Efficient Data Sharing in Healthcare

More and more efforts are underway in different countries on sharing data among doctors and hospitals in healthcare for achieving higher quality and efficiency of clinical care. By accessing a more complete patient's records at the point-of-care, it helps reducing medical errors and duplication of tests and streamline collection of data for quality measurement; however, conflicting standards and privacy concerns are always two major hurdles of sharing data betweens healthcare professionals and institutes.

Complexity of medical techniques in healthcare demands close co-ordination between the various forms of surveillance and the need for ensuring this within a broader risk management-based perspective, at the service of healthcare quality and safety. Unique identification is one of the key elements for sharing data and improving the traceability in and outside of healthcare institutions. It is becoming a major imperative and the associated tools must meet stringent safety standards.

Many healthcare professionals in different countries have already started implementing or even mandating their healthcare suppliers to provide unique identification. GS1 System offers a set of standards for data identification, data capture and data communication. It acts as a common language for healthcare professionals to communicate information accurately and efficiently improving:

- Patient safety, clinical care delivery and patient tracking within hospital and with others
- Product/supply logistics and material management coordination

Accuracy is essential to reducing healthcare errors. While bar coding / RFID alone will not reduce errors entirely, it is an important first step and allow the healthcare industry to dedicate more resources to sharing information for higher quality of patient care.

GS1 Standards in Healthcare

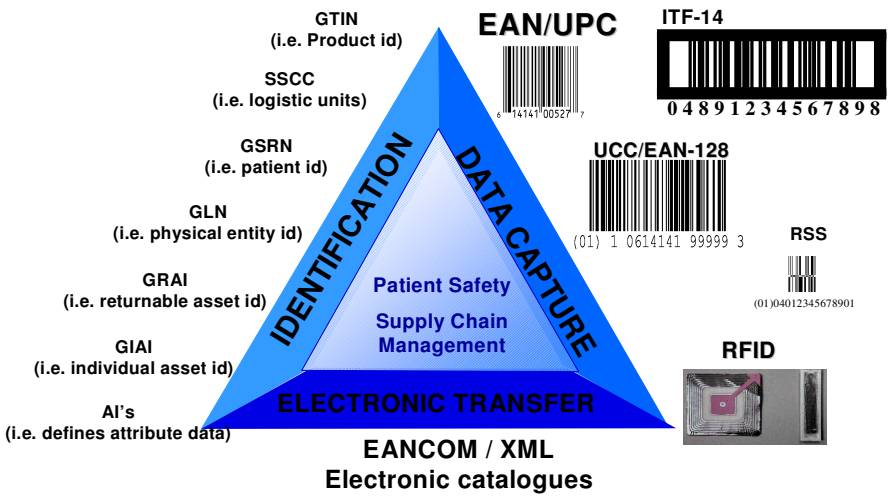
Unique identification, efficient data carriers and standard messaging in healthcare the all

ensuring protection of both patients and healthcare workers; helps to determine responsibilities and facilitates the information flow between parties.

The GS1 System allows health administrators to track and trace product with external suppliers. Information carried in a barcode format or RFID can be captured automatically. This improves a supplier's recall procedures, and gives the health administrator quicker response time to its customer needs, providing a competitive advantage for both parties.

The GS1 system comprises of three distinct components:

