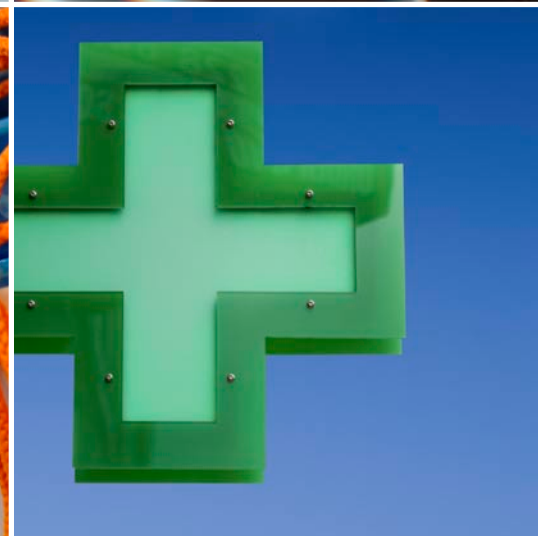
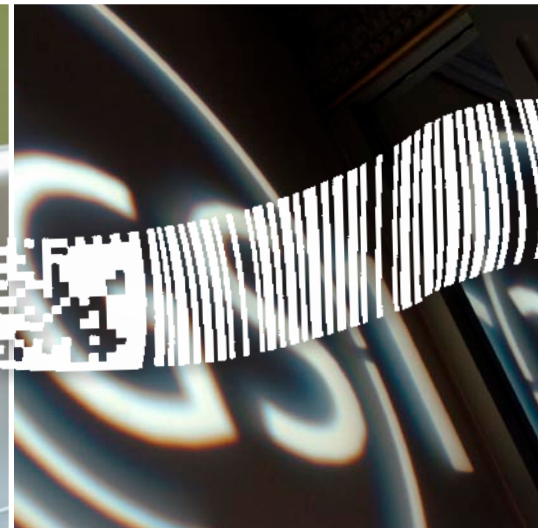




# GS1 Healthcare Reference Book 2009/2010



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Welcome to the first edition of the GS1 Healthcare Reference Book (Edition 2009/2010), a compendium of information on global standards in the Healthcare supply chain, adoption initiatives, lessons learnt from implementation projects, regulatory developments and more. Experts from different countries and different backgrounds share their perspectives on, and experiences with, supply chain projects, patient safety initiatives and regulations. We hope that you gain valuable information from this publication and we extend our appreciation to all the contributors that have made this possible.

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# GS1 Standards in healthcare: raising the bar on patient safety and supply chain efficiency

## ABSTRACT

Patient safety, supply chain security, traceability and efficiency in Healthcare are currently at the forefront of government regulatory and industry concerns around the world. As a result, numerous, and often incompatible solutions are being (or have been) proposed to the national and international supply chain stakeholders and, in some cases, adopted in preference to global standards. The cost of diverse government regulations, proprietary services and incompatible solutions being offered to stakeholders has made it clear that there is a need to define and increase adoption of open, global standards. This is the mission of GS1 Healthcare.



Article by **Ulrike Kreysa**  
and **Jan Denecker**

## Challenges and opportunities in the healthcare supply chain

Patient safety initiatives across the world tackle the challenges in the Healthcare supply chain, including the reduction of medication errors, the fight against counterfeiting, optimised post-market surveillance, etc.

More than 30% of all adverse drug events are preventable and appear to be consequences of medication errors<sup>1</sup>. Adverse events from medication errors represent a significant problem for Healthcare worldwide, as indicated by several studies in different countries. An Adverse Event Study in one country indicated that 9.3% of hospital stays incurred a serious adverse event, with medication errors being the main cause (37.4% of such events)<sup>2</sup>. The implementation of automatic identification systems, up to the point-of-care, has proven to significantly reduce medication errors; for example, the Veterans Affairs Medical Center in Topeka, U.S.A., has reported that bar coding reduced its medication error rate by 86% over a nine-year period<sup>3</sup>.

Counterfeit Healthcare products are in the first place a risk to public health. It is almost impossible for patients and dispensing Healthcare professionals to spot the fakes. Healthcare products are supplied through complex,

multi-echelon global supply chains that currently lack transparency, making it vulnerable to infiltration by counterfeiters. The introduction of a unique identification for each and every pack, where appropriate, will enable traceability and authentication systems with readily available technology. This will make it much more difficult for counterfeiters to intrude into the Healthcare supply chain, or at least, make it uneconomic.

Other patient safety initiatives are related to improving post-market surveillance and adverse event reporting, product recalls, disaster preparation, treatment documentation, etc.

Reducing costs and increasing supply chain efficiency will contribute to keeping soaring Healthcare costs under control. Diverging country requirements for supply chain data further complicate an already complex production, packaging and distribution system and add risk and cost. Manual systems and processes in hospitals are unable to efficiently and safely handle the constant change that occurs with supplies and pharmaceuticals. Standardised automatic identification and traceability systems will simplify and improve accuracy in a number of supply chain processes from production to point-of-care or point-of-sale.

## Welcome to the world of GS1 Standards

Open, technology-independent standards permit full interoperability and compatibility. End users are not locked into proprietary solutions and R&D resources can be freed up for other added value developments once standards have been adopted.

GS1 Standards are not only open and technology-independent, but also truly global, which is vital in supply chains that often cross borders.

First of all, the GS1 System of Standards incorporates 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 Identification Keys are fixed length, numeric and include a standard check digit

At the heart of the GS1 System is the GTIN (Global Trade Item Number) Identification Key. These numbers are allocated by the manufacturer, according to the GTIN Allocation Rules and include; a GS1 company prefix assigned to a company by GS1, an item reference assigned by the company and an automatically generated check digit. GS1 has published specific Healthcare GTIN Allocation Rules, due to the complex needs of the industry.

The GS1 System also incorporates a number of other Identification Keys, including GLN (Global Location Number), SSCC (Serial Shipping Container Code) and GRAI (Global Returnable Asset Identifier).

GS1 Identification Keys can then be carried on any type of data carrier, a GS1 bar code (linear or 2-dimensional) or an EPCglobal Radio Frequency Identification (RFID) tag, on the specific product or packaging.

The GS1 Global Data Synchronisation Network (GDSN), built around the Global Registry and GDSN-certified data pools, provides a powerful environment for secure and continuous synchronisation of accurate product and location data.



GS1 eCom (Electronic Data Interchange) provides global standards for electronic business messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners.

GS1 Traceability Standards provide a powerful tool kit for implementing traceability to enable full actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale or point-of-care, to ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.

### GS1 Fast Facts:

- User-driven standards organisation
- Member organisations in 108 countries
- 2,000 employees supporting 1.2 million companies
- 6 billion 'beeps' per day, based on GS1 Standards, make it the most widely used system of supply chain standards

## A voluntary, global Healthcare user group

GS1 Healthcare is a voluntary, global Healthcare user group bringing together all related Healthcare stakeholders. Members range from leading pharmaceutical and medical device manufacturers, healthcare providers, distributors and Group Purchasing Organisations (GPOs), governmental and regulatory bodies and associations including the U.S. FDA, Public Health Agency Canada and Eucomed.

The mission of GS1 Healthcare is to bring together experts in Healthcare to develop and implement global standards to successfully enhance patient safety and supply chain efficiencies.

GS1 Healthcare is now widely recognised as an open and neutral source for regulatory agencies, trade organisations 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 synchronisation.

### Healthcare suppliers advance global supply chain standards

Confronted with diverging country specific product identification requirements and developing traceability requirements, suppliers were instrumental in establishing the global Healthcare user group in 2004-2005. Many leading suppliers are members of the global Healthcare user group and actively drive global standards development and adoption at a global level.

At a global level, current supplier members include (dd. April 2009); Abbott, Alcon, 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.

At a national level, many more suppliers are member of a GS1 Member Organisation and are involved in national initiatives to drive adoption and implementation of GS1 Standards in the Healthcare supply chain.

Also other stakeholders, such as distributors, retailers, and logistics providers have been involved. Global members include; CVS, Cardinal Health, DHL Exel Supply Chain, and McKesson.

### Healthcare providers advance global supply chain standards

Leading Healthcare providers and Group Purchasing Organisations (GPOs) worldwide are endorsing GS1 Standards and are paving the way for sector-wide adoption.

Some notable examples are:

#### In the U.S.A.

- AHRMM, a professional membership group of the American Hospital Association serving more than 4,000 active members
- Amerinet, a GPO serving more than 2,200 acute care and 25,000 alternate care health systems members
- Novation, a GPO serving 2,500 members of VHA Inc. and the University HealthSystem Consortium (UHC) and nearly 12,000 members of Provista, LLC
- Premier Inc., a GPO serving more than 2,000 hospitals and 53,000-plus other healthcare sites
- SMI (Strategic Marketplace Initiative): 32 healthcare provider members, including for example Duke University Health System, Johns Hopkins Health System, Mayo Clinic, Sisters of Mercy ~ ROI, SSM Health Care, University Kentucky HealthCare, and Yale New Haven Health System

#### In Austria

- Orthopädisches Spital Speising GmbH, Vienna (Vinzenz Gruppe) and Wiener Krankenanstaltenverbund are members of the global Healthcare user group

#### In Canada

- CareNET, a not-for-profit organisation comprised of over 450 hospitals across Canada
- HealthPro, a GPO serving 485 hospitals
- MedBuy, a GPO serving more than 350 Healthcare facilities

#### In Chile

- Cenabast, the Supply Center for the Ministry of Health in Chile

#### In France

- UNIHA, a network of 32 university hospitals and 22 large hospitals

#### In Germany

- Comparatio Health, a GPO comprised of 6 university hospitals
- EK UNICO, a GPO comprised of 13 university hospitals, including 300 special clinics and more than 240 institutes

#### In Hong Kong

- Hong Kong Hospital Authority, a statutory body managing 40 public hospitals, 48 specialist clinics and 75 general clinics

#### In Japan

- Tokyo Medical University, Kanto Medical Center and Nagoya University Hospital, etc.

### In the Netherlands

- NFU (the Dutch Federation of University Medical Centre), comprised of 8 university medical centres
- Erasmus MC Hospital Rotterdam and Universitair Medisch Centrum Groningen are members of the global Healthcare user group

### In Switzerland

- Geneva University Hospitals are members of the global Healthcare user group

### In the U.K.

- The Department of Health best practice guidance Coding for Success recommended that both industry and the NHS adopt the GS1 System of coding standards. Over 175 NHS hospitals have registered for GS1 UK membership.

## GS1 Healthcare advocates global harmonisation

Global standards will enable all stakeholders to efficiently and effectively comply with various identification, traceability and product catalogue requirements. To this end, GS1 Healthcare user groups (local and global) aim to be a neutral and trusted source for governmental bodies, regulators and associations for all related matters. Some notable examples are:

- Providing input to the European Commission for the legislative proposals to ensure safe, innovative, and accessible medicines currently being developed

- Providing input to the Global Harmonisation Task Force (GHTF), U.S. FDA, the European Commission, and others, on the adoption of GS1 Standards for Unique Device Identification (UDI)
- Providing input to the Italian Ministry of Health who is currently reviewing the 'Bollino' system
- Providing input to the Turkish Ministry of Health to ensure full compliance with GS1 Standards
- Providing input to the WHO Technology work group of IMPACT (Anti-Counterfeiting Taskforce)
- Provided input to the Japanese Ministry of Health, Labour and Welfare, resulting in revised bar code guidelines for medical devices in line with GS1 Standards
- Provided input to the UK Department of Health resulting in the 'Coding for Success' programme
- Provided input to the Public Health Agency of Canada resulting in the GS1 Standards-based vaccine bar coding project
- Provided input to the EFPIA project for coding and identification of pharmaceutical products
- Provided input to the Australian National eHealth Transition Authorities (NeHTA) resulting in endorsement of GS1 Standards
- Provided input to the California Board of Pharmacy for ePedigree requirements to comply with GS1 Standards

GS1 Healthcare will continue to promote global supply chain standards and invites all stakeholders to join the user group, either at national or global level.

For more information about GS1 Healthcare, visit [www.gs1.org/healthcare](http://www.gs1.org/healthcare)

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- 3 "Strategies to Reduce Medication Errors - How the FDA is working to improve medication safety and what you can do to help", Michelle Meadows, FDA Consumer magazine May-June 2003

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# 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.



Article by **Joe Pleasant**,  
CIO and Senior VP,  
Premier, Inc.

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.

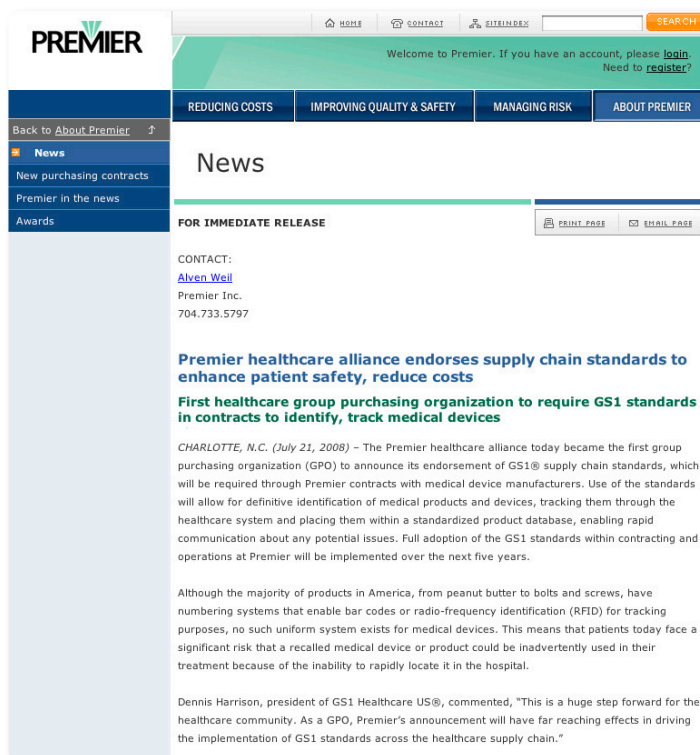
The absence of a UDI via a PDU also results in dirty or inaccurate product item masters that create mismatches in accounts payable; wasted clinician time searching for correct products; and inaccurate pricing, rebates, returns and credits. The data language problem exacerbates the broken supply chain, 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

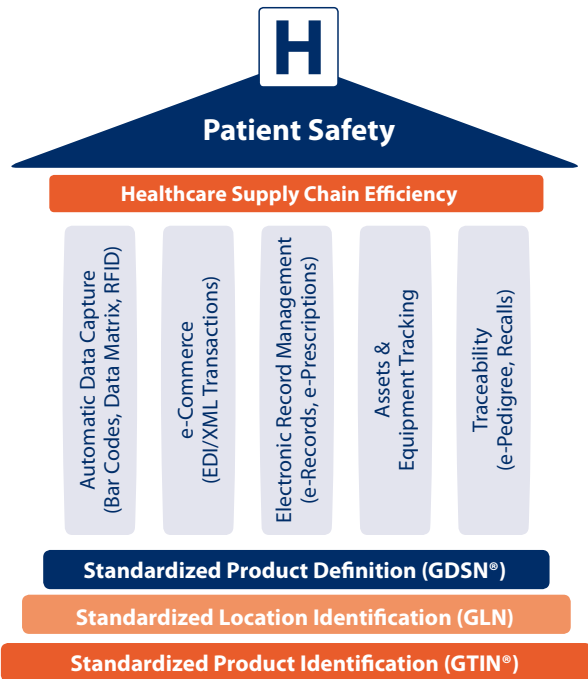
patient may have used. These standards will contribute to interoperability in healthcare, and will streamline the flow of information in the supply chain and beyond.

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.

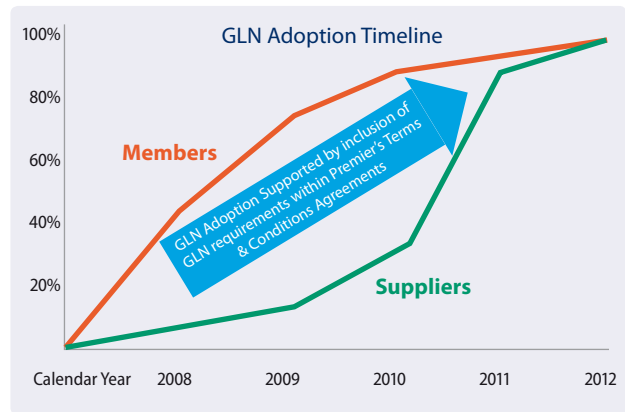
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**Joe Pleasant** is chief information officer and senior vice president of the Premier healthcare alliance. In his role, Mr. Pleasant oversees Premier's information systems infrastructure that includes legacy, enterprise and Web-enabled offerings. Premier participates in the DoD's ongoing pilot testing the GDSN as a potential industry product data utility, and serves on the Board of Governors for GS1 US.

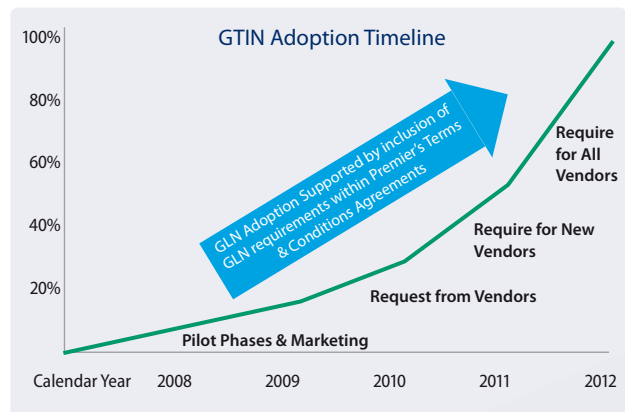
The Premier healthcare alliance is more than 2,100 U.S. hospitals and 54,000-plus other healthcare sites working together to

- 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.

# Shanghai Food and Drug Administration

## Implementation of a post-market traceability program for implantable medical devices adopting unique device identification

### ABSTRACT

This article discusses the distribution and traceability model of Implantable Medical Devices (IMD) for post-market surveillance purposes, and the IT and automatic identification technology that has been used in the supply chain to complete post-market tracking in Shanghai. To build up this system successfully, it was necessary to establish a Unique Device Identification (UDI) for IMD's, based on GS1 Standards, to define the minimum information in the tracking process, and to establish a central data pool to support automatic reading in the hospital management system. Meanwhile it is necessary to have a Shanghai FDA monitor platform to collect the traceability information from the end user. This article also contains a real case study that took place in Shanghai.



Article by **Liang Yan**

### Introduction

Implantable Medical Devices (IMD) pose the highest potential risk among medical devices, so they are subject to the most stringent management in the medical device regulatory system of each country, regardless of pre-market approval or post-market surveillance. Due to the high risk and high profit, such products can cause other disorderly management problems in their sales, purchase, pricing and service links, and even lead to injuries or doctor-patient disputes, so they raise serious concerns by the general public and the regulatory authorities. Shanghai began adopting Unique Device Identification (UDI) using GS1 Standards in 2007, and it was the first in China to set up a tracking system that links IMDs directly to patients.

### Computerisation is an effective pathway to address post-market tracking

Shanghai began to take legal supervisory measures on IMDs as of 2002, and a follow-up study after three years showed

that the actual effect of these legal measures fell short of expectations. The following three major aspects have caused traceability problems:

- Firstly, basic IMD use information recorded during the process was inaccurate.
- Secondly, manufacturers could hardly collect the actual use data from the hospital, so they could not fulfil their legal post-market responsibilities.
- Thirdly, the information of IMD use was not transparent, which could not safeguard patients' safety, rights and interests.

The most practical and effective means to address the post-market traceability of these high risk medical devices is to make use of current computer/IT technology and allow different legal entities to easily share IMD use data under the existing legal framework. The key to setting up such computerised tracking system is to establish a standards-based UDI, to determine the traceability management mode, and to set up a feasible tracking system.

## Standards for IMD identification

To establish a UDI system for IMD's, it was necessary to understand the basic requirements of its use, then determine the UDI coding rules, and finally determine the scope of traceability information.

### Basic use requirements:

- 1) UDI should be applied to any possible place of use;
- 2) UDI should be able to remain independent from the above place of use;
- 3) UDI should meet the compatibility requirements of current automatic reading technology environments and should be adaptable to current legal environments;
- 4) UDI should be based on a design structure with clear validation records and good stability and reliability;
- 5) UDI should have good technological expandability and be able to accommodate various data media;
- 6) UDI should meet the requirement for simple operations, without multiple conversions during its use;
- 7) The symbols making up the UDI should be easy to use;
- 8) UDI should be able to adapt to potential changes that may occur in the production and management environments;
- 9) UDI should be affordable for organisations to implement and the benefits should outweigh the burdens;
- 10) UDI should comply with the operating rules of other regulations prevailing in the international market, such as the World Trade Organisation (WTO) rules.

