

Change has finally come: U.S. Healthcare industry to implement common data standards to improve safety, reduce costs

ABSTRACT

Product information in the U.S. healthcare supply chain is inconsistent and inaccurate. Currently, the industry suffers from the lack of a systematic way to consistently identify distinct medical/surgical products, which negatively impacts the rest of the supply chain, including the quality of care delivery for patients. With e-commerce now defining the day-to-day business processes in the healthcare setting, the healthcare industry must leverage technology advances to create a more efficient and effective supply chain, to reduce unnecessary costs and to improve patient safety.



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After decades of studies, pilots and colorful debate, the healthcare industry is finally making huge strides toward the selection and implementation of a consistent set of supply chain data standards and a system to synchronize product information so that all trading partners can speak the same electronic language. These standards, by GS1, have been proven successful in other multi-billion dollar industries. They are being endorsed by healthcare's leading provider organizations, including the Premier healthcare alliance, as a means to ensure basic information in the healthcare supply chain is accurate, up to date and synchronized. Premier and others have taken steps to accelerate the implementation of the GS1 standards in order to bring about greater efficiencies, reduce costs and improve the quality of patient care.

Healthcare's Dirty Data

In 2008, healthcare spending in the United States reached \$2.4 trillion, representing a staggering 17 percent of the nation's gross domestic product. Medical supplies – a \$200 billion industry – typically account for up to 40% of a hospital's operating costs, and represent the second largest expense to hospitals after labor. Industry estimates point to more than \$11 billion of waste each year due to inefficient processes, rework, order and invoice errors and outdated information technology. At the core of these problems is bad supply chain data.

Healthcare's most basic data – electronic descriptions of the products used to treat patients, which companies manufacture these products and where the products should be delivered – is unreliable, inconsistent and out of date. Bad data has long served as the source of a negative ripple effect throughout the supply chain that adds billions of dollars in avoidable costs, creates inefficient processes and, most importantly, negatively impacts patient safety.

Other multibillion dollar industries, including grocery, hardware and retail, run their supply chains more effectively. What is their secret? These industries identify products using consistent electronic data standards, synchronized through a single source of accurate product information, to bring data truth to every part of the supply chain.

Unlike virtually every other product in commerce, medical supplies and devices cannot be identified in a systematic and consistent manner, and the healthcare industry is not able to reliably identify potentially life-threatening recalled or defective medical devices. Whereas other industries use consistent and synchronized data standards to ensure all trading partners and information systems speak the same electronic language, healthcare lags in the ability, for example, to track and trace a recalled product from manufacturer to end use, or the patient's bed side.

Recalled pet food contaminated with deadly chemicals can be quickly and efficiently removed from shelves, but we cannot reliably identify potentially life-threatening recalled or defective medical devices. Most experts also agree that one of the primary reasons for increased supply costs and the inefficiency of the healthcare supply chain is the lack of consistent Unique Device Identification (UDI), accessed through a synchronized Product Data Utility (PDU) – a single data source in healthcare that all constituents access for the most up-to-date product information available.

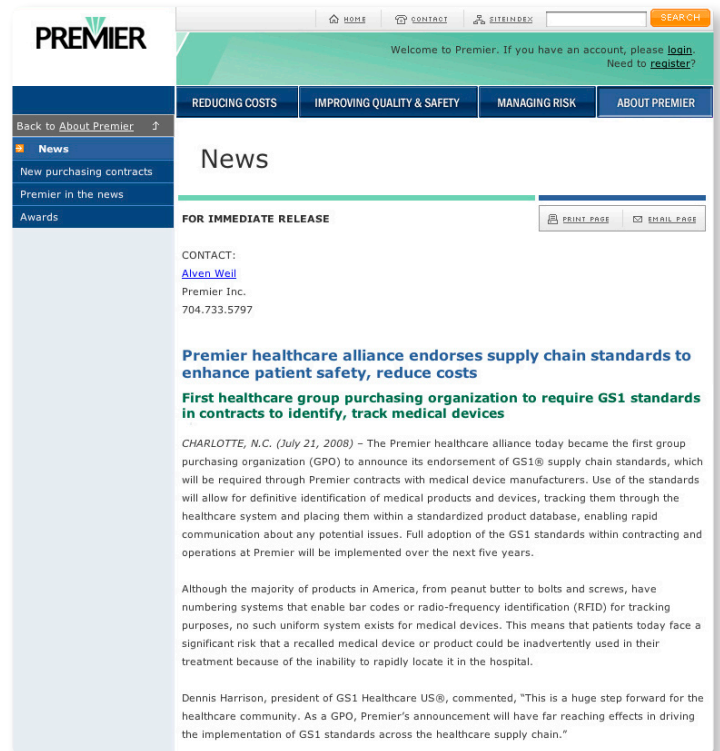
The absence of a UDI via a PDU also results in dirty or inaccurate product item masters that create mismatches in accounts payable; wasted clinician time searching for correct products; and inaccurate pricing, rebates, returns and credits. The data language problem exacerbates the broken supply chain, creating confusion and manual rework as the norm, with the impact being adverse effects on patient safety and increased costs.