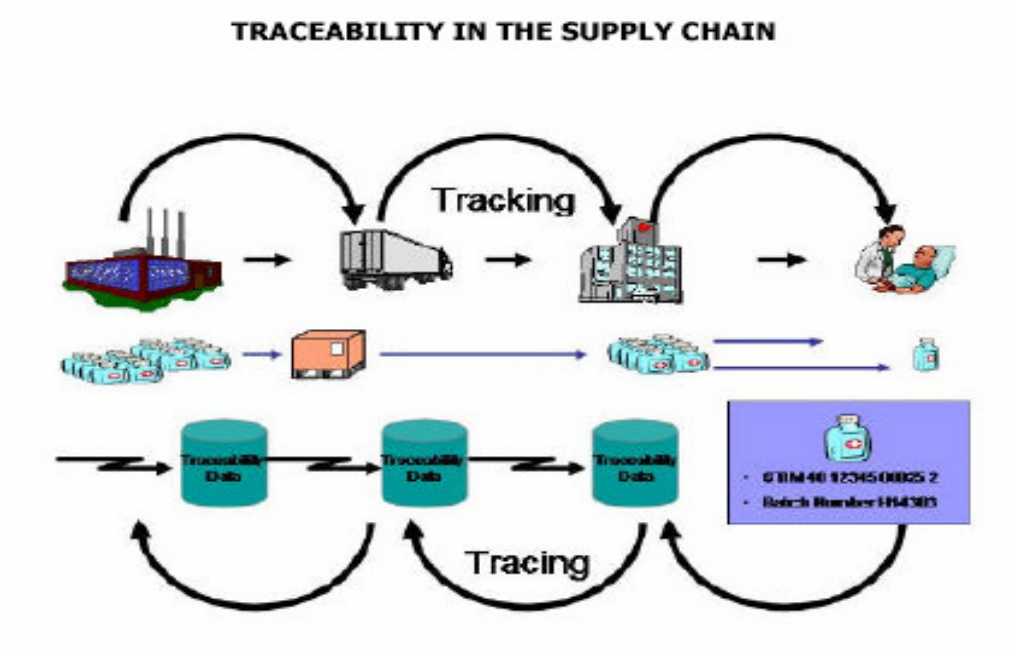
- **Unique identification numbers** to identify goods, locations, patients, assets and services uniquely worldwide
- **Data carriers** as standard bar codes or radio frequency tags (EPC/RFID[1]) for automatic data capture allow automatic data capture, which saves time and costs and reduces errors.
- **Messaging standards for electronic data interchange (EDI)** support the quick and safe exchange of data's between the partners in the healthcare supply chain.



Apart from tracking and tracing products from suppliers, it can also keep tabs on patients

[1] Refer to Appendix 2 for more details of EPC/RFID

and their treatment, monitor their medical devices, including implants and aids for the disabled, and track laboratory test samples, as well as diet requirements.



GS1 System for Risk Management

Through certainty of proper identification and product traceability enabled by the GS1 System, its application in healthcare directly benefits patient care and specifically greater patient safety. The use of a single global system to identify products, locations and people both in the external Supply Chain and also within the hospital or medical centre, enables a harmonized, consistent approach to information management, avoiding misidentification. This increased security, combined with the eradication of time consuming manual processes and paperwork, permits medical staff to focus their skills for the benefit of the patient.

In Summary

The GS1 System enables healthcare professionals to uniquely identify locations, goods, products and services, assets, staff members, patients and services globally. The system is designed to overcome the limitations of using company, organization or sector specific

coding systems, and thus making trading much more efficient and responsive to customers' needs.

GS1 identification numbers are keys to access computer files. They are unique across all countries and all sectors, meaning that each variant of an item is allocated a unique number that eliminates potential medical errors and sharing data moving in and outside healthcare institutions accurately and efficiently.

Appendix 1 - Reference Cases and Past Examples

There are many cases in different countries have already adopted and implemented GS1 Systems. Three cases have been consolidated, namely:

1) German hospital use Global Location Number (GLN) to optimize its e-procurement system.
2) Global Location Number Registry to improve electronic commerce in US healthcare industry.

CASE 1 - German hospital use GLN to optimize its e-procurement system

The German hospital purchasing association Einkaufskooperation kommunaler Krankenhäuser (EKK eG) has decided to use the GLN in order to optimize its e-procurement system, which it is implementing in order to help more than 40 hospitals coordinate their supplies.

In the course of this implementation, EKK has recognized the need for identifying not only each hospital, but also each individual delivery point within a hospital, such as a ward, clinic or cost center. This in turn enables direct delivery, in which, at the time of electronic order, the supplier is instructed by EDI which specific locations should receive which articles.