### Shanghai UDI rules for IMD's

- 1) Using linear barcodes. The technical environment for overall implementation of 2D barcodes and RFID is not yet mature, and in order to meet the current urgent need of tracking high risk medical device adverse events, we started from linear barcodes, and will then gradually develop into 2D barcodes and RFID;
- 2) Using the GS1 or HIBC coding standards. To allow every supplier to quickly implement the UDI system in the start-up phase, suppliers were allowed to choose either GS1 or HIBC barcodes. This rule may be changed later in the nationwide implementation of the UDI tracking system to simplify the technical system. (For reference: medical products that do not need to be traced can directly adopt the GS1 EAN13 barcode as used in the Chinese supermarkets);
- 3) Using primary and secondary barcodes; the primary barcodes are used to identify products and contain information on the country of origin, manufacturer,

product name, specification and packing level. The secondary barcodes are used to indicate key information of the product, including product's lot/batch number, and key dates, i.e. expiration date or manufacturing date;

## Key traceability information in the IMD traceability system

The information provided in the IMD traceability system needs to enable the effective handling of adverse events after their occurrence, such as product recall and patient identification.

### Accurately recording the UDI and patient ID is the most important link

To track the adverse event related to IMDs, regulators need the following basic information:

- 1) Basic information on product's use;
- 2) Information on the specific product involved in the adverse event;
- 3) Range of products that may have the same quality problem;
- 4) Patients involved in the product in question;
- 5) Location of the product(s) in question that have not yet been used.

Simply speaking, when we deal with an adverse event, we should use the UDI information of the product involved in the adverse event and identify the patients involved; then exercise control over the product held in inventory and bring the potential injuries under effective control in the earliest possible time.

To enable tracing to the patients, it is critical to record the UDI and patient identification (PID) at the time of use, and keep all the information in the quality system of the supplier and the hospital. Shanghai stipulates that upon completion of any IMDs surgical operation, the automatic identification of a UDI and recording of all relevant data of the patient shall be completed and linked outside the operation room of the hospital.

### Minimum traceability information

To trace an IMD to a patient, the UDI needs to be associated with the following supporting information: product name, model, specification, lot number or serial number, registration certificate number, expiration date of the registration certificate, manufacturer's name, name of the after-sales service company of the imported product, and

name of the final distributor. Patient ID information should include the hospital's name, the patient's inpatient number, the patient's name, sex, name of the surgical operation, place of operation, date of operation, surgeon performing the operation, the quantity of devices used and so on.

The basic information relevant to a product is generated by linking the UDI directly to the database; the information of the lot number/serial number and expiration date of the product is generated after the second barcode is scanned; the medical information of a patient needs to be extracted from the hospital information system through the patient ID.

Information on product pricing can be included for additional purposes. But for a system that needs to run for a long period of time and to gather information on a continuous basis, the principle of “the least information, the cost-effective” shall be followed in setting basic management information requirements.

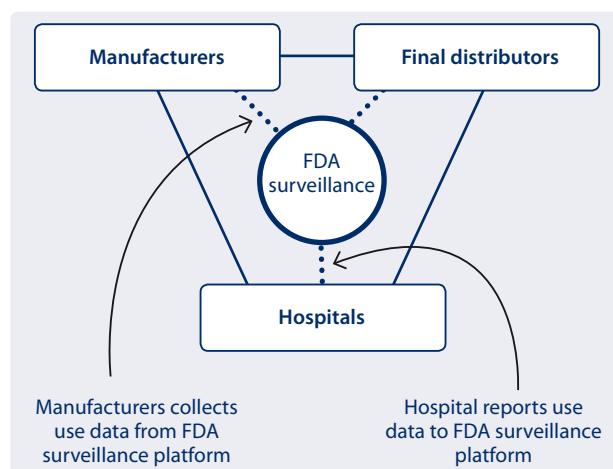
### Implementation of the IMD traceability system in Shanghai

Shanghai started to implement the IMD traceability system in November 2006 according to the above architecture and management principles. The tracking system covers more than 100 hospitals using IMDs in Shanghai, and the IMDs included high-risk devices such as orthopaedic internal fixation devices, orthopaedic implants, synthetic crystals, breast implants, pacemakers, heart valves, stents and catheters. By June 2008, and through manual and automatic online reporting, the data reporting platform of the tracking system has gathered more than 175,000 entries of use data. Data analysis showed that the tracking system plays a crucial role in addressing the post-market surveillance of those high-risk medical devices, preventing the occurrence of injury events, and managing such events.

#### Triangular sales and supervisory model for IMDs

Shanghai developed a triangular sales and supervisory model in the exploitation of IMDs. Theoretically speaking, it is the most simplified traceability management model (See Fig. 1).

Figure 1: IMDs sales channel and device use data reporting channel



The outside of the triangle as shown in Fig. 1 is the basic sales channel of IMDs where manufacturers sell their products to hospitals directly or through a distributing chain and final distributors.

Inside the above triangle is a data reporting platform administered by the Shanghai FDA/health authorities. Hospitals report data relevant to the use of IMDs to this platform, and through which, manufacturers / distributors can retrieve information about the use of their products. This addresses the problem encountered by regulatory authorities that manufacturers can hardly obtain data relevant to the use of their IMDs from hospitals.

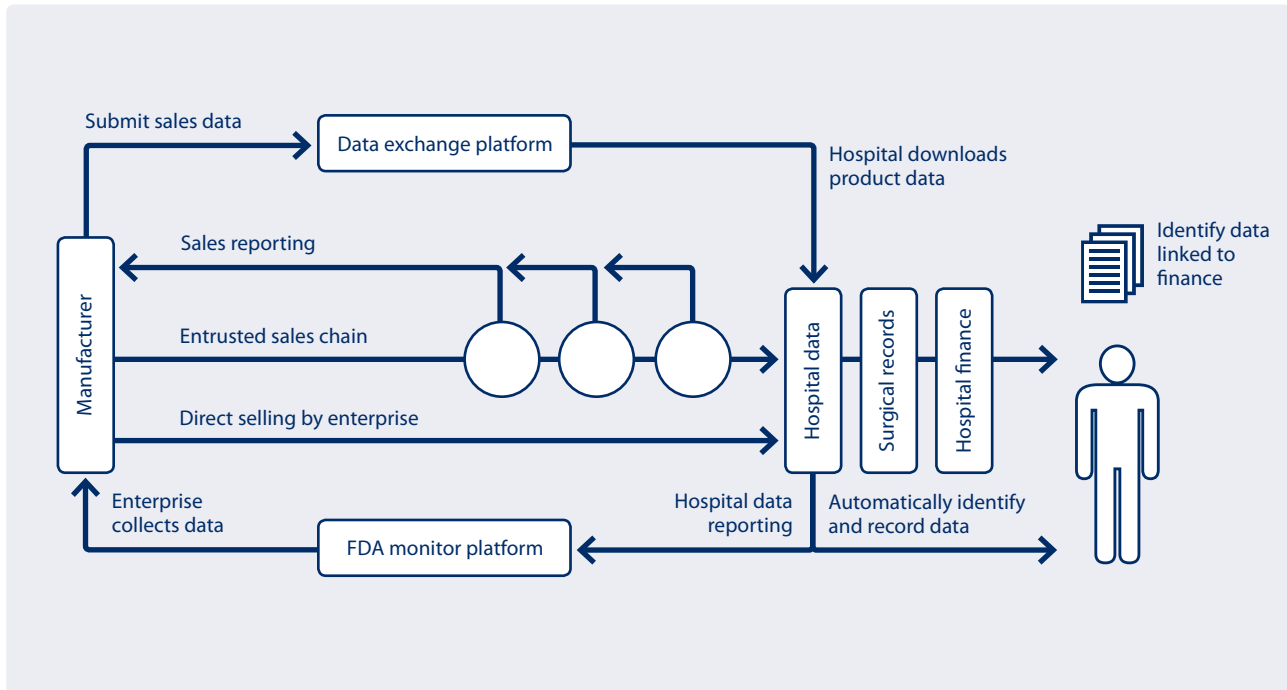
If an IMD manufacturer doubts the data available on the reporting platform and refuses to recognize such data, the post-operation safety of patients using such IMD can hardly be assured, so the government will discover it and supervision should step in as soon as possible.

#### Implementation scheme

The middle part in the schematic diagram of the tracking system in Fig. 2 is consistent with the triangular sales model described in Fig. 1. Enterprises sell their products to hospitals directly or through a sales chain.

Upon completion of a surgical operation, the hospital records the UDI using automatic identification technologies. The product information will be reported together with the patient information, collected from the Hospital Information System (HIS) to the Shanghai FDA health data reporting platform. At the same time, the information is linked to the

Figure 1: Schematic diagram of IMD tracking system



hospital's financial management system to manage financial records. The manufacturer can obtain hospital use data via the reporting platform.

To support hospitals in automatically reading the UDI, a product data exchange platform is set up in the tracking system. Manufacturers can submit their product data to the hospital's database, and can control distributors and hospitals directly and define the scope of the products sold to and used in the hospitals.

### Legal responsibilities of each responsible party

In post-market management, the depth of government surveillance in the tracking system should be different as risks related to products and treatments are different. Each party in the tracking system shall undertake the following responsibilities:

1) IMD manufacturers (or the domestic legal after-sales service institutions of imported products designated by manufacturers) shall be fully responsible for the quality of their products after market release, for the management and implementation of UDI marking, tracking, recall of their products and handling of patient injuries in adverse events, and for gathering and keeping the use data through the health data reporting platform.

- 2) Entrusted by IMD manufacturers, the IMD distributors shall be responsible for providing the traceability information on the IMDs, and take their own initiatives to assist manufacturers in handling those potential adverse events. IMD distributors shall not make UDI's without prior authorization of manufacturers. UDI making must be authorized by and the entire process must be under the control of the manufacturer's quality system.
- 3) Hospitals shall establish automatic identification management, registration and reporting system for UDI's of IMD's, and keep the use records of such patients.
- 4) Patients shall obtain relevant information of the IMDs. Hospitals and manufacturers shall take their own initiatives to provide such information.
- 5) In order to safeguard the interests of the public, the government shall assume the supervisory and regulatory responsibilities in the tracking system.

In the tracking system, manufactures are required to meet the UDI requirements in labelling their product, and medical institutions to implement automatic UDI and recording system. These are the core links to ensure successful product traceability.

## Discussion and suggestions on promoting a worldwide uniform tracking system

In order to enable effective worldwide tracking of key medical devices, we suggest that the domestic market tracking efforts of each country should keep pace with those in the rest of the world. The following work should be promoted and completed under the Global Harmonisation Task Force's (GHTF) medical device regulatory framework:

- 1) To coordinate the development of a globally uniform UDI system and its coding standard, allowing automatic identification equipment to be compatible with each other to the maximum extent;
- 2) To establish a global basic tracking model. The tracking model proposed by Shanghai can be utilised and discussed;
- 3) To coordinate the establishment of a unified scope of important and basic traceability information specific to medical devices; and
- 4) To facilitate the solution of a global nomenclature for medical devices as soon as possible; the globally unified nomenclature system should be used together with the UDI system in the global tracking system so as to improve the global medical devices reporting efficiency.

The establishment of the above medical device tracking system, according to our estimation, will thoroughly change the post-market surveillance of each country for medical devices, improve the pre-warning and reporting levels of medical devices, improve the efficiency of the adverse



medical device reporting and handling system, change the sales model of consumable medical devices, greatly improve the transparency of information on those high-risk medical devices, improve the safety of medical devices used by patients, and play an active role in speeding up hospital's informatisation construction and improving the efficiency of hospital's consumables management. We are willing to work with the rest of the world to establish a new global mechanism beneficial to patient safety management as early as possible.

### AUTHOR

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served as head of the Science and Technology Department of the Shanghai Pharmaceutical Administration Bureau, for Shanghai's pharmaceutical and medical devices industry research and development of new technology and products. In 1989, he organized a group for drafting China's first medical devices regulations. Afterwards, he continued to work with the drafting and implementation of China Medical Devices Regulation in Classification Rules, Medical Devices Registration, Medical Devices Recall area.



# Building traceability in Australian healthcare

## ABSTRACT

Concerned by a lack of traceability processes within the Australian healthcare industry, Clifford Hallam Healthcare (CH2), Australia's largest national Healthcare Service Provider, has embarked on a 10-year scalable plan to ensure our facilities have total supply chain integrity through use of the GS1 System. By implementing a Radio Frequency based bar code scanning inventory management system, and electronic messaging with key suppliers, we have made significant gains in supply-chain efficiencies such as reduced pick errors, faster put away, reduced backorders as well as improved data quality and improved logistics partnerships which leads to more favourable working capital investment ratios.



Article by **Ged Halstead**

## Background

Clifford Hallam Healthcare (CH2) is Australia's largest national Healthcare Service Provider. Trading with more than 11,000 facilities in all states and territories, the company has been in business for 35 years and has developed a business management system that meets the specific requirements of AS/NZS ISO 9001:2008.

CH2 operates seven warehouses nationally. All carry a comprehensive range of medical and surgical products, pharmaceuticals, general hospital consumable items and healthcare equipment. Our customers are located in metropolitan, regional and rural areas and include public and private hospitals, nursing homes, general practitioners, specialists, day surgeries, diagnostic imaging, pathologists, veterinarians, physiotherapists as well as Federal and State Government bodies such as the Armed and Emergency Services and the Justice Departments. CH2 now also delivers to home enteral nutrition (HEN) patients.

The company has 32,000 catalogue lines (or SKUs) offered, of which approximately half are stock lines. CH2:

- Delivers up to 320,000 lines per month
- Picks and ships over 3 million units per month
- Fulfils over 40,000 orders per month
- Has internal pick rates exceeding 96% and a Delivery in Full on Time (DIFOT) target of 95%

CH2 must comply with a number of Acts and Regulations at both Federal and State level and operates in a highly regulated environment. Our warehouses are temperature controlled and dust free, ensuring all products are kept constantly in a clean and controlled environment (25 deg Celsius or below) all year round.



## Traceability to Enable Efficient Recall – The End Goal

In 2008 there were 24 therapeutic goods recalls in Australia based on notifications provided to the Minister for Competition Policy and Consumer Affairs. For CH2, recalls can vary between full product recalls, single or multiple batches, supplier withdrawals or safety alerts. Some recalls may affect only one branch while others may affect every branch in Australia.

CH2 follows Australia's Therapeutic Goods Administration guideline, Uniform Recall Procedure for Therapeutic Goods<sup>1</sup>, when taking recall action. In the event of a recall the following procedure is adhered to:

- A manual check of CH2 branches is undertaken to determine which sites have affected stock.
- All affected stock on hand is quarantined ensuring further supply to customers is prevented.
- A report indicating customers who have purchased the product over a nominated period is sent to key personnel at CH2.
- The relevant customers are notified and are required to take their own action to collect any stock in question.
- The return and replacement of the recalled product is subject to the procedure set out by the manufacturer.

Currently, the processes for supply of medical and pharmaceutical products in Australia are mainly manual and this has led to concerns that both suppliers and their customers can not easily identify and locate products in the case of a recall. Such concerns have prompted CH2 to initiate a 10-year plan working with suppliers and customers to ensure that supply chain integrity is achieved.

Right now there is no easy way for many of our customers to locate products in the case of a recall without employees going into each and every ward, or hospital pharmacy or operating suite and physically checking if the product is there. This leaves room for error and when you are dealing with potential risk to human life, there can be no margin for error.

In Australia we do not have a mandate for suppliers to use the GS1 System for product identification. This is a voluntary system and CH2 are urging companies to adopt the GS1 System so we can ultimately improve patient safety.

### Working with GS1 Australia

To help drive this 10 year plan, CH2 has been actively working with GS1 Australia. CH2 is the chair of the GS1 Healthcare User Group (HUG) Australasia, the local chapter of GS1 Healthcare (the GS1 global healthcare user group). HUG Australasia is one of several such groups around the world reviewing, developing and refining the GS1 System to ensure it is applicable for all aspects of the global healthcare sector while remaining relevant to other industry sectors.

<sup>1</sup> *Uniform Recall Procedure for Therapeutic Goods*, Australian Government, Department of Health and Ageing, Therapeutic Goods, © Commonwealth of Australia 2004.

Along with other areas of focus, this has meant potentially extending the concept of a trade item to 'unit of use', which is the level of trade item dispensed to the patient in a hospital environment.

CH2 is also working with GS1 to help engage their suppliers to implement, where possible, GS1 Global Trade Item Numbers (GTINs) for product identification, Global Location Numbers (GLNs) as primary delivery/pricing records and Serial Shipping Container Codes (SSCCs) for tracking logistic unit movement (warehousing and distribution).

### Supplier Engagement – eMessaging

In 2007 none of CH2's 900-plus suppliers were undertaking electronic messaging with our organisation. As the first step in their supply-chain transformation, CH2 initiated eMessaging (using GS1's EANCOM purchase order, purchase order response) with seven suppliers, using GTINs as the primary item identifier and GLNs as the primary location identifier. Within two months of eCommerce implementation 100 per cent data accuracy rates were achieved in the messages exchanged, and much of this was due to the GTIN being used as the unique product identifier.

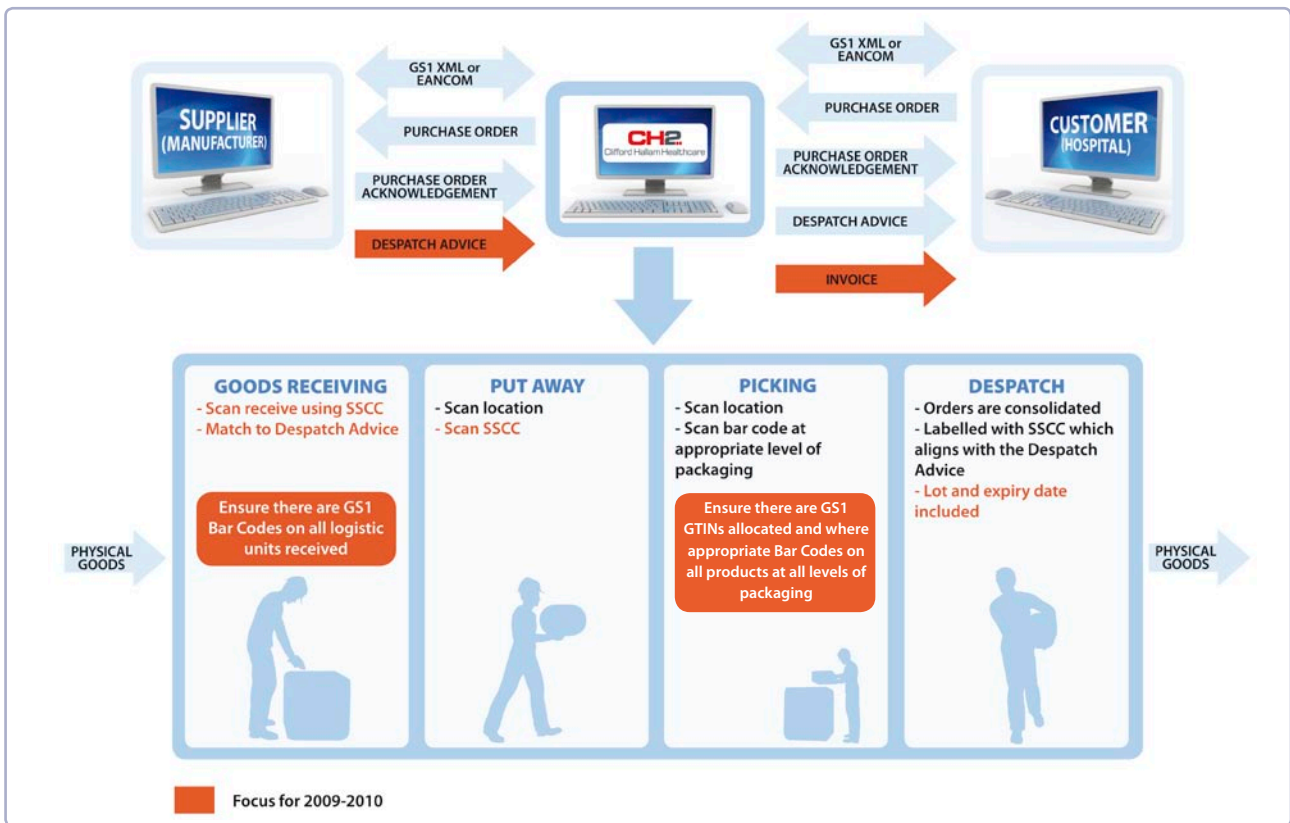
The use of the GTIN has provided another notable benefit as CH2 and its partners are now starting to overcome an issue that continues to plague the healthcare sector- differing Units of Measure.

