Scan a Med, Save a Life: Advocates Work to Introduce GS1 in the Healthcare Industry, Promise Safer Care

By Christian Hay

Originally designed to shorten long wait times at the grocery store checkout, UPCs—the black and white bars and numbers printed on nearly all consumer items—are now expanding into healthcare with the promise of improving medical device use and raising the quality and safety of provided care. UPC is part of the GS1 system of standards, which has been used globally for 40 years to address supply chain issues.

Developed and maintained by its users, the standards allow enhanced processes regarding traceability and supply chain integrity. The standard is used in many domains, including healthcare, and offers benefits to all parties in the healthcare industry.

Creating Globalized Healthcare Product Standards

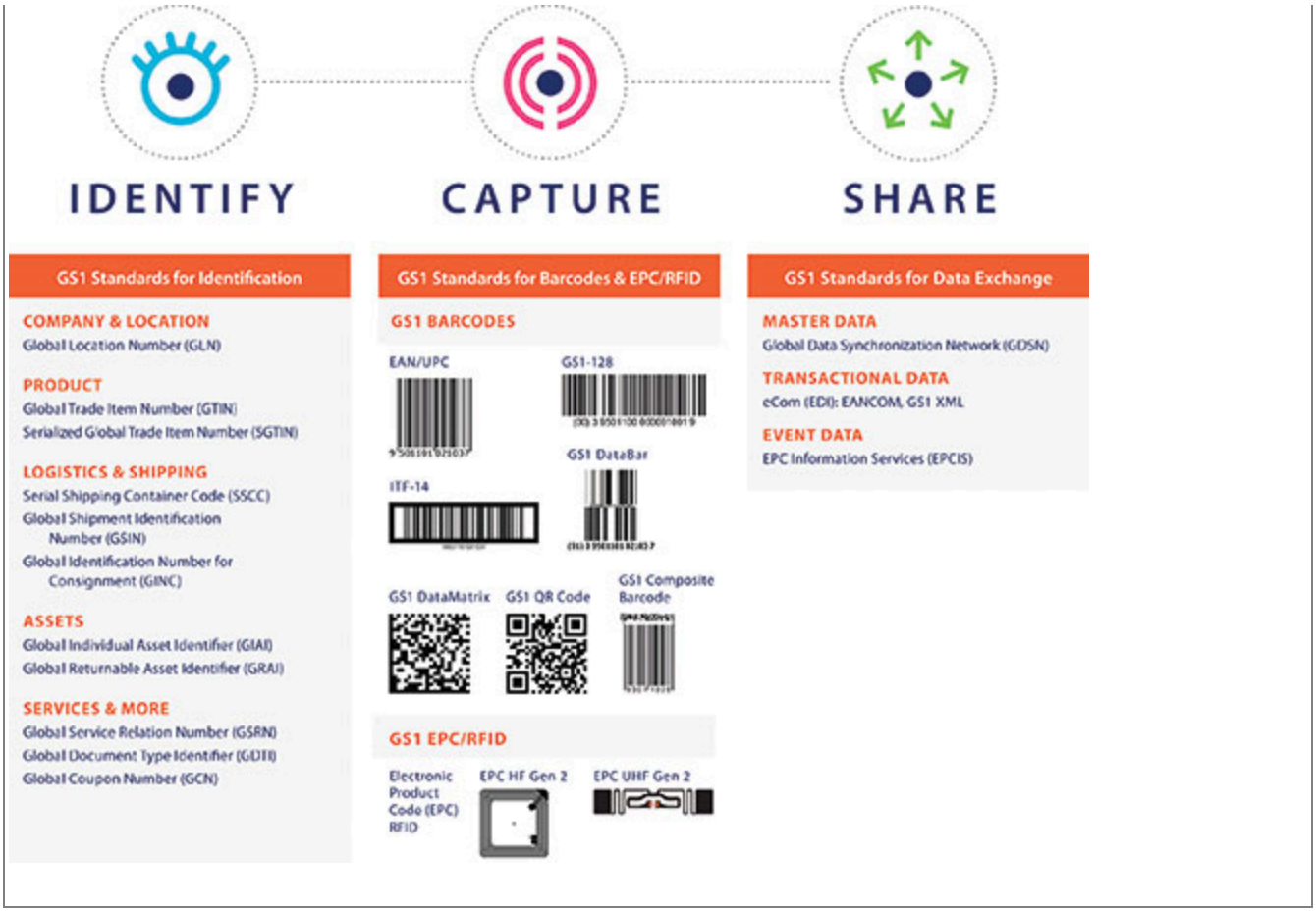
With more than 110 local member organizations and 1.5 million members, global standard development organization GS1 provides and maintains the supply chain standard that each of us experiences every day at some point of sale. From the first scan of a Wrigley chewing gum package 40 years ago to current scanning possibilities at the point of care, GS1 has been driven by its members to make the standards evolve and respond to market needs across the world.