In this manner, the costly and time consuming practice of delivery to the hospitals' own warehouses is eliminated to make the procurement process more efficient.

CASE 2 - Global Location Number Registry to improve electronic commerce in healthcare industry

The GLN Registry for Healthcare™ provides a comprehensive and accurate list of healthcare facilities, with corresponding Global Location Numbers in the United States.

Subscribers, which include hospitals, healthcare manufacturers, and distributors, will be able to access an updated and accurate list of industry manufacturers, distributors,

retailers, hospitals, clinics, and retail and mail-order pharmacies to ensure the accuracy of their supply chain activities. The enhanced data integrity will allow healthcare providers and suppliers to improve collaborative commerce activities in key electronic commerce processes such as invoicing and logistics.

GLN implementation is supported by GS1 to help the healthcare industry achieve end-to-end supply chain accuracy. This will allow healthcare suppliers and providers to reduce costly, time-consuming errors and help improve the quality of care for patients.

The GLN is a globally-recognized identification number used in the GS1 System to identify legal entities, trading partners, and customer locations in electronic commerce activities. Expressed as a 13-digit data structure, the GLN provides globally unique identification of a functional entity, such as a nursing station; a physical entity, such as a warehouse or a hospital wing; or a legal entity or trading partner, such as a specific company or supplier. The GLN is an open, global standard that supports 23 major industries conducting business in 150 countries.

GS1 US is working with leading healthcare organizations to promote the adoption and use of the GLN Registry for Healthcare.

Source: GS1 US, April 2004.

Appendix 2 - Electronic Product Code (EPC)

RFID/EPCglobal

EPCglobal Inc™ is an organisation resulting from a joint-venture between GS1 and GS1 US with the mission to make organisations more efficient by enabling true visibility of information about items in the supply chain.

EPCglobal Network

The EPCglobal Network is a framework that enables immediate, automatic identification and sharing of information on items in the supply chain. Using a combination of technologies and harnessing the power of current information systems, the EPCglobal Network will provide for immediate, automatic, and accurate identification and location of any item in the supply chain of any company, in any industry, anywhere in the world.

The EPCglobal Network uses Radio Frequency Identification (RFID) technology to enable true visibility of information about items in the supply chain. The network consists of five fundamental elements: the Electronic Product Code™, the ID System (EPC tags and readers), EPC Middleware, Discovery Services and EPC Information Services (EPCIS).

Electronic Product Code

The EPC is an identification scheme for universally identifying physical objects via RFID tags and other means. The standardised EPC data consists of an EPC (or EPC Identifier) that uniquely identifies an individual object, as well as an optional Filter Value, when judged to be necessary, to enable effective and efficient reading of the EPC tags.

An EPC number contains:

- *Header*, which identifies the length, type, structure, version and generation of EPC
- *Manager Number*, which identifies the company or company entity
- *Object Class*, similar to a stock keeping unit or SKU
- *Serial Number*, which is the specific instance of the Object Class being tagged.

Essentially, the EPC is a number designed to uniquely identify a specific item in the supply chain.

Benefits

Applying the technology can help satisfy regulatory and hospital requirements, increase product security and patient safety, enhance order accuracy and labour productivity and increase the efficiency and speed of recalls and returns.

The system effectively tracks products from the manufacturer's distribution facilities through the supply chain to the point of dispensing. This provided all necessary drug 'pedigree' information demanded by the regulatory authorities. RFID/EPC can therefore prevent counterfeiting or detect counterfeited drugs in the supply chain and provides great benefits in avoiding incidents of counterfeiting.*

Appendix 3 – Healthcare User Group (HUG) Press Release

What is the GS1 HUG™ ?

Leading global companies from the pharmaceutical and medical device industry have formed a global GS1 Healthcare User Group (GS1 HUG™). It is the first time that the healthcare industry is aligning around a global solution to enhance automatic product identification for the benefit of patients worldwide. The work of the HUG will help to improve the efficiency of the healthcare supply chain for pharmaceuticals and medical devices through the collaborative development and endorsement of recommended voluntary GS1 standards and best practices.