This is having a flow-on effect throughout the CH2 Supply Chain and has put our company in a stronger position to achieve Delivered In-Full, On-Time to Quality (DIFOTQ) with our customers – a key objective for 2009. This is consistent with our goal of having the right product in the right place at the right time.

The company continues to progress, aiming for all suppliers to be trading via electronic messaging, including providing Despatch Advices with lot and expiry dates as well as SSCC labels. If this goal is achieved, CH2 estimates a 45% reduction in receiving time.

### Warehouse efficiency

CH2 had identified that our warehouse processes were hampered by the inability to easily track goods. As the next logical step in our supply chain transformation, we identified the need to implement scanning of products on receipt, put-away, picking and packing.



CH2 worked with those suppliers already using GS1 Bar Codes to ensure these were entered in our database and then began their scanning based on these products. For those products without bar codes, CH2 applied internal identifiers and bar codes at carton level so we could track products and their location in our warehouses. Applying these internal labels has been clearly recognised as a non-value adding process, and elimination of this process by provision of supplier GS1 Bar Codes, has been identified as a key focus moving forward.

Of the CH2 suppliers, approximately 240 are now providing GS1 GTINs and appropriate bar codes, however it is recognised that there is much more work to be done to engage the remainder of the 900 suppliers. To address this, CH2 is partnering with GS1 and commencing a supplier engagement and education program.

The ultimate goal is to have products carrying bar codes, as the business benefit is clear. With the bar code scanning processes in place CH2 warehouse pickers are now picking and packing up to 400 lines a day, a very significant productivity improvement compared to the pre-scanning days.

### Organisational Consolidation

In early 2008 CH2 acquired the Cottman Australia business, extending their supply offering to other trading partners.

Cottman was a business with 50,000 line items, very limited eMessaging capability, no scanning and no use of the GS1 System. This had to be merged with CH2's 32,000 line items.

As a result of the work CH2 had already done to implement GS1 Bar Codes and eMessaging with suppliers, we found that we were in a strong position to merge the two businesses using the scanning processes we had implemented in our existing warehouses.

In what amounts to proof that using proprietary item identification does not cross-translate within the industry, CH2 were only able to match 3.12% of items between the two businesses using their vendor part number. This was a startling revelation and is a strong reason for the industry to get on board to use GTINs for item identification. The advent of the National Product Catalogue meant that there was now another valuable data source that was useful for the data matching exercise.

CH2's purpose-built warehouse in South Australia was the company's first site for physically merging the inventory of the two businesses. As a result of this merge, 500 pallets were moved in a day and put into bar coded locations. The merger was completed in 1.5 days and scan packing was then enabled in the warehouse. The Western Australian operations were merged next and by using scanners to

ensure inventory integrity, CH2 was able to complete the operation in a weekend. It is estimated that CH2 would have taken twice as long to merge the operations if the scanning process had not been in place.

### Customer focus

Turning to the customer side of our business, CH2 has initiated a multi-streamed eMessaging protocol using both GS1 XML and GS1 EANCOM.

The first stream entails establishing eMessaging with public and private hospitals. This involves a business-to-business (B2B) model with hospital pharmacy customers, using the GS1 System based on EANCOM messaging standards for purchase orders, purchase order response and despatch advice.

The second stream relates to CH2's proprietary online ordering system - Simple Order System (SOS). This system is used by the majority of customers not using EANCOM. CH2 is moving SOS to the GS1 standards and we have recently added a GTIN search capability.

Already, Melbourne's The Alfred Hospital Pharmacy, a 400-bed, acute tertiary referral hospital renowned for its specialist services, uses the SOS ordering system with products identified by GTINs.

### Looking forward

CH2 will continue to drive the implementation of GS1 eMessaging with suppliers and encourage them to apply GS1 Bar Codes to all levels of packaging as well as SSCCs to logistic units. Our vision includes being able to receive batch and expiry date information in electronic messages and to have that information physically bar coded on the products.

### AUTHOR

**Ged Halstead** is the Chief Information Officer for CH2. He has over 20 years experience implementing ERP systems for a broad range of industries in Australia and the United States. Ged has spent 12 years in the IT consulting space, principally engaged as a project manager and practice leader. He has 10 years in the healthcare industry delivering solutions for global leading brands in both medical devices companies here and abroad, and to medical services companies and pharmaceutical manufacturers in Melbourne, Sydney and Auckland. Other industry sectors



CH2 is confident that improved data interchange and collaboration between wholesalers and manufacturers and based on the GS1 standards will reduce stock holding across the entire supply chain and ultimately lead to improved patient safety.

The backbone of this system is accurate and reliable product data and CH2 is working to implement the National Product Catalogue, the Australian Healthcare data synchronisation solution hosted on GS1net, both as a recipient of supplier data and a source of data to their customers.

CH2 understands the value of quality data and is committed to implementing the GS1 System through our business and with our partners. The use of the GS1 standards for eMessaging, GTINs, GLNs and SSCCs are paramount to our industry moving forward. We believe the uplift in quality systems will lead to improved patient safety.

This is a very long journey for the Australian healthcare sector and we are just at the beginning. As a middle player we see suppliers taking steps to implement the GS1 System and now hospitals are making demands on us for a system that will give them better inventory management and traceability. This work requires patience, persistence and passion.

in which Ged has implemented financial, distribution and warehouse systems are petro-chemical, print media, grocery wholesale and frozen foods.

Ged is actively involved in the Healthcare standards community, notably as the current Chair of the GS1Healthcare User Group Australasia, on the leadership team for the Monash Medical Project, a member of the GS1Net advisory group, as well as participating on advisory groups for a number of eCommerce exchanges.

# Unique Device Identification of surgical instruments by DataMatrix 2D barcodes

## ABSTRACT

The Robert Ballanger Hospital is a 650 bed intercity hospital. It has developed a project of Unique Device Identification (UDI) for surgical instruments and clinical services instruments. Over three years they will identify 10,000 operating theatre instruments using laser DataMatrix 2D barcodes, as well as 12,000 clinical services instruments.

The initial results, using laser technology to identify small instruments, were very promising. However, the project highlighted the necessity for regulation of the UDI. For this project EAN 128 codes were chosen, but other hospitals in France chose to use their own code. A regulation of the use of UDI would provide clarity and avoid a situation where every hospital develops its own UDI.



Article by **Georges Nicolaos** (left photo), **Marine Tournoud**, **Yasmine Hassani**, **Jeanne Mignon**, **Frédérique Frémont** (right photo) and **Alexandra Fabreguettes**

## Introduction

In France, as in other countries around the world, UDI of surgical instruments is not yet regulated<sup>1</sup>. However, several French hospitals are undertaking their own UDI projects.

The Robert Ballanger Hospital is an intercity hospital. It has 650 beds: 450 medical, surgical and maternity beds and 200 psychiatry beds. 30 patient operations are undertaken in the 8 room operating theatre per day. The sterilization unit of the hospital sterilizes 120,000 products per year.

This case study presents the Robert Ballanger Hospital UDI project, and highlights two major considerations:

1. the kind of identifier and
2. the requirement of standardised UDI.

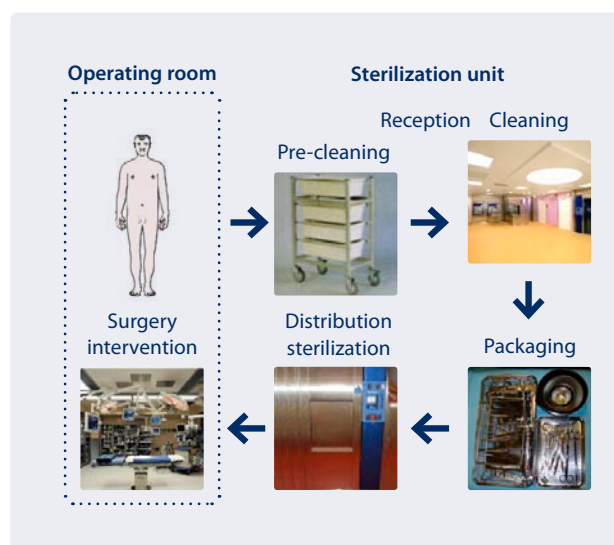
## The Robert Ballanger Hospital Project

In the hospital, 9,597 sterile medical devices are in circulation. 7,381 in clinical services and 2,216 in the operating theatre, contained in 724 surgical boxes.

Since 2005, the traceability of all sterile medical devices is the responsibility of the sterilization unit, using the t-doc software (Getinge, les Ulis, France). These medical devices

can be traced from the point of return to the unit through to their distribution to clinical services. The individual steps of the process are presented in the figure 1 and for each of these steps, the agents must identify themselves.

Figure 1: Sterilization process



Up to December 2008 traceability was at the surgical box level rather than the individual instruments within them.



Consequently, if the instruments in the box changed, that change was not traceable. The decision was therefore taken to trace the individual instruments in addition to the surgical boxes.

Several important points were considered before the project:

1. What level of traceability do we want?
2. What kind of carrier will we use?
3. Which instruments will we identify?
4. What kind of code will we put on each carrier?

### What level of traceability do we want?

In France, instruments are dedicated to a box. When an agent is assembling a box, the t-doc software displays its composition on a computer screen and the agent scans the instruments and must only include the associated instruments into the box.

This concept is very simple; it is easy to assemble surgical boxes and to identify the previous procedure/patient where the box was used. But there is little difference between this level of traceability and the traceability of a box.

In the Robert Ballanger hospital instruments are dedicated to a box, but it is possible to put the instrument in another box. But, as the level of identification is at the individual instrument level, traceability can be done on the box, for each instrument or for each box that included a particular instrument.

### What kind of carrier will we use?

The two major kinds of carrier are Radio Frequency Identification (RFID) tags and DataMatrix 2D barcodes (figure 2).

Figure 2: Different tags



RFID tags and DataMatrix 2D barcodes are the two carriers that can be used in the operating theatre and sterilization units. RFID tags on instruments could help avoid them being left inside the patient<sup>2-3</sup>. This system could also assist in the exchange of data between hospitals and to confirm the contents of surgical boxes.

DataMatrix 2D barcodes are represented in 2 dimensions (2D). They can be applied to instruments directly with a label or marking by micropercussion or laser.

For this project we chose the most pragmatic system of identifying the surgical instruments with a DataMatrix 2D barcodes. 3 major reasons lead to this choice:

1. the ease of laser marking existing or branded new instruments; Indeed, 500 instruments were industrially marked per week.
2. the cost of this kind of marking. In fact, a single laser mark costs between 2 and 3 Euros, whilst an RFID tag costs approximately 7 Euros<sup>4</sup>.
3. the existence of software that enables this kind of traceability.

For clinical services instruments, cost effective keydots were chosen.

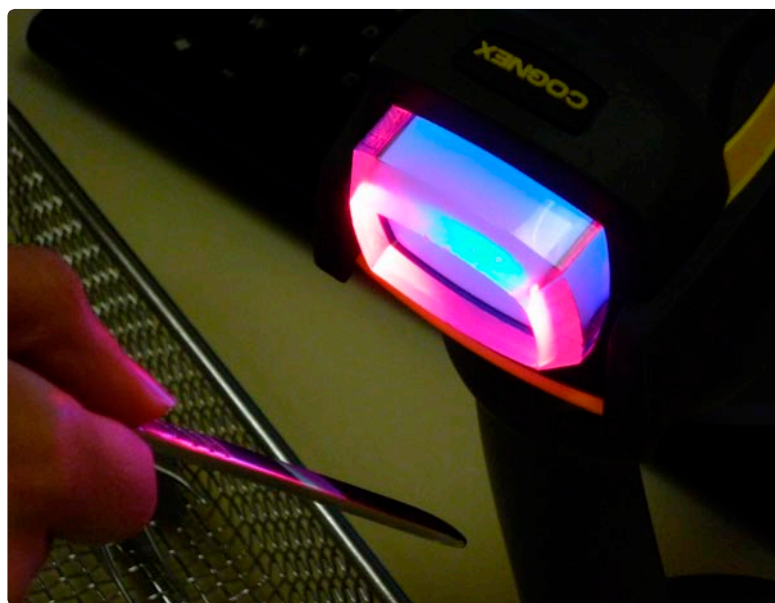
## Which instruments will we identify?

The decision was to identify surgical instruments and clinical services instruments. For clinical services instruments, all the instruments would be identified with Keydots. For surgical instruments, the simple strategy was to identify the instruments with the highest usage. For example, 5 types of surgical boxes represent 12% of usage. Identifying 10,000 surgical instruments equated to 80% of usage.

## What kind of code we will put on each carrier?

Due to the importance of instrument traceability, the Food and Drug Administration, the European Union or the Japanese authorities are leading reflections in this context<sup>1</sup>. Based on these international reflections, it was determined that UDI must be based on international standards, like the GS1 System of Standards, rather than local codes specific to each hospital.

Most French hospitals are developing their own code using micropercussion DataMatrix 2D barcodes. But using a proprietary code puts the identification responsibility solely on the hospital.



In conclusion, we think that French hospitals are in advance on the UDI, but we also think that they must integrate two important aspects of UDI:

1. the international reflections on UDI to adopt an international standard like GS1, and not a local code
2. the type of UDI - the DataMatrix 2D barcode is actually the most pragmatic system.

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# The NHS Procurement eEnablement Programme – Using information to deliver better healthcare

## ABSTRACT

Common standards hold the key to unlocking the benefits of procurement eEnablement in the NHS. This article describes the importance of information in the healthcare supply network and provides an overview of the NHS Procurement eEnablement Programme.



Article by **Rachel Hodson-Gibbons**

## Healthcare and information

Healthcare is an information intensive environment and the availability of quality information is essential for the delivery of safe and effective healthcare services. Decisions based on poor quality information provide ineffective healthcare services which adversely affect the outcome of treatment for patients and provide the NHS with a significant and avoidable cost.

The healthcare service in the UK is provided by a large number of organisations involving the private sector, the NHS and an increasing use of the retail sector. An equally large number of suppliers of goods and services supply into this network of healthcare providers. Purchasing and supply is essentially about relationships between organisations and processes; more effective processes and better relationships provide a higher quality supply chain.

To achieve stronger and effective processes and relationships, within and between organisations access to high quality information is required. To enable the effective delivery of high quality information organisations on the buy and supply sides of the healthcare network must be able to share data and order to achieve this common data standards are required.

## Current NHS position

The NHS has adopted a fragmented approach to the management of procurement and commercial information and systems and consequently the lack of common data standards has created many data silos. Data is available in very large volumes however quality information is in short supply.

An example from the English NHS illustrates this point well. Figure 1 provides an extract from the NHS Purchasing and Supply's Agency's pharmacy database which collates details of orders placed by NHS Trusts. The database contains 130 different descriptions, 30 of which are shown in figure 1, of a single product, Bleomycin 15,000 unit powder solution for injection vials.

The lack of a common commercial and procurement data standards in the NHS means that the analysis of expenditure and demand requirements across organisations is very costly in terms of time and resources. Without standards to accurately identify products and suppliers the accuracy can never be certain and visibility across the NHS is limited.

Effective information is the key foundation to an effective supply chain and effective healthcare.

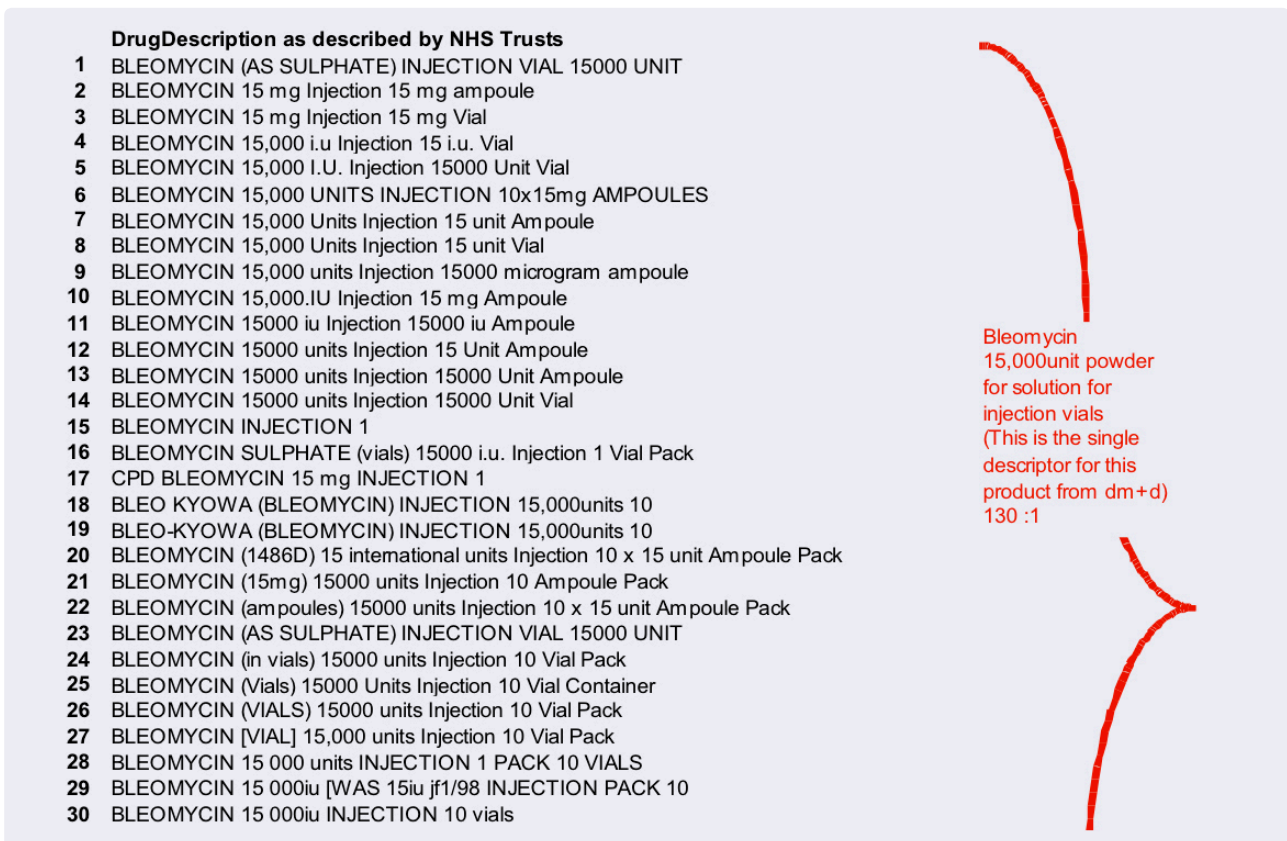
## Processes and data standards

The implementation of common data standards across the procurement and commercial systems by NHS organisations and its suppliers also enables information to be easily transferred between systems. This enables interoperability between systems, allowing automation which reduces the resources required, removes errors, increases compliance and reduces risk.

Beyond the business benefits the implementation of common procurement data standards enables traceability and this directly contributes to improvements in patient safety. This was demonstrated in *Coding for Success – simple technology for safer patient care*, a Department of Health policy document published in February 2007.



Figure 1

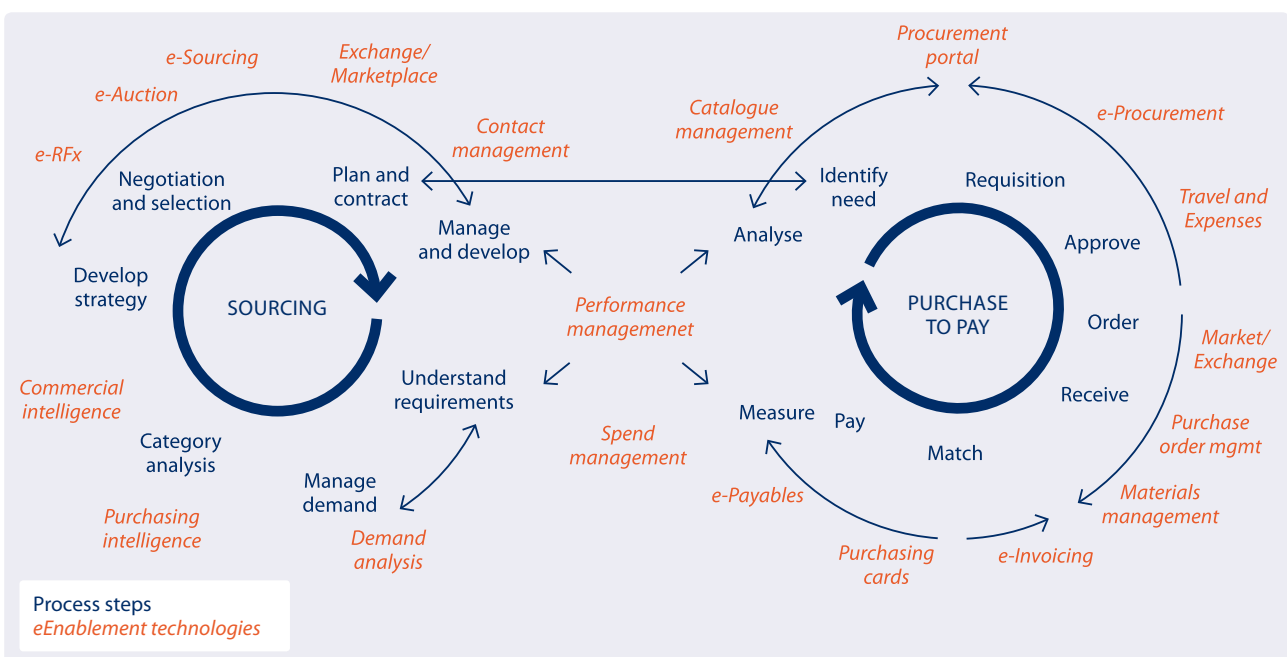


### Procurement eEnablement technologies

Procurement eEnablement is the application of information and communication technologies to the commercial and procurement functions. Figure 2 provides an overview

of this activity; the text inside the arrows describes the processes undertaken and the text outside the arrows describes the eEnablement technologies.