In addition, efforts to implement Electronic Health Records (EHR), Radio Frequency Identification (RFID) and other high-visibility patient safety technologies are important but will fall short if the data foundation is not in place in the nation's medical supply chain. In a society where scanning the barcode of a pack of gum is done in an instant and without a second thought, it is hard to fathom just why healthcare is so behind given the life-saving nature of its products.

The New Gold Standard in the Healthcare Supply Chain

In 2006, the Premier healthcare alliance, an alliance of more than 2,100 not-for-profit hospitals working to improve the quality and cost of healthcare, surveyed its members to better understand how the industry tracks and records medical device recalls. The survey showed that the recall "process" was more like a "guessing game", and 80% of respondents said they believed that an industry-wide UDI for medical devices would enhance patient safety.

Industry leaders are rallying to take a long-overdue stand against the dangerous status quo in the healthcare supply chain. In the past year, several influential organizations, including providers, group purchasers and industry associations, called for industry implementation of a common,



universal and global set of data standards and a system to synchronize critical product data. Even the U.S. Congress has mandated the use of a single UDI system, similar to what we see in pharmaceuticals and in every other industry, with the passage of legislation in fall of 2007.

The industry is voicing its support of three standards from GS1 based on their success in other industries, as well as other criteria such as their global applicability (see information box). Lessons from ongoing industry pilots, including the U.S. Department of Defense test of the Global Data Synchronization Network® (GDSN®), proves that such a system could serve as a platform for healthcare data synchronization, validates that data synchronization is achievable in the near term, on a large scale, with immediate value realized.

Many provider organizations have taken an additional step by requiring their manufacturer partners to incorporate certain standards in order to win contracts. Premier announced in July of 2008 that suppliers who win their national contracts must adopt GS1 standards within five years, and the industry endorsed implementation dates for GLN (2010) and GTIN® (2012). The decision was made to issue the requirement based on years of input from member hospitals and participation in industry standards efforts. Our belief is that the timing of the requirement will

accelerate implementation of the standards that are needed to improve patient safety, reduce costs and drive efficiency (see timeline and roadmap graphics). Due to our purchasing power, organizations like Premier can play a significant role in the acceleration of standards implementation, a responsibility that we take seriously.

It is anticipated that the U.S. Food and Drug Administration will issue its requirement to manufacturers to use a uniform system that recognizes the GS1 standards, a system that has proven itself in other industries and around the world. In addition, healthcare manufacturers are already using GS1 standards to support their other markets here and abroad.

This initiative, which will impact hundreds of thousands of medical devices and supplies, complements and strengthens the FDA's work to create a uniform and nationwide system and will accelerate adoption by the industry as a whole. Collaborating with suppliers on standards adoption will help ensure correct products are delivered to correct locations, leading to an increase in patient safety, and a decrease in supply chain costs.

The GS1 standards – the GTIN, GLN and GDSN® – are used by Wal-Mart and other large retailers, and support the supply chains of the hardware, electrical and consumer goods industries among others. They are tried and true in those industries, with results showing that clear visibility to product information by both suppliers and buyers leads to more efficient business processes, reduced costs and increased revenues. Everyone has something to gain. Studies in healthcare show the same promising results, with the added benefit of increased patient safety.

In healthcare, the three GS1 standards will help electronically describe important information needed to effectively move and track a product throughout the supply chain. They will also help communicate that information between different information systems within a hospital, or between a hospital and supplier, at any point in the supply chain and in any direction.

Back to Basics

Basic information technology elements must come into play in healthcare in order to make a real difference on how efficient the industry can become. It is not enough, for example, to create an EHR when, right now, that EHR may not have the accurate information about which products a

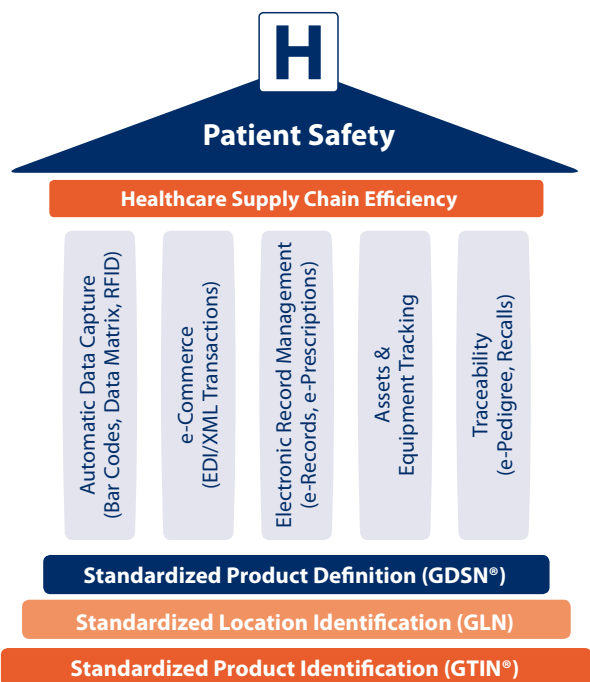
patient may have used. These standards will contribute to interoperability in healthcare, and will streamline the flow of information in the supply chain and beyond.