The healthcare industry was added to its top priorities in 2005, and since then has been governed by a Leadership Team, elected by a growing number of global members. The vision adopted by the Leadership Team is "to be the recognized, open, and neutral source for regulatory agencies and trade organizations and other similar stakeholders who are seeking input and direction for global standards in healthcare for patient safety, supply chain security and efficiency, traceability, and accurate data synchronization." And the mission remains unchanged: "To lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies."

In eight years, a considerable journey has brought major changes in the medical device and pharmaceutical industry. In both segments, the main driver has been to focus on a global approach to GS1 which allows increased efficiencies on the manufacturer side as well as on the provider side. This has recently been investigated and quantified by McKinsey in the detailed report "Strength in Unity: The promise of global standards in healthcare."[1]

The Right Product at the Right Place

The GS1 system of standards help the healthcare industry better track products and services using three domains—identify, capture, and share.



Supply Chain and Patient Safety

It has been recognized that a good supply chain enhances patient safety. For example, immunization campaigns in low-income countries are successful when there is the right quantity of a vaccine available at the right place and at the right time. This means in order to be successful, the healthcare industry should have a supply chain that allows the following:

- The right product is at the right place. It is neither expired nor the subject of a recall.
- Pharma supply chain's safety is enhanced by providing unique identification on each medicinal product package. (This is achieved by serialization.)
- Medical devices are globally and unambiguously identified according to the recent US Food and Drug Administration (FDA) regulation on Unique Device Identification (UDI), which is currently in progress, as well as other future regulations in other regions.
- Because pharmaceuticals and medical devices are labelled with bar codes on the lowest level of packaging, care processes can be improved (reducing errors), be better documented (reducing key entry errors), and be the subject of precise cost calculation.

The Right Product at the Right Place

GS1 standards for identifying, capturing, and sharing information about products, business locations, and more make it possible for companies to speak the same language, connect with each other, and move their business forward. Thus, the GS1 system of standards consists of three major domains: identify, capture, and share.

The domain "identify" includes a semantic, the purpose of which is to ensure that every single supply chain actor across the world uses the same definition for a "trade item," a "document type," or a "location." Other definitions exist for "service relation," "assets," "shipping containers," etc.

Each of these clearly defined objects corresponds to a specific identification key. For example, a "trade item" such as a medicinal product package corresponds to a "Global Trade Item Number" (GTIN), which is made up of a fixed length, 14

numeric digit.

Once the object is defined and identified, the user will allow its supply chain partners to "capture" the information by using, for example, a bar code. Detailed guidance for the selection of the appropriate data carrier helps users in their data carrier selection.

The "share" component of the GS1 system helps a shipper and a recipient exchange electronic information so that the identification keys documented by the shipper can be understood and processed by the recipient. Good supply chain management using GS1 includes electronic synchronized catalogues and messages to document supply chain integrity.

Supply Chain Integrity and Medication Verification

Intrusion of falsified medicines in the legitimate supply chain is a concern for a growing number of regulators across the world. Beside overt and covert features that provide safer packaging—thus making it more difficult to falsify pharmaceuticals—regulators have implemented or are working on requirements to serialize secondary packaging (retail packs). Some packaging safety features include using holograms or features that require the package to be damaged when opened.

Serialization means that each medicinal product's packaging has to be identified uniquely and unambiguously. This can be achieved with the GS1 system of standards and has already been implemented in countries such as Turkey and Argentina. Along the supply chain each actor has to document incoming and outgoing items. This gives regulators and others the ability to check the integrity of the supply chain and is sometimes called "electronic pedigree." This corresponds to the objective of the California Board of Pharmacy, for example.

In Europe, stakeholders have another approach to the fight against falsified medicines in the legitimate supply chain. The concept is to verify that the unique number on a retail pack has been issued by the manufacturer (or re-packager), and not previously queried, when dispensed in a retail pharmacy. For every market party, the use of one single identification standard provides benefits for the necessary IT infrastructure. For instance, one global manufacturer has estimated that each new additional identification solution would cost an extra $150,000 just to enable its IT systems to host that supplementary feature. Increased production costs are also a factor. That increases costs for all.

Medical Devices: Unique Device Identification (UDI)

In September 2013, the FDA released their "UDI rule," which mandates medical device manufacturers to label their products so that supply chain and clinical processes gain efficiency. Historically, medical devices have been labeled by manufacturers in very diverse ways due to a lack of regulation. The UDI rule hopes to enhance efficiency by requiring the use of standardized product identifications.

Regulators have set criteria that require the labelling standard organization to be accredited by the FDA. GS1 is one of the organizations that have made steps for such an accreditation. Difficulties in vigilance processes in the last years have illustrated that there is a real need to regulate the way manufacturers have to identify the devices they market. UDI is actually an internationally shared project—the FDA has published its rules a little earlier than other regulators, such as the European Union.