Figure 2



Procurement eEnablement technologies are important to the NHS as to be effective they demand common data standards across the NHS organisations and their suppliers. Implemented procurement eEnablement technologies provide the NHS with an important opportunity to significantly enhance its capability to manage procurement information, improve its commercial and procurement processes and remove waste and duplication.

### Procurement eEnablement and the NHS

Though the NHS has been using procurement eEnablement technologies since the early 1990's the approach to the implementation of these has been fragmented. Consequently the NHS has a wide range of standards in use and therefore limited interoperability between systems and little visibility of its expenditure across the network. The NHS has also failed to exploit sensible once-only opportunities that procurement eEnablement technologies offer; such as the management of product data for electronic catalogues and pre-qualification.

### NHS Procurement eEnablement Programme

The NHS procurement eEnablement Programme (NPEP) is about providing the NHS with the capability to effectively use procurement eEnablement technologies and achieve the significant benefits that are available. The programme implements the strategy *Procurement eEnablement in the NHS, June 2007*.

At the core of the programme is the implementation of common data standards for procurement and commercial processes.

The programme has four key outputs, described in Figure 3.

The outputs of the programme are delivered through a range of projects which have two levels of delivery:

- **Level 1 projects** establish common data and business message standards for commercial and procurement systems; provide a library of knowledge and guidance in conjunction with a range of tools for the NHS to improve awareness and understanding.
- **Level 2 projects** drive the delivery of procurement eEnablement capability into the NHS by directly providing resources to work directly with NHS organisations, suppliers and technology providers to achieve the following:
  - The capability for all procurement eEnablement systems in the NHS market to support NHS standards and interoperability requirements.
  - The capability within NHS organisations to make appropriate use of procurement eEnablement technologies.
  - The capability within the NHS to co-ordinate investment in procurement eEnablement technologies.
  - A transfer of skills and knowledge into NHS organisations to establish a mature understanding of procurement eEnablement by NHS organisations.
  - To implement a once-only approach to the provision of product and pre-qualification data.

The NPEP projects were developed in consultation with a range of stakeholders from NHS organisations, suppliers of goods and services and technology providers. The NHS Procurement eEnablement Programme is focused on delivering pragmatic steps that put into place the key enablers required for the effective implementation of procurement eEnablement technologies in the NHS and drive forward the adoption of these technologies.

Figure 3: NHS Procurement eEnablement Programme

|                                    |  |
|------------------------------------|--|
| <b>DIRECTION</b>                   | To provide a clear direction for the NHS, its suppliers and technology providers on the requirements for NHS procurement eEnablement. Through the provision of a strategy and then a model that describes the capability requirements. |
| <b>AWARENESS AND UNDERSTANDING</b> | To put into place a strong awareness and understanding in the NHS of the benefits available from procurement eEnablement, the current position of the NHS and the actions that are required to enable the significant benefits.        |
| <b>NHS STANDARDS</b>               | To establish NHS data and business message standards and requirements for interoperability between procurement eEnablement systems and provide guidance.   |
| <b>NHS CAPABILITY</b>              | To significantly improve the capability of the NHS to effectively implement and utilise procurement eEnablement technologies.  |

The level 1 projects are funded by the NHS Purchasing and Supply Agency and work on these commenced in mid 2008/09. The level 2 projects will be run over a three year period and require significant additional funding for which a business case has been presented to the Department of Health (October 2008).

## NHS Procurement data standards

The key building blocks of common data standards for NHS commercial and procurement processes are coding systems that enable the unique identification of suppliers and products and a classification system to enable the analysis of expenditure. The NHS standards are:

### Supplier codes



Duns numbers from Dunn & Bradstreet are the NHS standards for supplier codes. Duns numbers are available free of charge for all legal entities. The NPEP programme has provided a web portal to enable suppliers and the NHS to identify Duns numbers.

### Product and location codes



GS1 GTINs (Global Trade Item Numbers) are the NHS standard for products and GLNs for the identification of locations.

## REFERENCES

- Coding for Success – simple technology for safer patient care, Department of Health, February 2007
- Procurement eEnablement in the NHS, NHS Purchasing and Supply Agency, June 2007

## AUTHOR

**Rachel Hodson-Gibbons** is a purchasing and supply professional and currently holds the post of Head of eProcurement for the NHS Purchasing and Supply Agency in which she is leading the NHS Procurement eEnablement Program. Rachel's most recent posts have been Category

## Classification

### NHS-eClass

The NHS standard for classification is NHS-eClass. This classification system is owned by the NHS and is mapped to several other classification systems to ensure that NHS-eClass can provide an effective analysis of expenditure.

## NHS Procurement eEnablement Delivery Group

The NHS Procurement eEnablement Programme is owned by the NHS Procurement eEnablement Delivery Group (NPEDG), the NHS stakeholder group for procurement eEnablement, which was formed in late 2006. Membership of NPEDG is drawn from organisations across the NHS and includes representatives from the home countries. The current Chair of the group is Chris Slater, Head of Supplies from Leeds Teaching Hospitals NHS Trust.

In June 2007 NPEDG published a strategy for procurement eEnablement in the NHS within ministerial sponsorship and the NHS Procurement eEnablement Programme implements this.

For further information visit [www.pasa.nhs.uk](http://www.pasa.nhs.uk) or contact [eenablement@nhs.net](mailto:eenablement@nhs.net).

# Integrating information flows in orthopaedics at Leeds Teaching Hospitals NHS Trust

## ABSTRACT

The Leeds Teaching Hospitals NHS Trust's demand management project has produced significant efficiency savings in the orthopaedics supply chain. The project highlighted the need for global synchronisation of product codes for automatic identification and data capture, including RFID within healthcare.



Article by **Graham Medwell**

## Background

Leeds Teaching Hospitals NHS Trust started to roll out materials management in 1999 and now has over 270 materially-managed stocking points. It has derived significant benefits from controlling stock levels in major areas like Cardiology, where stock usage is updated live on the system through barcode scanning at the point of use.

The Chapel Allerton Orthopaedic Centre (CHOC) was an area identified in 2006 as a priority for increased stock management and as a stand-alone service for elective surgery (orthopaedic trauma carried out at the Leeds General Infirmary) which had a problem with high stock levels and system integrity problems arising from consignment stock and vendor-managed inventory. The system became known as "CHOC Stock" and is now linked to the main patient systems enabling product costing and track and trace of product.

## The wider healthcare vision

Patient safety was at the forefront of the DH paper 'Coding for Success' which featured 'islands of application within the NHS' of Automatic Identification and Data Capture including the bar coding system implemented in the Leeds Teaching Hospitals' Catheter Labs. The report highlighted that around 10% of NHS inpatient episodes result in errors of some kind – of which 50% are preventable. Of 8 million admissions each year, about 850,000 result in patient safety incidents that cost the NHS £2billion in extra hospital days.

With the advent of payment by results, it is important that consumables are recorded by each procedure for which

they are used, to ensure that the true cost of that procedure is recorded accurately. In orthopaedics there is an additional requirement to record any implanted products and update the National Joint Registry (NJR) for track-and-trace.

The vision at Leeds is that the patient administration system and the stock systems are integrated to update stock records and patient data automatically in order to improve accuracy and provide live data to suppliers and the trust budget holders. The data recorded would be invaluable in supporting activity-based costing.

## Data flows – the challenge

Within healthcare, unlike other sectors, there is a lack of consistency in the identification of product within the supply chain. It is for this reason that Leeds Teaching Hospitals has been a major supporter of the DH in the implementation of GS1 standards. From our experience in linking manufacturers' bar codes to product within cardiology and radiology, we understood the scope of the problem in mapping thousands of codes within our systems. The suppliers of the products had no means of providing the data, so we were left with the following alternatives:

- Map the codes ourselves
- Use our own bar codes

We decided to map the codes ourselves, but work with the suppliers through GHX, the healthcare e-commerce exchange provider, to enrich the data used throughout the supply chain. In September last year GHX announced that it was to become a GDSN-certified data pool to accelerate use of GS1 standards in healthcare.

## Data Management

The resources required to enable the introduction of an inventory control system should not be underestimated. The need to find, identify and record stock for over 2,500 product lines required a full team from the supplies department working over a public holiday in the elective area. (A later trauma theatres project did not have the benefit of a shutdown as they work 24/7.)



**Labour Intensive** – Supplies staff checks stock and allocates bar codes to products in orthopaedic theatres – May 2007. The CHOC Stock project highlighted the need for global synchronisation of product codes for automatic identification and data capture within healthcare.

## The Supplier Performance and Communications Enablement project (SPaCE)

Leeds was an early adopter of GHX's e-commerce Exchange and has been at the forefront of the search for even greater accuracy and improvements in efficiency. In addition to the use of PowerGate Inventory in theatres and PowerGate Web Requisitioning, the Trust has embarked on a programme to improve catalogue management, for which it is using GHX's Nexus cataloguing solution. Nexus is a web-hosted

catalogue management system that incorporates an online data repository containing catalogue information with secure shared access for both providers and suppliers. It features approved lists of centrally-managed product information grouped by supplier, with customer specific pricing. Both customers and suppliers can maintain the catalogue data.

SPaCE has involved Leeds and the suppliers Johnson & Johnson and Covidien and even though the suppliers ordinarily compete, SPaCE is bringing about an unprecedented level of co-operation as all parties involved – including members from the National e-Enablement Group and GS1 User Group – see the potential benefits in which they could all share. SPaCE aims to move dispute management from end-of-process (invoicing) to the beginning (demand management). As part of this process, Leeds is involved in the synchronisation of contracts through the GHX Nexus web-based interface. The GHX Exchange is also being enhanced to handle more documents, including the remittance advice and proof-of-delivery and to share internal workflow with the supplier for invoice reconciliation.

Although currently at the 'proof of concept' stage, the resulting GHX Nexus project has already proved invaluable in understanding the data flows within healthcare purchasing and supply.

## The challenge for orthopaedics

The orthopaedic supply model, where stock is held on consignment at the hospital, was hugely inefficient, and manufacturers are typically applying a 15-20% on-cost as a result. At Leeds, where the annual orthopaedic spend exceeds £3 million, the long-term reduction in consignment stocks has cut £500,000 from that figure.

Although joint replacement procedures have become routine and are subject to long waiting lists, it remains difficult to forecast product demand accurately. The complex nature of many procedures means that a vast range of sizes of prosthetic and ancillary products required (instrumentation, screws etc) is held on consignment in theatres.

Clinical preference also meant that a number of suppliers were represented, with the result that costs and wastage rose. A team comprising the leading surgeons and procurement staff agreed to standardise the range and as a result new contracts were agreed with the suppliers. Data

from the contracts was then enriched (classified, coded and priced) and fed from the GHX Nexus catalogue system to the inventory system.

## Stock management

The Leeds IT team worked hard to engineer the data process so as to provide live and accurate updates to both stock and patient systems. The solution is simple, as it mirrors the award winning processes successfully implemented in cardiology and radiology at Leeds General Infirmary. The inventory management system chosen was GHX PowerGate, which was integrated into the Trust's Oracle e-Business system alongside GHX Exchange for the electronic transmission of order and invoice data and the GHX Nexus catalogue management system. The area is connected to the Trust-wide Patient Administration system (PAS) and the theatre management system, Galaxy.

All the stock that might be required for a procedure is taken to the theatre from the stock room by the clinician, but the stock record is not updated. Once the stock is in theatre, the patient arrives and their ID is entered onto the patient administration system. From that point all scanned consumables used in the procedure are allocated to that patient and procedure type through PowerGate. It is only when the next patient ID is entered that the scanner will record product against the next ID.

Any unused stock is returned to the store (as it remains on the stock record) and from only scanning the stock that was

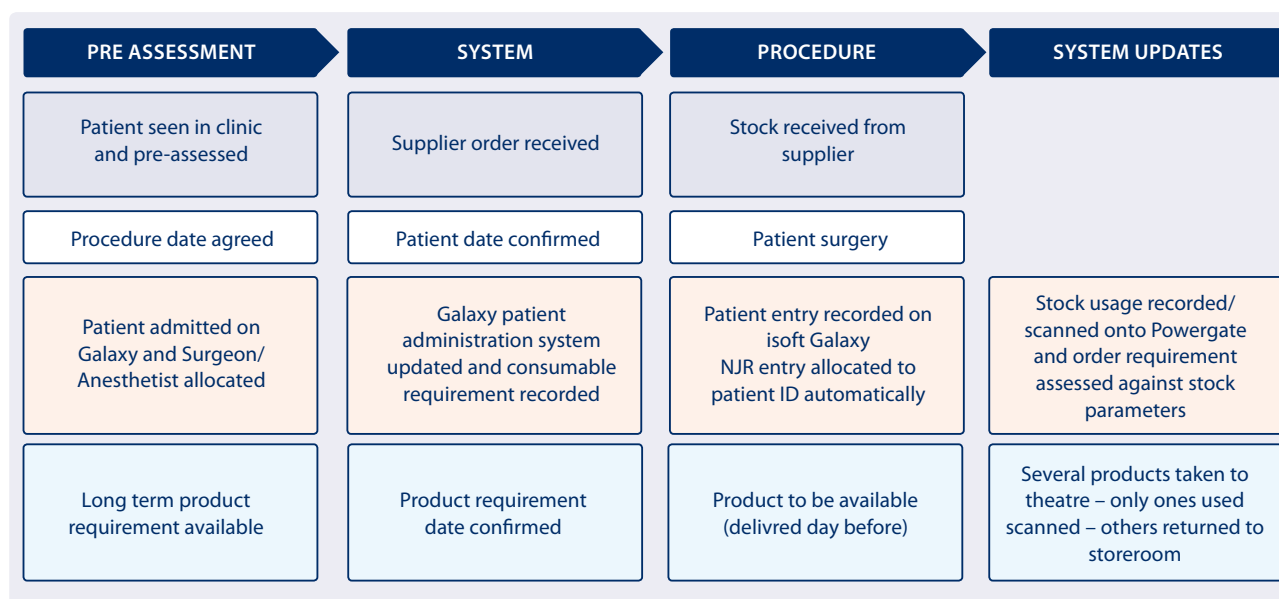
actually used, the information on costs by procedure and implant data for the National Joint Registry can be recorded in real time.

## Data capture

1. Before the day of surgery patient records are sent from PAS to CIS (demographics and patient history)
2. At reception PAS admission is entered and time of arrival; Galaxy time into department update; patient then gets changed and enters anaesthetic room; time in anaesthetic room; time induced; Anaesthetic given; ASA score all entered on Galaxy by theatre staff.
3. Patient enters theatre – time recorded then time recorded knife-to-skin by theatre staff – also recorded is people in theatre and roles performed.
4. On completion closure time recorded; surgical outcome recorded; time into recovery; time out of department recorded.
  - Knife-to-skin
  - Closure
  - Out of department

These three updates trigger a message to CIS (clinical information system) which will now update PowerGate.

5. On CIS the information has created a theatre list, from which the surgeon can select patient and input operation notes. (surgeon and anaesthetist information) including procedure details and implants used. Alongside CIS updates the consumables used are recorded by theatre staff on to 'CHOC stock' – the Trust's nick-name for GHX's PowerGate.



## Actual or projected benefits of the new system

### Financial benefits

- Stock to the value of £400,000 was found over and above the consignment levels. This eased the pressure on the clinical area (in the year of introduction), which had been seen as a failing area in terms of finance. Ongoing revenue benefits are being achieved by using quality inventory information to rationalise-down stock holding levels without the risk of stock outages.
- If the Trust could invest in reducing the consignment stock, both the supplier and the Trust would reduce process and write-off costs. As a result, contract prices could be reduced to share savings.
- If consignment stock was only used for slow moving products (extremes of ranges) and new products with no demand patterns, then efficiencies would be maximised.

### Clinical benefits

- Stock turnover increased, so any new products can be used quickly (no residual stocks to exhaust)
- System stock integrity improved thereby improving stock availability
- All supplier relationships formalised, eliminating invoice queries with clinicians
- Supplier training, product development and new product introduction still facilitated
- National Joint Registry updated accurately and immediately
- Kit availability greater as a result of better forward planning
- Increased training quality as procedures and product requirements planned in advance.

### Procurement benefits

- Increased notice for kits – opportunity to schedule procedures requiring same kit in sequence
- All products to be part of a contract negotiation process, thereby ensuring best price
- Reduced supplier costs reflected in reduction of prices to the Trust.

### Supplier benefits

- Reduced consignment stock
- Reduced need to manage stock levels
- Reduced write-off of expired consignment stocks
- Increased information for forward demand planning.

### Supply chain benefits

- Reduced stockholding for system stock
- Consignment stock on system, so order screens reflect true position when determining replenishment requirement
- Reduced obsolescence through stock visibility, stock rotation and stock levels that ensure usage within expiry
- Reduced emergencies thanks to improvements in forward demand/stock planning
- Reduced cost of carriage as stock delivered on efficient lead times and using scheduled deliveries.

### The vision for the orthopaedic centre

The vision for the orthopaedic centre is to automate all information flows through the patient administration system, PowerGate stock control system and updates to the national joint registry database. To enable this, Leeds Teaching Hospitals has data capture points (barcode scanners) in the storeroom and in each orthopaedic theatre suite. The next stages are:

1. orthopaedic kit RFID tagging proof-of-concept project and
2. early demand capture.

### Orthopaedic kit RFID - Proof of Concept

Orthopaedic kits or modules, which contain hip and knee joints in a variety of sizes, are commonly utilised in the Trust. Although these kits simplify the sourcing of components for a surgical procedure, they also complicate the administration process that supports it.

Each kit is loaned to the Trust on a consignment basis and only the elements that are utilised or not returned to the supplier are invoiced. This produces a manually-intensive checking exercise at each point in the lifecycle of the kit. Before delivery, the supplier checks that all components are present in the kit. The variety of kit complexity can mean that this is anything from a ten minute to a two hour process. This checking is then repeated by the Trust on receipt of the kit from the supplier, as the absence of any component can mean a cancelled operation. The checking is carried out again after the surgical procedure, to ascertain which components have been used and to record them manually for the creation of a purchase order that will match the supplier's invoice. One more check takes place on the return of any kit components to the Supplier as a final reconciliation.



Orthopaedic kits or modules, which contain hip and knee joints in a variety of sizes, are commonly utilised by the Trust.

What is a module?

An inventory code with a bill of materials below. e.g 5421

Each module has a build/lot number. E.g 5421/6

Each item in the build has product and lot number.

Johnson & Johnson are committed world-wide to implementing GS1 standards and these will form the basis of future RFID projects within Leeds. The timescales for the J&J adoption of GS1 standards will vary by J&J business unit.

Radio Frequency Identification (RFID) is potentially a perfect remedy to all of these manual checks. Leeds Teaching Hospitals, in conjunction with GS1, Depuy, Sybase and GHX, have piloted a test case of RFID-tagging a kit to simplify ad-hoc checking, receipting, issuing and final return of orthopaedic kits.

The solution has been built around Sybase's RFID Anywhere software. The advantage of this three-tier solution is that it translates inputs from a variety of sources into an homogenous message type which is then filtered for relevance. Filtered messages may then pass onto the business layer. This approach means that a number of input sources can easily sit alongside each other and should the initial RFID tags / readers change then the effects are insulated from the rest of the solution. The variety of built-in adaptors to communicate to ERP systems also means that the business layer is easily portable should their corporate solution(s) change and the solution can again be easily ported to other organisations with entirely different ERP solutions.

Leeds Teaching Hospitals integrated the solution into GHX's PowerGate inventory management system, which is in turn deeply integrated with Oracle Applications Purchasing, the Trust's corporate ERP system.

