply Chain Efficiency with GS1 Standards <http://www.gs1us.org/Default.aspx?tabid=207>
- White Paper: Mayo Clinic/Cardinal Health GLN Implementation: Improving Patient Safety and Supply Chain Efficiency with GS1 Standards May 2009 <http://www.google.com/search?source=ig&hl=en&rlz=&q=Mayo+Clinic%2FCardinal+Health+GLN+Implementation>
- What are data standards, and why are they important in the healthcare supply chain industry? http://www.ahrmm.org/ahrmm_app/ext/standards/
- Deborah Templeton, "Be an early riser—there's still time to prepare hospitals for Global Location Number Sunrise," *Modern Healthcare*, March 8, 2010 <http://www.modernhealthcare.com/article/20100308/MAGAZINE/303089947#>