Similarly, for nearly five years Turkey has mandated that the suppliers on its market identify their devices and load supply chain information into a government database. This has led to the Turkish market growing in security and transparency, according to information presented at various conferences. The national Turkish product catalog (similar to the US "Global UDI Database") already includes 2.5 million items, with over 90 percent of them being identified with GS1 GTINs.

When addressing UDI, the regulators expect the market and providers to enhance their processes and develop implant registries where appropriate, and organize patient data so that vigilance can be secured in a timely and efficient manner. Currently in the US, a UDI demonstration project is underway led by Mercy Health, based in Chesterfield, MO, with the support of many stakeholders. This project is demonstrating how coronary artery stent device UDI can be integrated into electronic health records, serve as data sets containing clinical and device information, and prepare linkage to other health systems and national registries.

Barcode Scanning at the Lowest Level of Packaging

Medication verification at the point of care has risen in the US as a high priority since the Institute of Medicine Report "To Err is Human" was released in the late 1990s. In the US, the FDA has adopted rules mandating manufacturers to provide a barcode to allow automatic data capture at the point of care on each single medicinal unit.

According to Mark Neuenschwander, president of The Neuenschwander Company, one of the major advocates for patient safety enhancement, more than 70 percent of US hospitals scan medication units before administration to check their accuracy to the electronic prescription. In various other countries, such as the Netherlands, Belgium, and Switzerland, hospitals have implemented systems to improve medication safety. The European Association of Hospital Pharmacists encourages manufacturers to label their products, such as injectable and solid forms, down to the single unit package so that "bedside scanning" can be deployed in a growing number of hospitals.

During 2012 and 2013, a US Centers for Disease Control and Prevention pilot about the use of GS1 DataMatrix on vaccines has demonstrated the benefits of automatic data capture on the vials; accuracy enhancement and reduction of key entry mistakes were the major benefits measured. This impacts not only the electronic health record (immunization file), but also the Immunization Information System and the tracking of the item used (with its GTIN, lot number, and expiration date).

In France, a regulation requires that providers must be able, for each reprocessable surgical instrument, to track back the last five patients with whom that instrument has been used. This requires every single reprocessable instrument to be identified. To achieve this, several hospitals have engraved a GTIN and a serial number in a GS1 DataMatrix to meet that requirement. It is expected that the number of source-engraved instruments will grow, thus preventing the provider from undertaking this cost-intensive task on their own.

GS1 Partnering with HL7 International

GS1 is the organization providing expertise in linking the "real world" to the "information world" when it comes to medical product tracking. GS1's semantics and data carriers should be captured across the supply chain, down to the use by the subject of care. GS1 feels the manufacturer can best identify medication, vaccines, or medical devices with all the necessary attributes, such as batch number, expiration date, or serial number. The manufacturing processes are subject to very sharp regulations, which contribute to the quality of the labels. GS1 helps these manufacturers follow their tracking standards and comply with regulations.

Safer dispensation and safer administration require standardized product identification. The necessary IT components currently lack standardization guidance (i.e., How does one store documentation about ePedigree verification or authentication in the retail pharmacy system?). That is one of the many components of a new work item which has recently passed international ballot in the ISO TC 215 context.

Experts from around the globe have been nominated to work on this issue. Additional expertise from AHIMA members is still welcomed—a US mirror group working on this standard is named "US-TAG," and its secretariat is hosted at AHIMA.

Guidance on documenting the right product—being administered to the right patient at the right time and through the right route of administration—is a work item that needs to be addressed in the near future. The work of GS1 and HL7 International will help make this dream a reality for all countries.

Collaboration between GS1 and HL7 is a key success factor. Identification and semantic from the supply chain has to be leveraged in the clinical world, including public health. Boundaries between the two standards (i.e., for electronic messaging) and paths for interactions are to be described and made available to the users' community. HL7 and GS1 renewed their statement of understanding in October 2013. Each organization recognizes the other's expertise and the benefits in terms of safety that comes from providers fully using GS1 identifications in their processes. Large US providers are already committed to extensive use of global comprehensive identification standards (see www.healthcaretransformationgroup.com/index.php), which illustrates that collaboration between standard development organizations is a recognized direction (see www.jointinitiativecouncil.org).

Stop Thinking in Silos

Recent regulatory initiatives such as the FDA "UDI rule" enable the vision that supply chain identifiers can and should be used along the care processes and ultimately get stored in the medical record. This requires all parties in the healthcare industry to no longer think in isolated silos but to address traceability and safety issues in a transversal manner.

In particular health IT strategists will likely take GS1 identifications into consideration instead of generating proprietary coding. The hope is they will have conversations with the supplier community to understand what has been made available to them and express their requirements for improvement. This new dialogue will allow all parties to improve their processes by bridging supply chain assets in clinical IT. While the journey to healthcare quality will continue forward, GS1 allows healthcare to walk a bit faster.

Note

1. Ebel, Thomas et al. "Strength in Unity: The promise of global standards in healthcare." McKinsey & Company. October 2012. http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf.

Christian Hay (christian.hay@gs1.ch) is healthcare delegate, GS1 Switzerland.

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