PowerGate allows the Trust to create a shopping list for each kit so orders can be generated by simple drag-and-drop-style requisitioning.

These requisitions are then matched with Oracle Purchasing, where they produce purchase orders which are then transmitted via GHX's e-trading exchange and routed via GHX to the supplier.

The outcome of implementing these technologies is that:-

1. Orthopaedic kits become their own receipts, while issues and returns are recorded in the inventory solution without the need for manual intervention
2. Consumed components create receipts against the purchase order which then act as a complete three-way match control for invoicing
3. Clinical staff are able to check the contents of a kit instantly, without the need for manual counts at each step in the administrative and clinical process
4. The Trust can meet legislative prompt payment requirements for invoices which otherwise would be delayed, due to the reconciliations required
5. Supplier stock-to-cash cycle is improved.

The technology is scalable and the concept has been proven but we now need a full pilot to prove the concept within the wider healthcare orthopaedic arena.

### Early demand capture

This area is in the next phase of development at Leeds. The patient is assessed several weeks before the procedure takes place (normally 6 weeks). At this point the surgeon, given demographic characteristics and procedure type, can predict with a degree of accuracy the product requirement (through a lookup template). The early demand information should help suppliers to optimise production, resulting in improved service efficiency and performance. The forward demand could also help the trust to ensure that any kits required are used for sequential procedures and so reduce rental costs.

The first phase of the implementation has been successful and Leeds now automatically updates patient records and joint registry information in the theatre environment through scanning equipment.



### NEW PROCESS FLOW

|   |   |   |  |  |   |
|---|---|---|--|--|---|
| The day prior to surgery patient records are sent from PAS to CIS<br><i>Patient history and demographics recorded</i> | Patient arrives in orthopaedic centre                     | Patient ID entered onto PAS (isoft Galaxy)                        | <b>Procedure takes place</b><br><i>Time of theatre entry, knife-to-skin and people present recorded on CIS</i>                               | <b>Patient leaves theatre</b><br><i>Surgical outcome recorded, patient recorded out-of-theatre</i> | Once a new patient ID is entered the scanning is completed for the previous procedure |
|   | All products potentially to be used are issued to theatre | <i>Type of procedure, arrival time and 'into-department' time</i> | All consumables used are scanned in theatre into PowerGate and allocated to the procedure code for costing and to the patient ID for the NJR | Unused products not scanned and returned to stock  |   |

**NOTE**

**PowerGate** Locally known as CHOCSTOCK – is the stock control and forecasting system  
**CIS** Clinical Information system  
**PAS** Patient Administration System (isoft Galaxy)

**Output from PAS to CIS and PowerGate**  
*Knife-to-skin time  
Closure time  
Out-of-department time*

### POSSIBLE FUTURE PROCESS FLOW

|   |   |   |  |  |   |
|---|---|---|--|--|---|
| The day prior to surgery patient records are sent from PAS to CIS<br><i>Patient history and demographics recorded<br/>Information shared with suppliers for production planning</i> | Patient arrives in orthopaedic centre                     | Patient ID entered onto PAS (isoft Galaxy)                        | <b>Procedure takes place</b><br><i>Time of theatre entry, knife to skin and people present recorded on CIS</i>                         | <b>Patient leaves theatre</b><br><i>Surgical outcome recorded, patient recorded out-of-theatre</i> | Once a new patient ID is entered the scanning is completed for the previous procedure |
|   | All products potentially to be used are issued to theatre | <i>Type of procedure, arrival time and 'into-department' time</i> | All consumables used are scanned into the Galaxy 'equipment module' – implants used recorded and consumable usage updated to PowerGate | Unused products not scanned and returned to stock  |   |

**Output from PAS to CIS and PowerGate**  
*Knife-to-skin time  
Closure time  
Out-of-department time  
NJR data  
Implants and consumables used*

### MANAGING THE TRANSITION

- STEP 1 – Agree stock levels**  
Clinical and supplies staff agree practical minimum stock levels, reorder levels and consignment levels
- STEP 2 – Training**  
All staff taken to see the barcode recording system working in other departments (cardiology) and at other trusts.
- STEP 3 – Procedures**  
To ensure the new system is as efficient as possible and benefits are maximised, the processes are recorded and monitored
- STEP 4 – Stakeholder engagement**  
All stakeholders engaged in stock level review and the importance/benefits of recording all products used communicated. Cross-functional group set up to review quarterly and agree new product lines
- STEP 5 – System transition**  
After 6 months the order history is on the system and the ordering function is transferred to predictive ordering – significant service improvement.

### AUTHOR

**Graham Medwell** is the Business manager for the Leeds Teaching Hospitals NHS Trust, with sixteen years experience in developing purchasing systems within the public sector as well

as working on health event linkage for the local health authority. He is a member of the GS1 UK HUG and the NHS National e-Enablement Programme.

# RFID and barcode based management of surgical instruments in a theatre sterile supply unit

## ABSTRACT

To effectively use surgical instruments Kanto Medical Centre NTT EC in Tokyo has introduced automatic identification and data capture (AIDC) technologies in the Theatre sterile supply unit. Both two-dimensional barcode (DataMatrix, 3~5mm square in size) and RFID tag are used for verification of surgical instruments and their containers, respectively. Although statistically meaningful data has not yet been drawn, effectiveness of AIDC technologies has already been well recognized among the staff in the operating room (OR) because accuracy and fluency of the sterile and supply unit (SSU) after the introduction of AIDC technologies are apparently improving.



Article by **Dr. Chikayuki Ochiai**

## Introduction

Kanto Medical Centre NTT EC (Nippon Telegraph and Telephone East Corporation) is located in the south of Tokyo. It was remodelled at the end of 2000 as a 606-bed general hospital fully, equipped with modern information communication technologies (ICT) including an electronic medical record (EMR) system. Barcode scanning for verification of patient identity via a wrist band was also introduced in 2008. The hospital treats 2,300 outpatients daily and more than 15,000 admissions annually. Surgical case volume is reaching 6,000 a year.

In order to overcome a shortage of operating rooms caused by unexpected increase of surgery, we have started to implement AIDC technologies in the Theatre sterile supply unit. We report here how we utilise radio frequency identification (RFID) and barcode for maximising the operating room facility (OR).

## Process improvement in the Sterile Surgical Unit (SSU)

Standardisation of surgical procedure and outsourcing of non-specific tasks of medical staff are essential issues for increasing efficiency of the OR. In the past, most surgeons used to require their own surgical instruments and materials for performing surgery in their own way. Today, however,

if a surgical procedure is the same, common surgical instruments and materials should be used regardless of surgeons. Standardisation of surgical procedure is essential not only for simplifying workflow in the Sterile Supply Unit (SSU) but also for saving cost in the OR. Outsourcing is very effective as proven in all aspects of hospital management. Freeing surgical nurses from such tasks as cleaning operating rooms and washing surgical instruments enables them to play their own roles in their original field.

Where outsourcing of tasks has taken place, outsourced staff, who work in the SSU, are often not familiar with the tasks. Declining efficiency in the SSU due to outsourcing might affect the entire efficacy of the OR. Process improvements in the following areas in the SSU were mandatory:

- Simplification of tasks
- Standardisation of workflow
- Improvement of safety and reliability
- Traceability of instruments (Frequency of use, sterilisation, repair, storage, event history etc.)
- Reduction of sets

Workflow of the SSU forms a loop composed of retrieve, sort, washing/decontamination, assembly, sterilisation, supply and storage. These processes, instruments going back and forth between OR and SSU, are very suitable situations

for applying AIDC technologies; data capture can provide information as follows:

- When the surgery started and ended
- When and by whom instruments were retrieved and washed
- Which instruments are in each container
- How often instruments are being used
- When and which instruments have been repaired
- When, how and by whom the container were set, sterilized and stored
- Which patient the instruments were used upon (AIDS, Creutzfeldt-Jakob disease, etc)

Not only simplification of the task but also recording of event history will become possible with using barcodes and RFID.

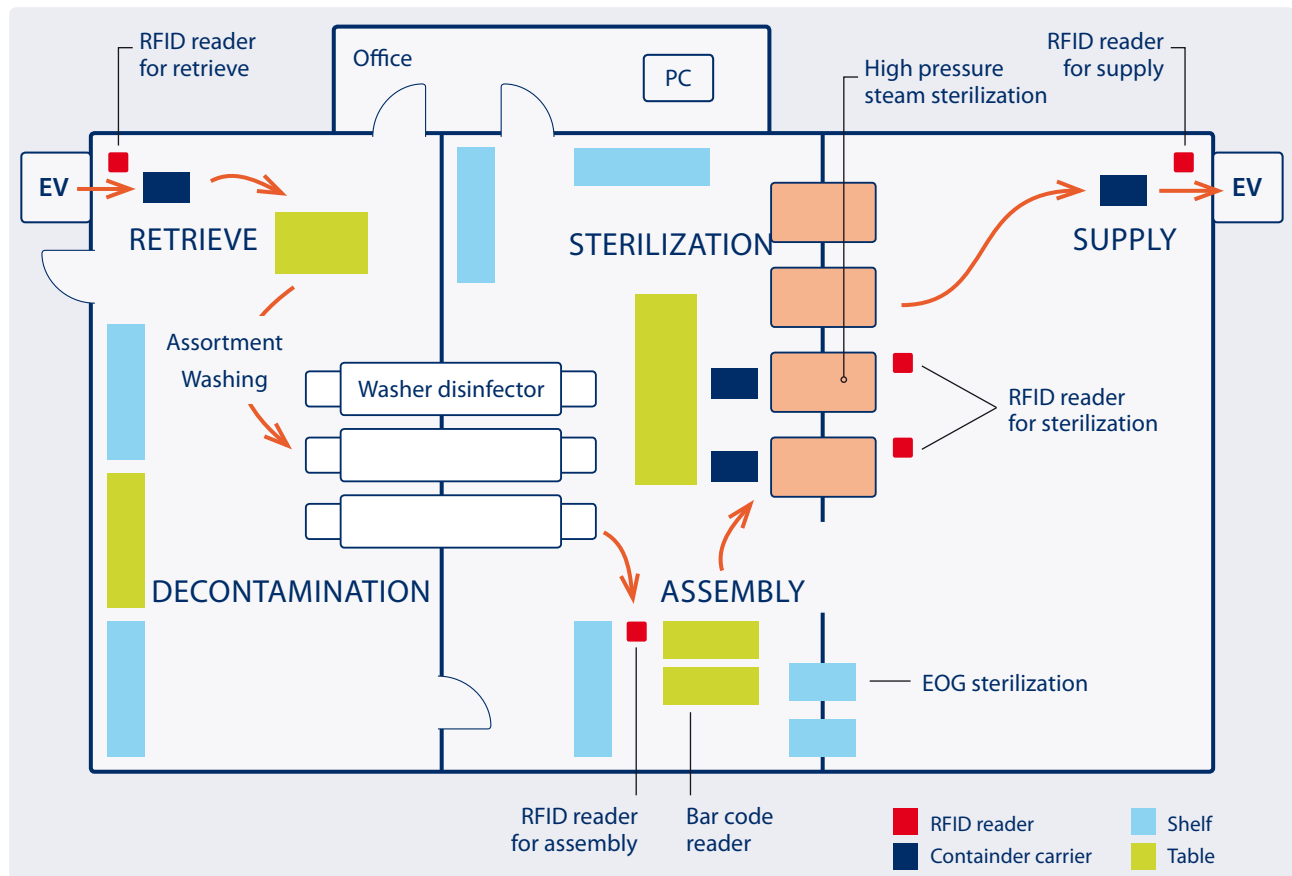
### Introducing Unique Device Identification and Traceability

As a unique device identification (UDI) for metal instruments we have employed DataMatrix, two-dimensional bar code, 3~5mm square in size, according to the guideline of JAMEI (Japan Association of Medical Equipment Industries).



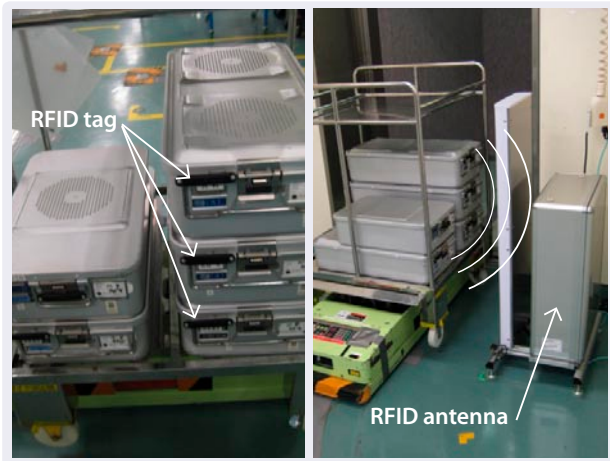
Direct part marking to each instrument was carried out on its flat mirror-like surface by laser printing in cooperation with Mizuho Ika Kogyo Co. Ltd. Durability of barcode printing to rust and friction had already been proven through five-year tests. Reversed reading was chosen for increased legibility of barcodes.

Figure 2: Theatre sterile supply unit in Kanto Medical Center NTT EC



Instruments are grouped together into a set by surgical procedure and housed in a container. For identifying the container an RFID tag was applied to it.

In Kanto Medical Center NTT EC the OR is located on the third floor and the SSU on the B2 floor. Both floors are connected with two elevators (EV) specific for surgical instruments. Automated guided vehicles carry used instruments in their containers to the entrance of the SSU.



After here, used instruments proceed along the arrows shown in figure 2.

A total of five RFID antennas are in place in the SSU:

- One at the entrance of the SSU  
Retrieval of multiple containers is simultaneously verified while they are passing in front of the antenna. Name of the set, which department used it and when it was retrieved are automatically recorded.
- One on the table for assembly



After housing a set in the container the tag on it is read to record name of the set and time when assembly was accomplished.

- Two at the exit of high pressure steam sterilizer



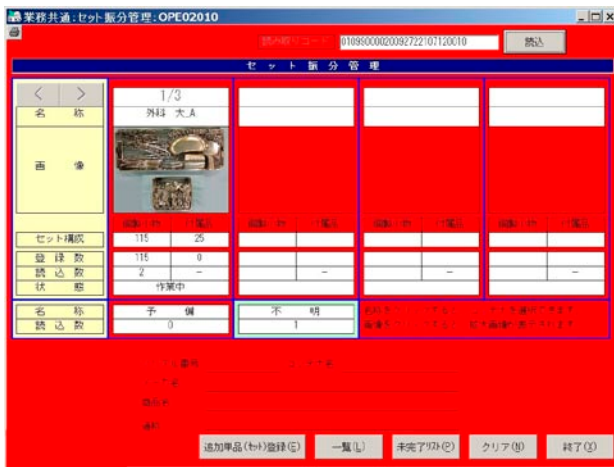
Multiple containers are put into the sterilizer with the tagged face directed left. When sterilisation is completed and the containers are pulled out from the opposite side, tags are simultaneously recognised by the antenna at the exit. Data relating to sterilisation are recorded, namely which sterilizer was used, when sterilisation started and ended, completeness of process, name of the set and method of sterilisation.

- One at the exit of the SSU  
Finally containers are sent to the OR via EV for storage. The RFID antenna set here collects date of supply and name of the set.



Following the process of washing/decontamination via washer disinfector instruments are sent for assembly, where a barcode reader is installed to support tasks of assembly. Staff are requested to hold each instrument over the barcode reader before grouping it together into a set. A green light on the display indicates the instrument belongs correctly to that set. If a red lights appears this indicates the instrument is in the wrong set. Staff not familiar with assembly, while holding the instrument over the bar code reader, can refer to the name of the instrument and its photograph displayed on screen. The display also shows the number of individual

instruments that comprise the set. During this process if an instrument that needs to be repaired is found, it can be replaced with a new one.



We started the introduction of barcode and RFID in April 2008. Management error of surgical instruments relating to the SSU occurred in 108 out of 5,712 surgical cases (1.89%) from April 2007 to March 2008. 58 errors were in assembly (53.7%), 13 in retrieve (12.0%), 13 in washing/decontamination (12.0%), 10 in supply (9.3%) and 4 in storage (3.7%), with the remainder in other areas. Among the 58 assembly errors one third of them was due to poor inspection and one fifth of them due to lack of devices. During the first four months from April to July 2008, we experienced 31 errors among 1,913 cases (1.62%). However, only three errors occurred among 2,729 surgical cases (0.11%) from August 2008 to January 2009. Regular use of barcode and RFID possibly decreased the errors during these six months.

## REFERENCE

MIZUHO IKAKOGYO CO., LTD, 30-13, Hongo 3-Chome, Bunkyo-Ku, Tokyo, 113-0033, JAPAN, <http://www.mizuho.co.jp>

## AUTHOR

**Dr. Chikayuki Ochiai**, M.D., D.M.Sc is the Chief Executive of Kanto Medical Center NTT, Tokyo. After graduating from the University of Tokyo, Faculty of Medicine in 1971 he majored in neurosurgery. Before being promoted to his current position in 2002, he held various posts including a professor of neurosurgery in the University of Tokyo Hospital, as assistant professor of

## Conclusion

We have not yet obtained enough data. However, every staff member in the SSU believes that workflow of assembly has become simple and accurate.

At present, we have accomplished barcode printing on approximately 6,800 instruments. In 141 out of 208 sets an RFID tag has been installed on their containers. Printing on 8,000 instruments is the goal. Recently, printing on both sides of the instrument has been started to make barcode reading more convenient. Direct part marking to each instrument, however, is too costly for end users to do themselves. To increase the utilization of AIDC technology in OR and SSU, globally standardized UDI, such as GS1 DataMatrix barcode, should be marked on every product by the manufacturer. If such an identification system for instruments is built, in the near future, all sorting and distribution of surgical instruments and sets could be done automatically and more accurately using a robotic distributor, avoiding human error and saving manpower. Similar problems occur in the field of medication administration.

If AIDC technologies are applied to everything used, spent and wasted in the hospital, we will be able to track forward and trace back every care and every event for each patient as a link to records, composed of 5W1H, along the time line from his/her admission to discharge. It should ultimately assure patient safety and enable cost management in the field of health care.

# BPOC/eMAR spotlight on performance improvement

## ABSTRACT

The implementation of an electronic medication administration record (eMAR) and utilization barcode point of care technology (BPOC) in the medication administration process can dramatically improve patient safety and prevent the wrong medication from being administered to a patient. While the realization of this technology in our health-system has prevented countless medication errors, we continue to experience errors that should be prevented by using BPOC. This article outlines how we have trended medication errors and developed performance improvement activities to improve patient safety following the implementation of BPOC.



Article by **Noel Hodges**

## Implementing eMAR at HCA

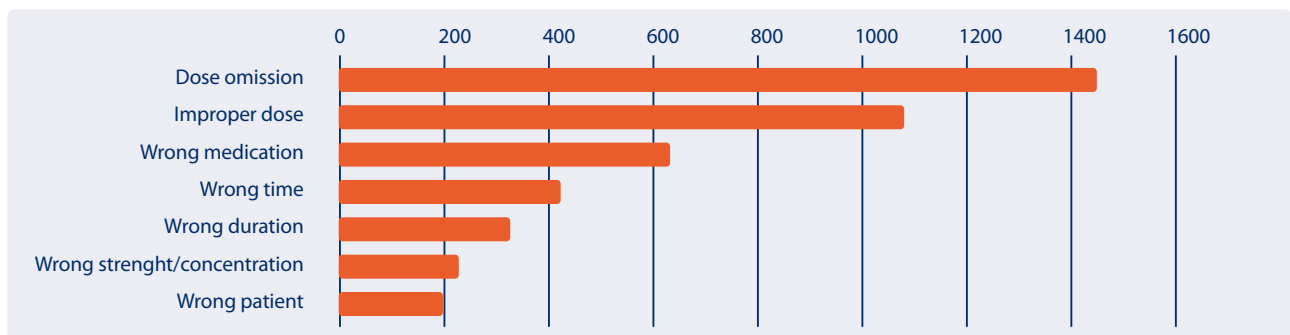
In early 2002, the Hospital Corporation of America (HCA) began a pilot to implement an electronic medication administration record (eMAR) and to utilize barcode point of care technology (BPOC) for medication administration in approximately 171 of their acute care hospitals in the United States.

In 2003, HCA started this initiative in their Richmond Market, consisting of six acute care hospitals supporting 1620 operating beds in Richmond, Virginia (USA). A major reason for implementing eMAR was to enable the healthcare provider to administer medications with confirmation of the Five Rights of medication administration: right patient, right dose, right route, right time, and right medication. Secondly, the

organization wanted to create a more complete electronic documentation system without compromising the functionality of the existing paper MAR. Today our eMAR is being used to display the patient's current active medication list; and a bar-coded, unit-of-use medication is scanned prior to administration to the patient (BPOC).