Mission and Vision

The mission of the GS1 HUG™ is to lead the healthcare industry to the effective utilisation and development of global standards with the primary focus on automatic identification to improve patient safety. The vision of the GS1 HUG™ is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, distributor, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.

Objectives

The objectives of the HUG are to:

- Work with key partners in the healthcare supply chain to develop and optimise the use of global standards to ensure accurate and fast movements of goods from manufacturer to distributor, healthcare provider, hospitals or public pharmacies.
- Facilitate awareness in the healthcare sector of new technologies and methods of doing e-business.

• Provide advice and recommendations to GS1 on issues and opportunities in the healthcare sector.
• Promote best practice implementation in the healthcare area including the whole product and service portfolio of GS1.
• Promote the implementation of GS1 voluntary, global business standards throughout the healthcare sector.

Four Working Groups

The main focus areas for the group are the following:

1. Prevention of Medical Errors

Encoding of the unit dose or unit of use package to enable automated verification to ensure the right dose, for the right patient at the right time. Encoding of the unit of use package to enable automated verification to ensure the right device for the right patient.

2. Product Authentication

Ensure that the packaging and associated labeling are genuine by utilizing a GS1 data structure, enable authentication of individual packages, cases or pallets.

3.Tracking and Tracing

Utilizing a GS1 data structure, work with supply chain trading partners to enable an electronic pedigree for individual packages such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

4. Increase Total Supply Chain Efficiency

Through greater visibility, accuracy and velocity.

Note: For more information about HUG, please visit http://www.gs1.org/hug/

Press Release

November 2005

PATIENT SAFETY IS THE FOCUS OF THE HEALTHCARE INDUSTRY AND REGULATORY BODIES

The second meeting of the global GS1 Healthcare User Group (HUG) was held on 13 – 15 September 2005 in Brussels. It focused on gaining an understanding of global regulatory requirements regarding patient safety as well as reporting progress the group has made since the kick-off meeting in May.

Speakers from the European Commission (DG Enterprise and DG Sanco), the European Agency for the Evaluation of Medicinal Products (EMEA), the USA Food and Drug Administration (FDA), the Italian Ministry of Health, the National Patient Safety Agency of the NHS, United Kingdom and the Regional Healthcare Service Area of Andalucía, Spain presented their work and views about patient safety. The participants and speakers appreciated the opportunity to have an open discussion and to exchange information exchange and agreed to carry the work of the HUG forward by working together more closely.

Delegates from 22 leading global pharmaceutical and medical device companies and 10 GS1 Member Organisations discussed the HUG work plan and listened to the requirements of regulatory bodies. The HUG is concentrating particularly on ensuring that appropriate data structures are selected in order to meet common business needs, and to help ensure data standardisation in healthcare. If standardisation is applied globally, systems to improve patient safety will be developed and implemented quicker than if individual countries were to pursue separate solutions. The three work teams (Standards Development, Standards Implementation and Regulatory Affairs) made good progress with regards to their objectives under the lead of chairs from Baxter, Johnson & Johnson and Medtronic.

Miguel Angel Lopera, Chief Executive Officer of GS1, welcomed the broad participation of the healthcare industry and said, “I'm pleased that the healthcare industry has chosen GS1 standards to develop a global solution for the benefit of patients worldwide. Under the coordinated and unified leadership of the industry GS1 standards will be optimised

for the use in healthcare and global guidelines will drive and promote implementation around the world."

Volker Zeinar, B.Braun, HUG Co-Chair, commented: "Patient safety has many faces and standardised machine-readable product identification can make an essential contribution. Where better to discuss and improve all the related aspects than in a global working group, open to all healthcare supply chain stakeholders. The GS1 HUG offers an excellent platform to work together to find harmonised solutions. We engage ourselves in this initiative with the intention of sharing our expertise, learning from others and optimising product identification for the benefit of patien