With these standards serving as a basic foundation, hospitals and suppliers will be better able to automate the data capture process via RFID and bar coding. The current challenges inherent in healthcare's e-commerce transactions – varying levels of system sophistication, outdated IT, manual data inputting, inaccurate information – will be a distant memory, making room for more effective methods and providing a baseline for electronic records management. With everyone in the supply chain "speaking the same electronic language," products can be better tracked and traced throughout, improving healthcare's chaotic recall process and reducing the potential for the introduction of counterfeits. Increasing efficiency will reduce costs and positively impact patient safety – the mission shared by all constituents of undeniably the nation's most important supply chain.

The U.S. healthcare industry is pursuing the extraordinary opportunity to leverage technology advances to create a more efficient supply chain, reduce costs and, most importantly, to improve the safety of patients that use medical products as part of their care. The question has evolved from "if" to "when" the industry will reap the benefits of adopting and implementing consistent supply chain data standards, and that time has come.

The GS1 standards required in Premier contracts include:

- Global Trade Item Number® (GTIN®) – A GS1 standard used to uniquely identify products at all packaging levels, such as medical devices, ranging from syringes to pacemakers, reducing transaction errors and inefficiencies.
- Global Location Number (GLN) – A GS1 standard used to uniquely identify locations and legal entities from manufacturers, distributors, hospitals, all the way down to nursing stations. Reducing transaction errors while ensuring that the right product, procedure, and/or treatment is delivered to the right location.
- Global Data Synchronization Network® (GDSN®) – Stores GLNs, GTINs and associated product definitions or attributes, allowing users to access accurate product information including changes and updates. The GDSN is used by more than 18,000 companies for more than three million products.



Standardization → Interoperability

GS1 Healthcare US describes its standards as the foundation needed to build a safe and solid supply chain in healthcare. With the 3 Gs at its foundation, hospitals can perform many effective supply chain functions, such as automatic data capture, e-commerce, electronic records management and other applications that serve as the pillars to improve patient quality and safety, as well as efficiency in the supply chain.

Premier's iterative approach toward comprehensive standards adoption:

- 2008 – Launch and education; modify contract to include requirements for standards compliance.
- 2009 – Request that providers and suppliers recognize GLNs and that the suppliers begin to register GTINs for their products.

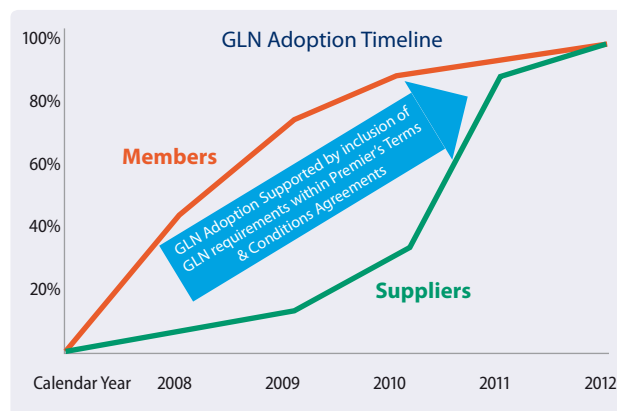
AUTHOR

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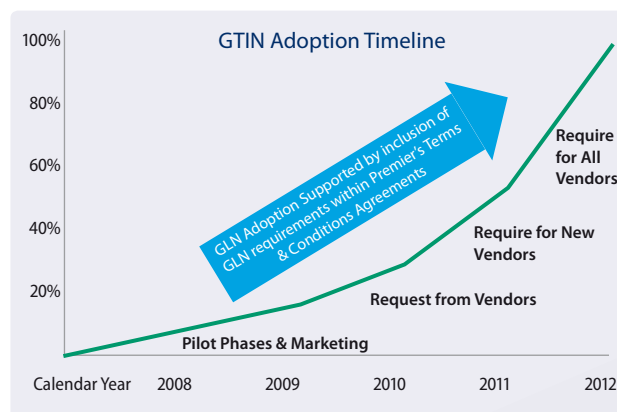
The Premier healthcare alliance is more than 2,100 U.S. hospitals and 54,000-plus other healthcare sites working together to

- 2010 – Require recognition and use of GLN by all providers and suppliers.
- 2012 – Require GTIN for all products from the suppliers; require the use of GTINs by all providers

Coordinating GLN adoption by Members & Suppliers



GTIN Adoption Timeline for Suppliers



Premier's GLN initiative targets 244 member hospitals, and as of Feb. 2009 is 54% complete. Premier is reaching out to representatives from 51 supplier partners to work with them to get medical products registered for GTINs.

improve healthcare quality and affordability. Premier maintains the nation's most comprehensive repository of clinical, financial and outcomes information and operates a leading healthcare purchasing network. A world leader in helping deliver measurable improvements in care, Premier works with the Centers for Medicare & Medicaid Services and the United Kingdom's National Health Service North West to improve hospital performance. Premier has offices in San Diego, Charlotte, N.C., Philadelphia and Washington.