HCA's longstanding relationship with Medical Information Technology, Inc. (MediTech), their hospital information system, made implementing their eMAR and BPOC system extremely easy. The system integration allowed nursing and pharmacy to communicate in real time and improve patient safety. The systems also provided data and information that was never captured before, including medication errors.

Figure1: 2006 Medication Events by Event Code



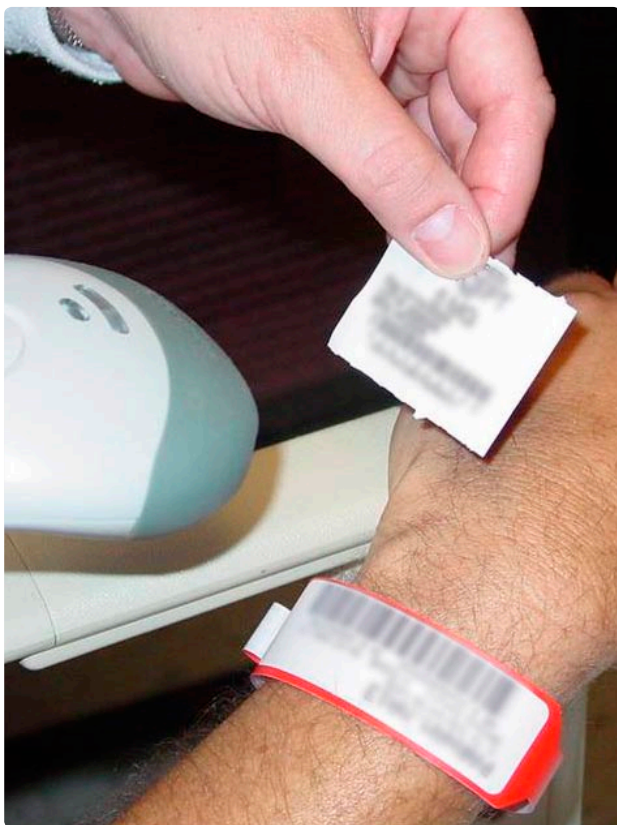


Figure 2: HCA's Patient Safety Goals

- Establish patient safety and a visible commitment to “putting patient first” philosophy
- Move from blaming people to improving processes
- Improve use of technology to prevent and detect error
- Use data to identify and measure improvements

### Post eMAR Implementation: Reporting and Monitoring of Medication Events

To improve patient safety utilizing eMAR and BPOC within the hospital environment, medication errors must be identified, reported, reviewed and properly categorized. Only after each of these steps has taken place, can the data be analyzed and used to develop a performance improvement process. The purpose of this project was to provide hospitals a standard taxonomy that could be used in classifying the specific cause of each medication error reported. This standardization would assemble data that could trend specific error causes within a health system and present opportunities for improving the medication use process.

Within our health-system, the medication error reporting tool in MediTech was modified to include a standard taxonomy for documenting the specific cause of each medication error. This taxonomy focused on event codes, such as wrong patient or wrong medication, it then further classified errors by a general cause such as communication or staff competency. The final stratification was identifying the specific cause, like illegible handwriting or miscalculation of dose. Our taxonomy was adapted from The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)<sup>1</sup> and modified to include specific cause codes relative to BPOC such as “medication barcode will not scan”, “patient armband will not scan”, “wrong medication packaged or bar-coded”...etc. These specially created cause codes gave us the ability to track and trend medication errors related to our bed-side technology.

A multidisciplinary team of pharmacy directors, risk managers, and quality management staff reviewed the

<sup>1</sup> <http://www.nccmerp.org/pdf/taxo2001-07-31.pdf>

In 2007, medication event data began to be reviewed from our 2006 data in aggregate from each of our facilities. Notably, we were still experiencing “wrong patient” and “wrong medication” events (Figure 1). It was our original hope that by using eMAR and BPOC, which required every patient and every dose to be scanned, that wrong patient and wrong medication errors would become never-events.

Within our health-system, our average patient scan rate was 96.58% and our average medication scan rate was 96.10%. Based on 11,862, 865 doses administered in 2006, approximately 462,000 doses were given outside or bypassed our system checks. These startling discoveries lead us back to HCA's original patient safety goals (Figure 2). We needed to use the data that was collected to improve our medication administration process and enhance our technology to make it easy to do the right thing and harder to do the wrong thing.

Medication doses given without using BPOC demonstrated a gap in our process that resulted in a greater opportunity for a potential error. In addition, we also experience medication events when the system was used as designed or partially used. We recognized our focus must be on tracking and trending both of these variations.

Figure 3

| EvCode                           | ORDER ENTRY ERROR | ACK INCORRECT/OMITTED | MISCALCULATION OF DOSE/RATE | DISPENSING ERROR | CHART CHECK PER HOSP POLICY | PRESCRIBING ERROR | ORDER INTERPRETATION | COMMUNICATE BETWEEN CLINICIANS | COMPETENCY/NOT TRAINED | DUTIES NOT PERFORMED | ORDER MISSED | P&P NOT FOLLOWED | INATTENTION | PHARMACY CENTRAL ORDER ENTRY | ORDER EXECUTION | ILLEGIBLE HANDWRITING | EQUIP PROGRAMMED/SETUP WRONG | OTHER | COMMUNICATION BETWEEN CLINICIA |
|----------------------------------|-------------------|-----------------------|-----------------------------|------------------|-----------------------------|-------------------|----------------------|--------------------------------|------------------------|----------------------|--------------|------------------|-------------|------------------------------|-----------------|-----------------------|------------------------------|-------|--------------------------------|
| Improper dose                    | 185               | 115                   | 47                          | 15               | 19                          | 21                | 20                   | 17                             | 18                     | 19                   | 17           | 17               | 16          | 18                           | 14              | 9                     | 8                            | 8     | 10                             |
| Wrong dose form                  | 31                | 14                    | 3                           | 9                | 2                           | 2                 | 2                    | 3                              | 1                      |                      | 1            | 1                | 2           |                              | 2               | 4                     | 1                            | 2     | 1                              |
| Wrong strenght/<br>concentration | 50                | 27                    | 7                           | 19               | 7                           | 3                 | 3                    | 4                              | 2                      | 2                    | 3            | 3                | 2           | 1                            |                 | 2                     | 3                            | 2     |                                |
| Grand total                      | 266               | 156                   | 57                          | 43               | 28                          | 26                | 25                   | 24                             | 21                     | 21                   | 21           | 21               | 20          | 19                           | 16              | 15                    | 12                           | 12    | 11                             |

specific causes assigned to each general cause. Once the list was finalized, staff education was done to ensure the coded of errors was consistent in each facility. A recommended team of pharmacy, nursing, risk and quality professionals within each facility was charged with reviewing each error and applying the correct error cause codes. This process was done weekly in many of our facilities to ensure medication events were analyzed in a timely manor.

Error tracking based on specific cause codes was provided to each facility on a monthly basis while trends throughout the health system were reviewed and performance improvement processes were implemented. By using this taxonomy medication errors can be tracked and trended within each institution and provide a system-wide approach to establishing safe medication practices in all facilities. For example in Figure 3, we found the most common cause or a patient to receive the wrong dose of medication (improper dose, wrong form, or wrong strength / concentration) was due to pharmacist order entry errors. But we also found mathematical calculations, physician prescribing and communications also contributed to these types of errors.

At a corporate level, a small team of pharmacy, quality and nursing professionals then developed training tools and system changes to assist individuals at each facility on

reporting and categorizing medication errors. This team also provided leadership for medication error reduction and process change, monitor data integrity, interpret data with trending analysis, and identify systems breakdown. This group focused on performance improvement activities that could be implemented in our hospitals to prevent future medication errors.

### Post eMAR Implementation: Performance Improvement Activities

By analyzing our medication event data and through direct observation of the medication administration process we have identified several key areas for performance improvement: only medications with viable barcodes reach the patient, all medication should be scanned before administration, and scanning all pills required for a complete dose.

It was imperative as part of the pharmacy process to ensure each unit-dose or unit-of-use medication reach the patient with a viable bar-code. During the drug procurement process, our pharmacies tried to source only bar-coded medications. This strategy was supported by our contracting department in selecting pharmaceutical manufactures that bar-coded their products. Our purchasing process required the scanning every medication received in our pharmacies. For those medications without bar-codes or



those medications where the bar-codes would not scan, pharmacy would quarantine those products until a bar-code could be applied.

During direct observation many medications were either not scanned or scanned after the medication administration process. Several factors contributed to these work-a-rounds, but one of the most common reasons given by nursing staff was the reliability of the medication bar-codes. If an individual medication package failed to scan correctly, the nurse was required to wait for the pharmacy to resolve the issue or replace the package. We found some nurses would save an empty package they knew would scan as a back-up and therefore not having to wait for pharmacy to resolve the error.

Many of our medications require multiple tablets to equal the prescribed dosage. For example, an order for acetaminophen 650mg required two 325mg tablets. We experienced incidents where only one tablet was scanned or the same

package was scanned twice to complete the administration of this order. In both of these cases where only part of the dose was scanned, patient safety checks are bypassed.

These and other “short-cuts” or “work-a-rounds” start with the pharmacy ensuring proper, viable bar-codes. This important quality assurance process begins in the pharmacy and must be done for every medication procured and ultimately dispensed for patient administration.

## Conclusion

In conclusion BPOC is one of the most important technologies we can use in our hospitals to improve patient safety. Bar-code technology is used in virtually every industry and for multiple applications. Health-care must implement and maximize the patient safety benefits from BPOC.

## AUTHOR

**Noel Hodges** is a licensed pharmacist in the Commonwealth of Virginia. As the Director of Pharmacy Services for HCA Central Atlantic Supply Chain, he is responsible for facility supply chain pharmacy operations and to identify and execute continuous improvement opportunities. Hodges completed his pharmacy degree at Purdue University and his Master of Business Administration from Strayer University. Hodges led the pharmacy implementation of Electronic Medication Administration Records (eMAR) and Bed-side Point of Care (BPOC) for the HCA Richmond Division, and

provides continuous monitoring of bedside scanning compliance and patient safety. He was also responsible for developing a centralized bar-code packing operation for his health-system. He has authored multiple articles and presented posters at American Society of Health-System Pharmacists meetings and The National Patient Safety Foundation on the topic of eMAR and BPOC. He has spoken locally, nationally and inter-nationally on bed-side scanning system, drug packaging, and BPOC.

# eCommerce within the hospital pharmaceutical supply chain lays foundation for improved patient safety

## ABSTRACT

The Monash Pharmacy project, a phased project with participants representing healthcare manufacturers and wholesalers, hospital pharmacy and tertiary education institutions, aimed to set the standards for eCommerce and supply chain management in the healthcare and pharmaceutical industries in Australia. Phase One, completed in mid-2004, demonstrated that the GS1 System could deliver benefits when implemented within the hospital pharmaceutical supply chain. This phase incorporated the use of EANCOM-format electronic purchase orders, purchase order acknowledgements and dispatch advice messages between suppliers and the hospital pharmacy of a major Australian hospital. Phase Two commenced in mid-2005 and involved broader implementation of the processes used during the first phase to additional suppliers as well as to all hospitals in the Southern Health network. In addition, the scope was expanded to include a data synchronisation pilot via the National Product Catalogue (NPC). Phase Three commenced in mid-2008 and will broaden the project scope further.



Article by **Nigel Allsop, Ged Halstead, Anthony Keyes and Ian Larmour**

## Background

The supply of pharmaceuticals and other goods to Australian hospitals is complex due to the mix of state, federal and private interests as well as a plethora of regulatory requirements. Yet while other Australian industry sectors, such as retail, have gained irrefutable benefits through the use of electronic commerce, the supply of healthcare products has remained predominantly paper-based with manual processing.

In 2003, seeing an opportunity to introduce greater efficiency in their supply chain, a group of proactive and leading health sector companies banded together to participate in a project to demonstrate the use of electronic commerce in a tightly defined but manageable project, the Monash Pharmacy Project. The pharmacy department of a major Melbourne hospital, the Monash Medical Centre, chose to work with suppliers, representing small, medium

and large enterprises: Clifford Hallam Pharmaceuticals, Hospital Supplies of Australia and Orion Laboratories as well as key stakeholders including Health Purchasing Victoria (an independent statutory authority for the procurement of services, equipment and goods for Victorian public hospitals and other health agencies), National Supply Chain Reform Task Force (NSCRTF), Pharmhos Software and the project managers, EAN Australia (now GS1 Australia).

## The GS1 System

At the heart of an effective electronic commerce system is a global way to identify trade items and logistic units: the GS1 System of global standards. To gain unilateral support across the Australian pharmaceutical/healthcare sector for 'one standard' identification system, the Monash Pharmacy Project team needed to illustrate the benefits to all industry suppliers.

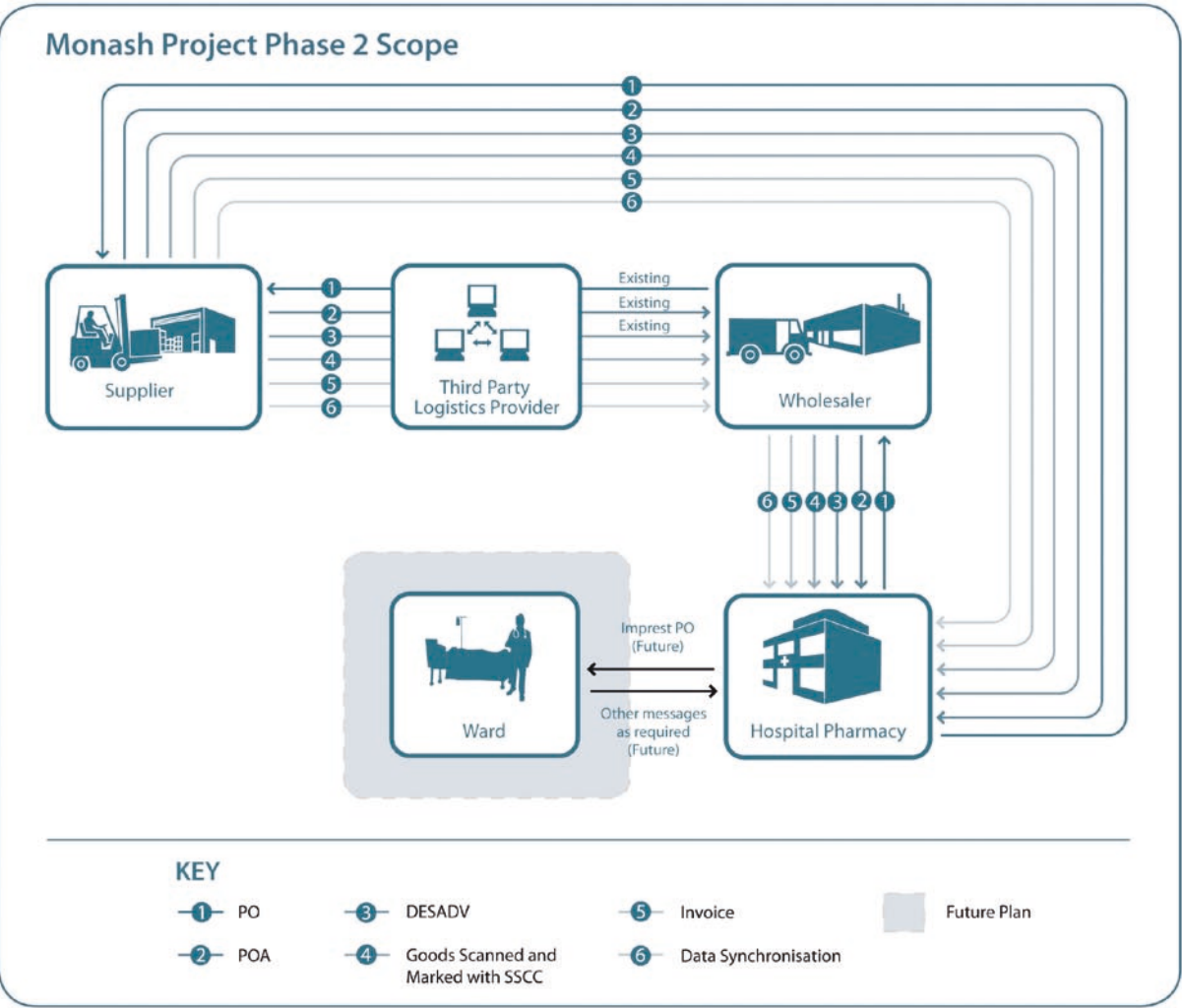
The premise of the GS1 System is that by introducing standards to key aspects of supply chain identification and communication, organisations can more easily implement best-practice processes because all trading partners will understand the standards used and not request proprietary solutions. Everyone speaks the same language when standards are used. This project used GS1 Standards for identification, electronic messaging, bar coding and data synchronisation.

The GS1 System identifies trade items using Global Trade Item Numbers (GTINs). These are internationally unique, non-significant numbers assigned by GS1 members (who are product brand owners) using their GS1 company prefix. Each different variant of an item and packaging level is identified by a different GTIN.

Logistics units are identified using Serial Shipping Container Codes (SSCCs). These globally unique identifiers are issued by the creator of the logistics unit, using their GS1 company prefix. Global Location Numbers (GLNs) are issued by GS1

or created using the GS1 company prefix of the issuing GS1 member company, to identify physical, functional and legal entities during electronic messaging exchanges. GS1 identifiers provide trading partners with an accurate and abbreviated means of referencing entities, trade items, and logistics units in their databases.

GS1 EANCOM provides a standardised and predictable structure for electronic business messages, enabling business partners to communicate business data rapidly, efficiently and accurately, irrespective of their internal hardware or software. As a subset of the UN/EDIFACT standard (United Nations Electronic Data Interchange for Administration, Commerce and Transport), GS1 EANCOM provides for the collection of the message elements needed by business applications and required by the syntax (mandatory elements). GS1 EANCOM also incorporates the GS1 standards for the identification of trade items, logistics units and trading partners which allows for the integration of the physical flow of goods with related information sent by electronic means.



## Phase 1

Phase 1 of the Monash Pharmacy Project, completed in mid-2004, was a demonstration of electronic messaging using the GS1 System in the hospital pharmaceutical supply chain.

During Phase 1, the ability to send or receive (as appropriate) standards-compliant purchase orders, purchase order acknowledgements, and receive despatch advices was put in place by both the Southern Health pharmacy and suppliers. SSCCs were placed on the logistics units being supplied to the pharmacy and a project was undertaken to study the process and requirements for bar coding pharmaceutical items.

Phase 1 successfully proved the application of the GS1 System of identification, bar coding and electronic messaging in the areas of hospital pharmaceutical ordering, picking, packing, despatch and receipt of goods.

The outcomes of Phase 1 established that improved trading efficiencies and cost savings could be achieved by the healthcare industry through the use of electronic messaging and improved supply chain processes underpinned by the use of the GS1 System.

The immediate benefits included a reduction in stock receipt time at the hospital pharmacy of 25 per cent, improved accuracy in order fulfilment accuracy of about 50 per cent, and an embracing of the new processes and technologies by staff. In addition, a number of key issues were identified which needed further investigation, including:

- The allocation of GS1 Global Trade Item Numbers (GTINs) and bar coding at a higher level
- Packaging (inner and shipper/carton level)
- Future requirements for batch/expiry date tracking
- The need for broader adoption of supply chain standards
- The need for data quality to be maintained continuously through master data synchronisation

Primarily, the first phase of the project provided the incentive and confidence to undertake Phase 2.

## Phase 2

Phase 2 of the project furthered the Phase 1 concept, by broadening both the project team and the implementation scope, whilst focussing on ease of implementation and further roll out of the standards. Seven pharmaceutical manufacturers (Abbott Australasia, Baxter Healthcare, Bristol

Myers Squibb, Hospira Australia, Novartis Australia, Orion Laboratories and Pfizer Australia), two wholesalers (CH2 and Symbion Hospital Services) and the Southern Health Pharmacy Department, operating from five hospitals, participated in Phase 2. Others involved included Monash University, Health Purchasing Victoria, and GS1 Australia.

Three areas of implementation of the GS1 System were identified for the Phase 2 project scope. These related to the project objectives outlined above and were driven by the learnings from the Phase 1 demonstration:

- Identification and bar coding of trade items
- Electronic messaging (using GS1 EANCOM) and improving order fulfilment accuracy
- A pilot of data synchronisation via the National Product Catalogue (aligning with the objectives of National E-Health Transition Authority or NeHTA<sup>1</sup>)

For data synchronisation between trading partners the project piloted GS1net, the Australasian data pool service for the synchronisation of item, price and industry specific data between buyers and suppliers. This simultaneously provides all trading partners with accurate and consistent item data. Compliant with the Global Data Synchronisation Network (GDSN), GS1net minimises data errors by eliminating human intervention and the need to maintain multiple catalogues.

The NPC is hosted on GS1net, allowing for supply chain and healthcare industry specific data to be exchanged.

Participant organisations selected their scope from the three project options, in line with their organisation's business goals, objectives and short-term capabilities. As the project proceeded and participants understood the benefits of their chosen project implementations, some began to introduce aspects of this with other trading partners outside of those originally selected.

Quantitative Key Performance Indicators (KPIs) were defined for each of the possible sub-projects. In addition to these, structured interviews were conducted with key project participants to ensure anecdotal, qualitative data was captured.

Key outcomes from Phase 2 of the project included:

- Scanning Serial Shipping Container Codes (SSCCs) and matching these with the electronic Despatch Advice

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<sup>1</sup> NEHTA was established by Australian Health Ministers to develop national eHealth standards and infrastructure requirements.

resulted in a quantitative reduction of 60 to 92 per cent in time taken to receive stock into the Southern Health pharmacy system

- The Southern Health purchasing staff recognised that the benefits are increasing as more companies implement standards-based electronic messaging
- Implementation of the project electronic messaging methodology beyond the current project team – to other customers and suppliers – was undertaken by a number of participating organisations
- Varying degrees of data discrepancy were reported as part of the GS1net pilot. This involved comparison of Baxter NPC to Southern Health Pharmacy system data: trade item description and label name (100 per cent discrepancy), brand (92 per cent), Baxter internal code (29 per cent), selling unit of measure (73 per cent) and classification (15 per cent) highlighting the need for data synchronisation via the NPC in healthcare. This pilot was the first instance in which healthcare data was exchanged on GS1net, a GDSN-compliant platform
- Anecdotal reports from the project team indicated that working in a collaborative environment mean implementation timeframes for electronic messaging could be reduced from 2–3 months to 2–3 weeks due to sharing of learnings – a significant saving of time and money
- A number of project learnings were documented for sharing with the broader industry

## AUTHORS

**Nigel Allsop** is Manager, Strategic Procurement, Health Purchasing Victoria. Nigel brings over 17 years experience to HPV covering such diverse areas as supplier management, strategic procurement, inventory management, E-procurement and process improvement across commodities and services. Nigel has achieved qualifications in Masters of Business, Bachelor of Arts with Honors in Business Studies, after successfully completing a trade apprenticeship as an Electrician.

**Ged Halstead** is the Chief Information Officer for CH2. See page 18.

**Anthony Keyes** is Customer Support Manager, Australia and New Zealand, Baxter Healthcare. Anthony has over 30 years experience in the healthcare industry. Anthony started with Baxter in 1978 and has been managing Baxter's national Customer Service and Homecare divisions in Australia since 2004 and New Zealand since 2006. Anthony was awarded the 2006 National Customer Service Manager of the Year by the Customer

## Looking forward

The Monash Pharmacy project is an excellent example of industry collaboration driving supply chain reform. What started as a small demonstration project, involving four trading partners, has grown to include representation from more than a dozen organisations throughout the healthcare industry.

Moving forward, the objective is to use the project to further refine and improve supply chain efficiency within the industry. The next phase will look to broaden the scope of customer participation across Victoria to develop a more comprehensive scope of activity for supply chain reform. This could be used as input for the next Victorian pharmaceutical tender, which will also focus on supply chain performance. The Monash project would then be an avenue to work with proactive partners to implement these supply chain reform activities and demonstrate the value that an efficient supply chain can bring to all stakeholders. This collaboration between stakeholders will also encompass opportunities for the Victorian implementation of the National Product Catalogue.

It is important to remember that all of the foundations being laid throughout the Monash Pharmacy Project are the foundations for the ultimate healthcare goal – improved patient safety.

Service Institute of Australia and in 2008 the Customer Support team won the Baxter Global Supply Chain Award. Anthony is a licensed customs broker and holds a number of business qualifications.

**Ian Larmour** has been a Director of Pharmacy, at a number of major hospitals, since 1981. Currently he holds the position of Director of Pharmacy for the Southern Health group of hospitals in Melbourne. Ian is a member of the Melbourne Teaching Hospital Drug Usage Group (now called Victorian Therapeutic Advisory Group) and was Chairman from 1993 until 1995. Since 2000, Ian has been a member of the Victorian Ministry of Health Poisons Advisory Committee. Over the years Ian has been involved in a variety of other organisations in a diverse range of roles and has published many articles on a wide range of topics, most notably a prospective study of Hospital Admissions due to Drug Reactions (AJHP, 1991, 21, 90-95).

# SmartLog: a Swiss drug traceability pilot

## ABSTRACT

SmartLog, a Swiss drug traceability pilot supported by Refdata, allowed all participating organisations to gain a better understanding of the benefits of an extensive use of GS1 Standards for their daily operations. The pilot also highlighted the need for good practices in the delivery process, especially between suppliers and hospitals. During 3 months, almost 39,000 retail packs have been serialised and traced in more than 7,000 events. Cross checks by Swissmedic on about 3.000 data sets demonstrated the consistency of collected data.



Article by **Laurent Médioni** and **Christian Hay**

## Environment

Pharma market observers in Switzerland considered 2 years ago trends and projects based on product serialisation, RFID and optical data carrier, pedigree and authentication. They noticed that these subjects were totally unknown in the Swiss domestic market. Representatives of wholesalers and regulators had preliminary talks about the benefit they could gather by running a pilot on the field with controlled drugs as narcotics. Two assets facilitate such a project: firstly trade of narcotics is monitored by law with a very efficient system for nearly 15 years; secondly Swiss healthcare disposes since 2001 of a foundation (Refdata) which objective is to facilitate processes by use of GS1 standards for product and party identification.

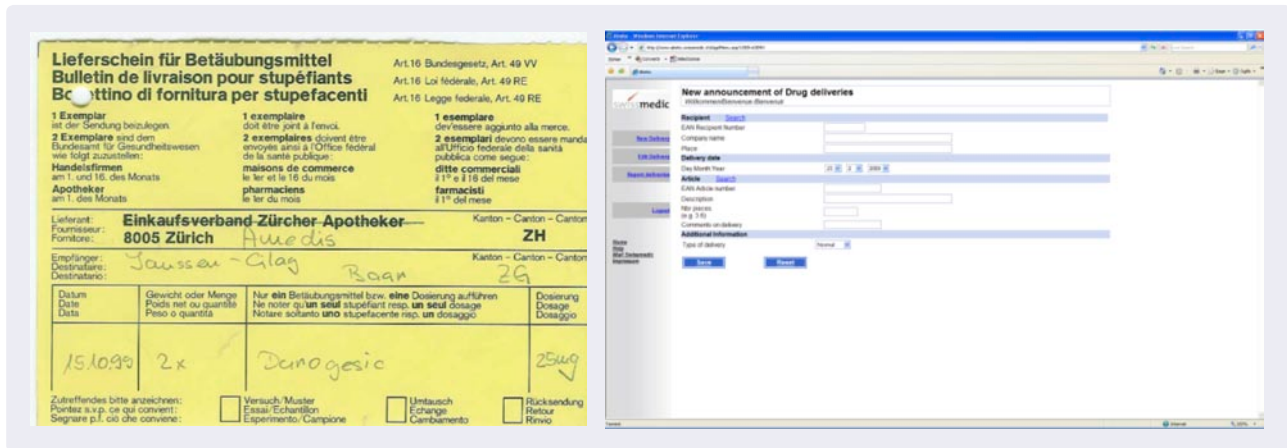
The discussion has been brought to the Refdata board, which decided to support the pilot which was then named "Smartlog". Refdata's board defined the scope of the pilot, delegated the operations to a team which had to deliver reports at the end of the pilot. A major role has been played by both e-mediati Ltd and GS1 Switzerland. E-mediati Ltd is a subsidiary of Galenica, a major player in the Swiss Healthcare, providing services as data management to the Healthcare industry. E-mediati runs since 2001 on behalf of Refdata the reference databases with GS1 identification keys for pharmaceuticals and for Healthcare parties. The databases are used for narcotic control, statistics, logistics and health invoicing; their use for eHealth and other areas is encouraged by Refdata. GS1 Switzerland provided its support by involving its user community as a validation

platform for various aspects of the pilot. Smartlog appears to be an additional "proof of concept" for the domestic market, illustrating that similar choices are made in surrounding countries for the next years.

## Narcotic control in Switzerland

Narcotic control has been reengineered in Switzerland in the early 1990. The purpose was to replace paper work by electronic data management, which allows increased efficiency both in human resources and in sparing public spending. After an in-depth study, the Swiss narcotic control office launched regulatory changes to mandate the use of GS1 keys to run narcotic control. GS1 keys were chosen as they were not specific to narcotic control, and thus reduce costs of database maintenance. Pharmaceuticals are identified in Switzerland with a GS1-GTIN since 1984; the Swiss pharma branch association (which was leading GS1 use on the marketplace at that time, and replaced since 2001 by the Refdata foundation) was planning to introduce GS1 identification for Healthcare actors countrywide – a project which suited narcotic control office's needs. Narcotic substances have been listed and allocated a GS1 identification key by the narcotic control office. 1994 all the conditions to deploy electronic data collection and processing were given.

Broadly, narcotic for medical use are controlled and involve 50 suppliers, over 1,300 retail pharmacies, 800 hospitals and 35,000 medical and veterinary doctors. The number of deliveries to be declared to the authority is about 350,000 per annum.



The role of the federal narcotic control office consists (among else) in collecting the declarations and providing appropriate information to the local authorities so that they can proceed in on-site controls where and when necessary. The power of the narcotic control system is to deliver within 30 days a country-wide picture of all transactions involving narcotics for medical use, and therefore concentrate on observations revealing peaks and other suspicious movements.

By disposing of that IT infrastructure (which can be accessed through the web: <http://www.abeko.swissmedic.ch/>) and by building on GS1 identification keys used for several other purposes on the marketplace, narcotic control is managed in the most cost-efficient possible way, by providing accuracy and full coverage to the federal and local authorities. It is further estimated that the user community saves considerable workforces because of the integrated processes with non-specific identification keys.

## Refdata foundation

Refdata foundation ([www.refdata.ch](http://www.refdata.ch)) has been launched in 2001 to group efforts and to maintain directions taken by a previous organisation. Its objective consists in securing identification of pharmaceuticals and healthcare providers across the country, with GS1 keys. Nearly all the Swiss healthcare industry is represented in Refdata's board: Associations of Pharmaceutical, Medical Devices manufacturers and wholesalers; for the care givers, the associations of medical doctors, pharmacists, droguists and hospitals; for the insurance side, the association of illness insurers and the pool of federal insurances (accident, disability, etc.). Swissmedic and the Federal Office for Public Health participate as observers.

Refdata has contracted with e-mediat Ltd for the operative activities, consisting in maintaining and developing the reference databases with GS1 identification keys for the Swiss market.

## Project participants

Lead of the pilot is delegated by Refdata to a pluridisciplinary team grouping representatives of wholesale, manufacturers, pharmacists and GS1 Switzerland. E-mediat, a service provider which is managing databases for the healthcare market in Switzerland, has been designated to manage the project and develop the necessary IT infrastructure. Pilot participants were invited to monitor the project from its conception to its delivery in a few joint meetings.

## Technical concept

By tracking and tracing individual drug packs, the project corresponds to the US-Pedigree model; full traceability is provided by documenting each "event" during the journey of each pack, from the manufacturer's premises (or its representative), to the dispensing to the patient.

The project was planned for a limited time frame: 3 months. As a consequence it was not foreseen that each project participant integrates the new processes into its operational IT environment; a separate "in vitro" framework has been developed by e-mediat Ltd, which allowed some simplifications (i.e. only one "event" database; central serial number allocation).

The set of operations was therefore built on a web-application with a safe level of protection and access. Each project participant accessed the web-application with its own data and had visibility to the previous and the next step

in the supply chain. Only Swissmedic benefit of full overview through the supply chain, so that comparison with the usual monitoring system became possible.

At the end of the project, participants are informed about aggregated data, whilst Swissmedic receives all details to assess the results towards the usual monitoring system.

## Project participants and selected project products

Four Pharma Manufacturer (Janssen-Cilag, Mundipharma, Novartis Pharma [pre-wholesaler: Voigt], Pfizer [pre-wholesaler: Alloga]) joined the pilot by selecting one pack size of one of their controlled products. All the wholesalers participated with a small number of retail pharmacies.

The project did not address hospitals: the supply chain to hospitals in Switzerland is very simple because they are usually supplied directly from manufacturers or their representatives.



Before being sent on the market, the selected retail packs were stickled with a linear barcode and a Datamatrix. The two data carriers included a GS1 data structure, the linear GS1-128 including only the GTIN and the serial number of that retail pack, whilst the Datamatrix included GTIN, lot, expiry date and serial number. With the double bar-coding, project participants wanted to secure that any retailer could participate to the pilot without needing to purchase a new scanner.

The pilot was limited to 3 months: compliance in maintaining separate, additional processes on a relatively large scale was a challenge; it was not necessary for the pilot to request longer efforts from the participants. 38,825 retail packs have been serialised and traced in 7,221 events. Because the small number of participating pharmacies, only 281 retail packs made their journey within project participants. Manufacturer (pre-wholesalers) delivered 23,504 retail packs to project participants, mostly wholesalers. Cross checks made by Swissmedic on about 3,000 data sets, based on the narcotic control processes in place, and demonstrated consistency of the collected data within Smartlog. The reduced number of discrepancies (~1%) concerned recipient identification in

Smartlog's records and was due to the non-integration of the processes and to human errors in selecting the recipient of a delivery.

## Project outcome

Participant feed-back has been very positive in general. Without surprise, wholesalers declared that optical marking is not appropriate to track and trace at the speed they have to work in preparing deliveries. Retail pharmacies expressed their interest in disposing of a better instrument for their stock management, including the management of recalls.

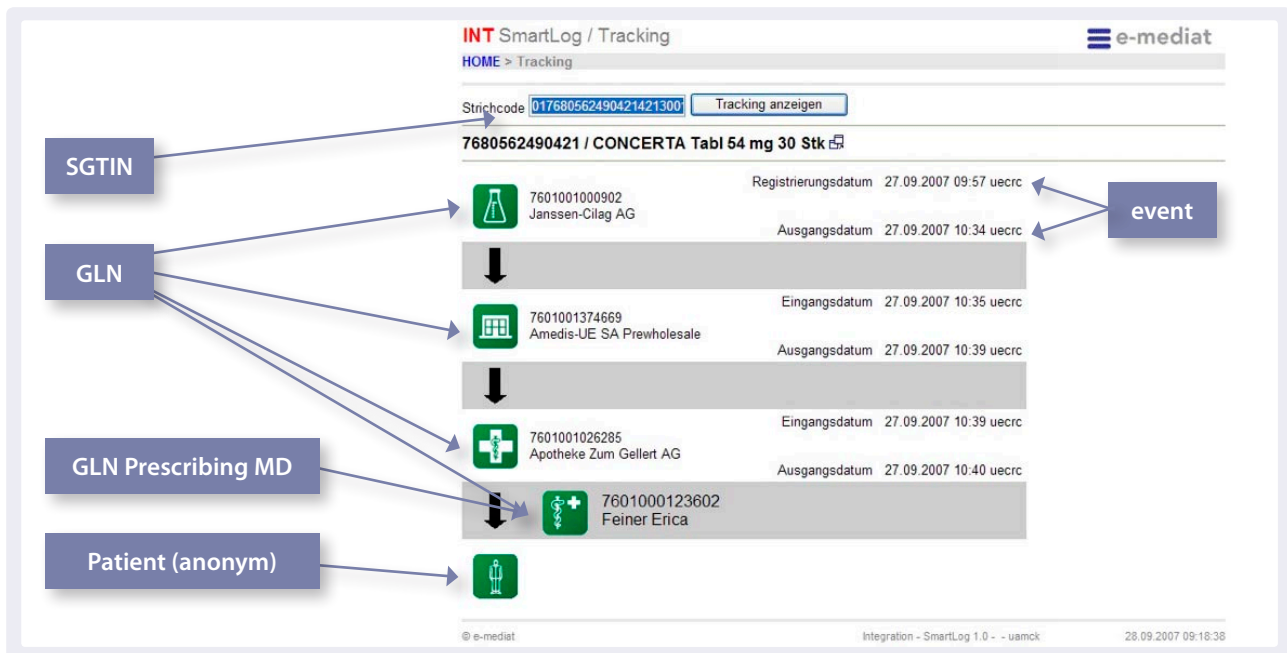
Smartlog raised questions about ownership, access to and sharing sales data. During the pilot, participants had only access to their direct supply chain data (one step before, one step after). This met requirements on data ownership. As an instrument to fight against counterfeiting, individual product tracing needs the development of intelligent tools to automatically discover unwished entrants in the supply chain as well integrity disruptions. The intelligent tools will alert concerned parties with appropriate information each time suspicion of counterfeiting is captured.

Because of its simplified organisation Smartlog did not include the "intelligent tools", which in return were recognised by project participants as a key to meet the objective of fighting counterfeiting, whilst respecting ownership of sales data.

Smartlog's outcome is published in two reports: a technical report, explaining the project from its origins to its achievement, and a strategic report presenting learnings and statements as a message to the community.



## Example of product flow for Swissmedic



## Conclusions and vision

From a series of articles in the specialised press across the country to the adoption of the final reports, through the running of the pilot, numerous actors in the Swiss healthcare have developed a better understanding of the benefits of an extensive use of GS1 standards for their daily operations. The reports, which are publicly available ([www.gs1health.net/smartlog](http://www.gs1health.net/smartlog)), list statements and lessons which help stakeholders in preparing future activities. This includes hospitals, even if these were not part of the pilot (in Switzerland hospitals are currently mainly supplied by the manufacturers or their local representative; the supply chain is therefore the most direct possible and excludes practically any counterfeiter to supply its pharmaceuticals to hospitals).

For GS1 Switzerland's user community, Smartlog helped understand the need to develop good practices in the delivery processes, especially between suppliers and hospitals. A working group has been set up immediately after Smartlog to address this subject.

We expect the federal authorities to dispose of a good information base in the case of any sudden incident involving the trade of counterfeited drugs, through the usual supply chain.

## AUTHORS

**Laurent Médioni** is currently canton's pharmacist in Fribourg. He was previously head of the Swiss narcotic control office and led the reengineering of narcotic control in the early 1990. He started his career as a hospital pharmacist in a regional hospital before joining his first position as canton's pharmacist in Neuchâtel. Beside narcotic control, canton's pharmacists are in charge of surveying retail and hospital pharmacies and to maintain plans for public health, as in the case of pandemics.

**Christian Hay** works currently for GS1 Switzerland and GS1 Global Office. Educated as a lawyer, he worked for the pharmaceutical branch since mid of 1980s in various positions. He was involved since the early stages in GS1 standard deployment in the Swiss healthcare.

# Transforming the Canadian healthcare supply chain: creating the future roadmap for success

## ABSTRACT

This article describes the efforts that are underway to create a standardized healthcare supply chain in Canada, affecting change and eliminating obstacles that have prevented full adoption in the past. Recent developments will accelerate the creation of one of the most modern supply chain systems in the world, with the full involvement of the government, healthcare provider (i.e. hospital), supplier, group purchasing organizations (GPO), and service provider communities.



Article by **Herb Martin**

## Introduction

Looking back, there is little doubt that 2008 will be considered a major turning point for the Canadian healthcare supply chain. Two organizations with similar goals and aspirations – standardized supply chain, state of the art electronic commerce environment and cost reduction – amalgamated into a single organization with a common objective: patient safety. CareNET, an association of healthcare facilities and suppliers across Canada, signed an agreement to amalgamate with GS1 Canada. Equally as important, various provincial governments provided funding and leadership to expedite the movement to a supply chain that utilized GS1 global standards. These events will enable Canada to create a sustainable model for the future – a model that will achieve the supply chain goals that the entire industry has strived to attain for so many years. A 15-month initiative, the Canadian Healthcare Supply Chain Standards Project, will develop the necessary standards and provide implementation guidelines and tools to drive consistency and interoperability across the sector.

In a parallel initiative, GS1 Canada also has made significant inroads in the pharmacy sector, among both retail pharmacies and pharmacy sites within the hospital community. The GS1 Canada Healthcare Pharmacy Sector Board is comprised of 18 senior executives. The Board identifies projects that support the adoption of a common system of supply chain

standards in healthcare institutions and retail pharmacy in order to improve patient safety, cost efficiency and staff productivity, ultimately ensuring that Canada's healthcare trading partners are able to fully operate in an increasingly e-driven global supply chain reality.

The Board views the pharmacy supply chain from the point of manufacturing to the point when the pharmacist receives payment for prescriptions, including the insurance claims process. Traceability has been positioned as the foundational supply chain element to drive efficiencies and safety.

Projects to enable complete supply chain traceability include the identification of Canadian requirements in pharmaceutical product identification (such as information imbedded within a bar code), the population of a national pharmaceutical product registry, as well as the GS1 Canada Certificate of Authority Service, which enables the secure, electronic procurement and tracking of controlled substance (narcotics) orders.

## Background

In the late 1990s, a group of industry leaders – including healthcare institutions, suppliers and GPOs – formed a Canadian version of Efficient Healthcare Consumer Response (EHCR). This committee proceeded as a healthcare sector-driven initiative with a mandate to significantly reduce



healthcare supply chain costs. Ten years later, the committee no longer exists and many of the recommendations that were not fulfilled still remain as valid now as they did then. Why did this happen? The most often-quoted reason is that all of the past efforts were made by volunteers who devoted as much of their time as their full-time employment would allow, but it simply wasn't enough. As well, funding and strategic priorities pushed supply chain projects to the back-burner. However, as we progress, supply chain perception is shifting from simply moving boxes to becoming the key enabler of patient safety, traceability, sustainability, interoperability and cost containment. Looking back at the events of history has provided the motivation to ensure that this situation does not reoccur.

CareNET represents over 450 hospitals across Canada, more than 95 suppliers and distributors, and the two national GPOs (HealthPRO Procurement Services Inc. and Medbuy Corporation). Since 1990, CareNET has been instrumental in promoting the advancement of electronic commerce (e-commerce) in the healthcare sector, along with the e-commerce standards for electronic trading, with a goal of reducing supply chain costs.

Since 2007, GS1 Canada has been moving forward with its plan to integrate GS1 standards into the Canadian healthcare system. GS1 Canada's goal is to introduce to the healthcare sector the same efficiencies that have already

been experienced by others, including grocery and retail. The vision of tracking and tracing all healthcare products – from the point of manufacture to the point of use (patient bedside scanning) – would result in an efficient and safe supply chain.

At the close of 2008, CareNET members voted and the agreement was signed to amalgamate with GS1 Canada.

Another 2008 milestone occurred when GS1 Canada, with CareNET's strong endorsement, received approval for its application for funding from the Ontario Ministry of Finance's OntarioBuys program to promote supply chain efficiencies for its broader public sector (hospitals, schools, universities, etc.). The application outlined the first three phases of an ambitious program to define and implement a standards-based structure for the healthcare supply chain. OntarioBuys agreed in principle to fund up to 70% of the proposal entitled the Canadian Healthcare Supply Chain Standards Project, subject to GS1 Canada receiving commitment for the remaining 30% from other provincial jurisdictions and corporate enterprises. OntarioBuys added the stipulation on partial funding to ensure that all of Canada was behind this new approach to healthcare. By implementing an aggressive outreach campaign, GS1 Canada has received approval for over half of the remaining 30% from the provincial governments of British Columbia, New Brunswick, Nova Scotia and Alberta, as well as a number of corporate contributions.

## The New Direction

All of the necessary building blocks are in place to create the groundwork for future success. Already, we are beginning to see the results of these efforts, including:

- The former CareNET Board of Directors (10 hospitals, 10 suppliers) remains in place as the CareNET Healthcare Sector Board in GS1 Canada, with the mandate to set the future direction for healthcare in Canada
- A majority of board members have also agreed to participate on a newly-formed CareNET Healthcare Standards Council to approve the future direction for healthcare standards development and implementation timelines
- A Healthcare Technical Standards Working Group has been formed to create the standards for future e-commerce in healthcare. This group of more than 30 individuals from across Canada, comprised of hospitals, suppliers, distributors, GPOs, network gateways (Value-Added Networks) and service providers, will prepare the recommendations for future standards and forward them to the CareNET Healthcare Standards Council for approval.

The GS1 Canada Healthcare Pharmacy Sector Board will have a representative on the CareNET Healthcare Sector Board, and vice versa, to ensure the transfer of knowledge

between the two boards. The pharmacy board is also supported by a Pharmacy Standards Work Group.

The proper structure for future success is now in place. CareNET brings the membership of devoted providers, suppliers, GPOs and service providers to the table. GS1 Canada brings an association with many years of experience in e-commerce and supply chain standards. More importantly, the onerous demands on volunteers to continue the momentum will be supplemented with the experience of GS1 Canada staff.

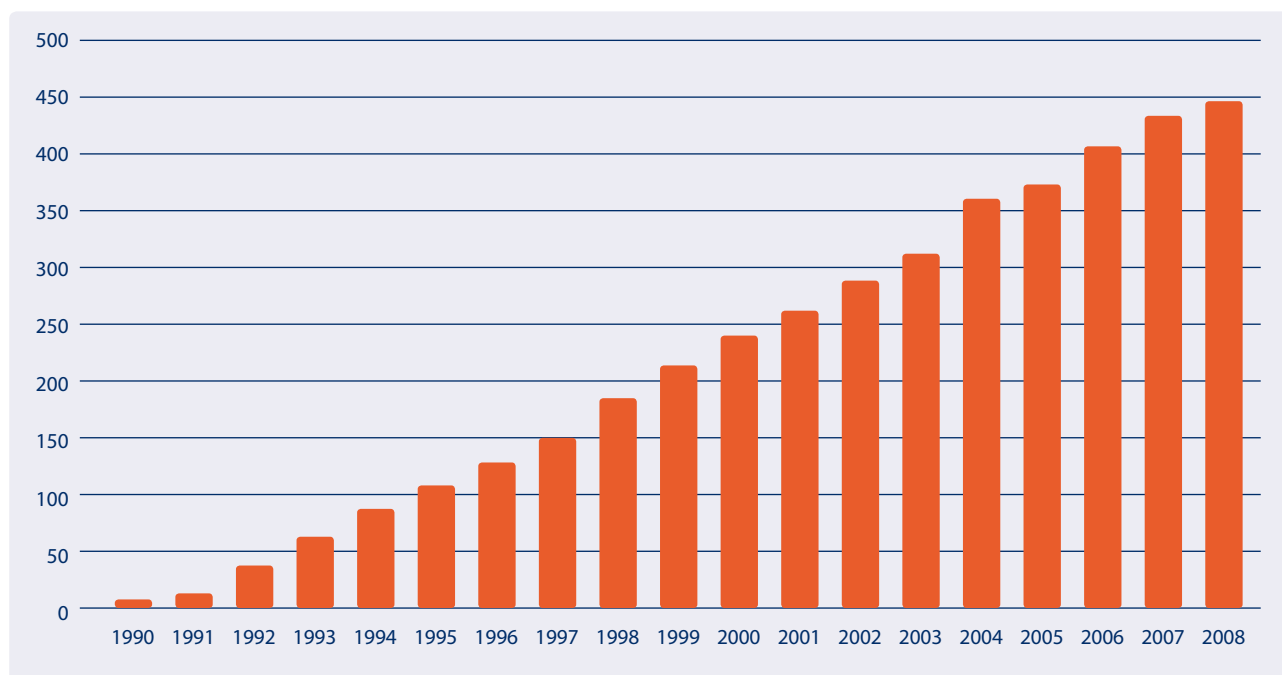
## What Are We Trying to Achieve?

Our ultimate goal is to achieve a standardized, efficient healthcare supply chain. This very simplistic statement, although it defines the objective, requires a great deal of advance planning and work.

Clearly, the initial benefits are obvious. By implementing a standards-based supply chain, using technologies that are designed with a global perspective, reduced costs will accrue to both the provider and supplier community. This cost effectiveness will enable additional funding to be directed to patient care.

Moreover, using global standards – such as Global Trade Item Numbers (GTINs) and Global Location Numbers

CareNET Hospital Member Growth



(GLNs) for product and location identification, respectively – throughout the supply chain will enable track and trace systems and automated product recall systems. Industry-adopted attributes and the exchange of clean data between trading partners will ultimately become entrenched in healthcare systems and drive efficiencies.

The final achievement will be enhanced patient safety. Future systems will track a product throughout the entire supply chain, from point of manufacture to point of use at the patient's bedside, ensuring that the right patient receives the right dose of the right medication at the right time.

Canada is not unique in moving forward with this plan for the future. This strategy is directly linked to the global GS1 Healthcare initiative. Although we track the efforts of other countries, we are confident that we shall soon have in place a sustainable model for others to follow.

## The Global Perspective

For the past 20 years, Canadian healthcare has been advancing its electronic transaction processing infrastructure, as more hospitals and suppliers upgrade and enhance their back-office systems to provide the functionality required by their trading partners. Although there have traditionally been shortcomings in the information exchange, for the most part, the advancement of electronic commerce has served the healthcare industry well.

We are now at a stage when we must assess the current environment and establish an industry roadmap for the future that incorporates both the experience that has been gained over the past years and the requirements for future technological changes and demand to operate a sustainable, efficient and safe healthcare system.

To properly develop the systems of the future, Canadian healthcare must define the basic requirements for the exchange of electronic business documents. These basic requirements will include global data requirements such as GTINs and GLNs to facilitate the tracking of products throughout the supply chain. Just as the retail and grocery sectors have successfully demonstrated for many years, guidelines for basic bar coding of all medical products entering the healthcare supply chain will be implemented and enforced. As Radio Frequency Identification (RFID) becomes a widely used technology in healthcare, the standards will be implemented and available for all members.

With all trading partners moving forward with a common set of global standards, products that arrive from within and outside Canada can move through the supply chain with confidence, and can be tracked to determine both their origin and their final destination.

## Conclusions

As of Spring 2009, we are now well on our way to creating a foundation for future success. The critical components of this foundation are:

- Start-up funding
- Strong government support
- Commitment from all stakeholders in the healthcare industry, across the entire country
- Combined efforts of a strong healthcare association and GS1 Canada
- The creation of a sustainable model for the future.

## AUTHOR

**Herb Martin**, in his role as the CareNET Manager, is responsible for the administrative tasks associated with the day-to-day operations of CareNET. CareNET is Canada's healthcare sector strategy to standardize the healthcare supply chain. Through its amalgamation with GS1 Canada, CareNET represents over 450 Canadian healthcare providers and 95 leading suppliers. CareNET

will identify projects that will support the adoption of a common system of global supply chain standards in healthcare institutions. CareNET's goal is to improve patient safety, cost efficiency and staff productivity, and ultimately ensure Canada's healthcare trading partners are able to fully operate in an increasingly e-driven global supply chain ([www.carenet.ca](http://www.carenet.ca)).

# Return on investment of standardised bar coding at Herz-Zentrum Bad Krozingen

## ABSTRACT

At the Herz-Zentrum Bad Krozingen, cost unit billing according to Diagnosis-Related Group (DRG) guidelines used to be time consuming and prone to error. The hospital has investigated the impact of the introduction of standardised bar coding: in addition to saving a significant 78% in documenting consumed materials, it has also shown that efficient, accurate DRG calculation is only possible when data is automatically entered by scanning the bar code. A cost-benefit analysis showed that the initial investment already paid for itself in the first year.



Article by **Holger Klein**

## Background

The Herz-Zentrum in Bad Krozingen is a hospital specializing in the treatment of cardiovascular diseases. It has departments for cardiology, angiology and cardiovascular surgery. The Herz-Zentrum has a total of 256 beds.

The project was initiated in response to the time-consuming cost unit billing by Diagnosis-Related Groups (DRG calculation): When the project started in 2006, some 65% of medical requirements were entered to "cost units", namely patients, and the manual processes required much effort.

On the one hand, the hospital uses cost unit accounting as an instrument for efficiency controlling.

On the other hand, the cost unit accounting data is supplied to the Institut für das Entgeltsystem im Krankenhaus (InEK) GmbH for review, as required by law.

Table 2: Sample data supplied to InEK GmbH (sample data)

| IK    | Releasing location | In-hospital code | Cost centre group | Cost type group | Purchase price (€) |
|-------|--------------------|------------------|-------------------|-----------------|--------------------|
| IK No |                    | Inventory No     | 7                 | 1               | 1,456.53           |
| IK No |                    | Inventory No     | 7                 | 3               | 247.59             |
| IK No |                    | Inventory No     | 7                 | 4a              | 29.07              |
| IK No |                    | Inventory No     | 7                 | 5               | 1,926.00           |
| IK No |                    | Inventory No     | 7                 | 6a              | 189.35             |
| IK No |                    | Inventory No     | 7                 | 6b              | 7,157.42           |
| IK No |                    | Inventory No     | 7                 | 7               | 253.92             |
| IK No |                    | Inventory No     | 7                 | 8               | 239.18             |

Table 1: Excerpt from cost unit accounting per DRG case (sample data)

| Booking date | KoA    | Description                     | Quantity | BzGr | Amount (€) | Voucher number | Voucher date | BP | Booking text     | Cost centre | Cost centre description |
|--------------|--------|---------------------------------|----------|------|------------|----------------|--------------|----|------------------|-------------|-------------------------|
| 12.10.2007   | 660400 | Medical and nursing consumables | 2        | st   | 30.09      | 10585          | 30.09.2007   | 9  | Outgoing invoice | 92232       | Electrophysiology       |
| 12.10.2007   | 661003 | Electrocardiogram requirements  | 1        | st   | 32.13      | 10585          | 30.09.2007   | 9  | Outgoing invoice | 92232       | Electrophysiology       |
| 12.10.2007   | 661350 | Intracardiac catheters          | 10       | st   | 7,095.20   | 10585          | 30.09.2007   | 9  | Outgoing invoice | 92232       | Electrophysiology       |
| 12.10.2007   | 661342 | Stents, coated                  | 2        | st   | 1,926.00   | 4234           | 30.09.2007   | 9  | Outgoing invoice | 92019       | Intracardiac catheters  |

## Preparation for the Herz-Zentrum Bad Krozingen project

The project was approved by the hospital management in February 2005 and has been in production since September 2007. The relatively long project duration was necessary so that suppliers could have the opportunity to identify their products with GS1 barcodes in accordance with the requirements.

A prerequisite for using scanners is that a product's master data be available and incorporated in the inventory management system. The first task was therefore to enter the GS1 item numbers of the suppliers. The challenge for the hospital was less in making IT adjustments, since the materials management system it uses is GS1-compatible, than in universally identifying products with barcodes.

An initial classification and stocktaking of the relevant items in March 2005 showed that a large number of suppliers had not identified their products with barcodes. In those cases where suppliers had identified their articles with barcodes, the challenge was to analyse the various barcode systems and impose a single standard, namely GS1. Non-GS1 barcodes meant an extra step was needed to enter the batches and serial numbers that are necessary for sending invoices to consignment warehouses and to comply with statutory documentation requirements.

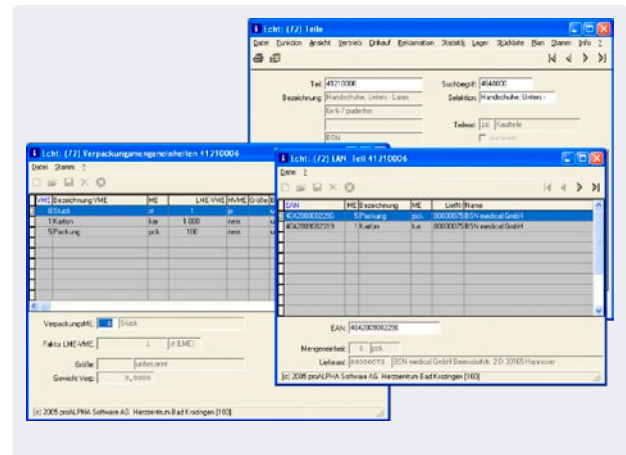
In order to conduct the project at all, the hospital decided on a stopgap solution: sufficient time would be dedicated to making IT adjustments so that this latter system could also be handled.

At the same time, with the support of GS1 Germany, the hospital asked the suppliers that still did not have any barcodes and those that had not worked with GS1 to identify their products according to uniform GS1 standards. Suppliers' reactions were largely positive and in some cases products were even relabelled specifically for the hospital.

As a result, two facts became clear: First, that hospitals can get things moving and, second, that manufacturers have become more aware of the benefits of GS1 standards.

By summer 2006, the majority of products had GS1 barcodes and after consultation with the specialised departments, the project could start. After the scanners were purchased, a test run was conducted, and after a successful run, the actual project was implemented in two catheter laboratories.

Figure 1: GS1 master data in the hospital



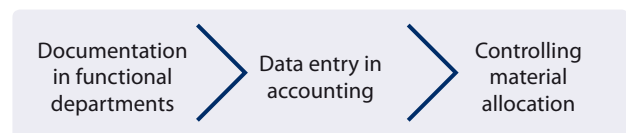
## Before and after

Three basic process steps were identified before scanners were introduced:

- documentation in the functional departments
- entering materials in accounting
- controlling upstream allocation of special products to patients.

Because the manual system was so prone to errors, time was also spent on harmonising the entry of activities and materials.

Figure 2: Schematic process flow before scanners were introduced

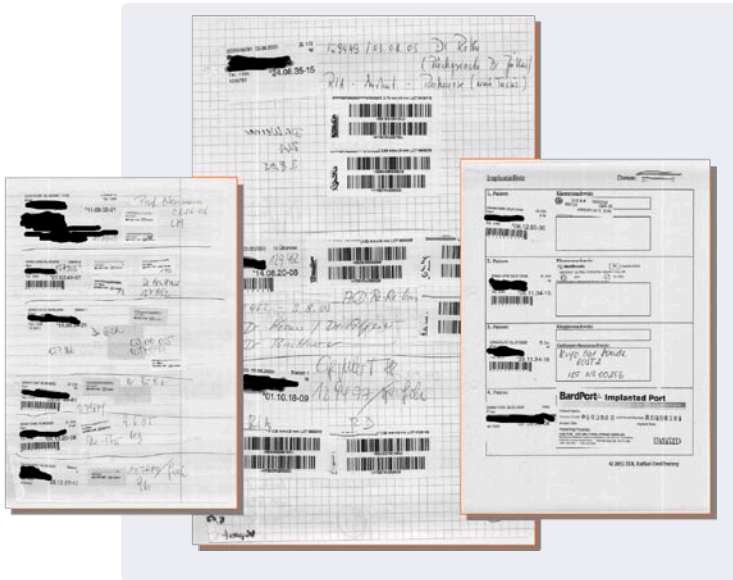


Consumed materials were not entered directly by the functional departments, but subsequently entered manually by the accounting department. In the functional department, labels were cut out from the consumed products or the patient labels often included by the manufacturer, were stuck on and passed on to the accounting department by internal post.

Also after scanner systems were introduced, the initial documentation on consumed materials remained the responsibility of the functional departments. However this is now done by scanning the GS1 barcodes on the consumed products. Materials are allocated directly to the patients through the IT system. Data entered in this way is thus available in fully electronic form for all further processes,

so that the accounting department is spared the time-consuming and error-prone entry of consumed articles and manual allocation to the patient when controlling.

Figure 3: Manual documentation of consumed articles in functional departments



There is no more need for patient stickers or cutting out labels. Instead, one simple and quick scanning procedure enters GS1 numbers, batches, serial numbers and in some cases expiry date, or any other relevant data for subsequent procedures.

For the functional departments in the hospital to document consumed articles, the use of bar codes resulted in work time savings of 78%.

Table 3: Before and after comparison: documentation in functional departments

|            | Average time spent per process | Number of processes p.a. | Total time spent p.a. |
|------------|--------------------------------|--------------------------|-----------------------|
| Before     | 00:03:10                       | 1,260                    | 66:30:00              |
| After      | 00:00:42                       | 1,260                    | 14:42:00              |
| Time saved | 00:02:28                       |                          | 51:48:00              |

Before, the accounting department used to receive documentation or a brightly coloured bunch of cut-out labels, with a delay, via internal post from the functional departments.



Information had to be manually entered and allotted to the individual patients which, depending on how many there were, took several days per monthly report.

After implementing the automated process in the functional departments, the accounting department was spared the entire entry procedure when it comes to controlling and allocating special products to patients in the catheter laboratories in question. Both tasks could be eliminated.

Table 4: Before and after comparison: data entry in the accounting department

|            | Average time spent per process | Number of processes p.a. | Total time spent p.a. |
|------------|--------------------------------|--------------------------|-----------------------|
| Before     | 00:01:25                       | 1,260                    | 29:45:00              |
| After      | 00:00:00                       | 1,260                    | 00:00:00              |
| Time saved | 00:01:25                       |                          | 29:45:00              |

Table 5: Before and after comparison: Materials allocation in the control system

|            | Average time spent per process | Number of processes p.a. | Total time spent p.a. |
|------------|--------------------------------|--------------------------|-----------------------|
| Before     | 00:07:48                       | 2                        | 15:36:00              |
| After      | 00:00:00                       | 2                        | 00:00:00              |
| Time saved | 00:07:48                       |                          | 15:36:00              |

The entire process flow was not only inefficient but also associated with a high error rate, since labels could go missing or product packaging could be forgotten and not passed on as anticipated. There was also the risk that materials could be allocated to and documented for the wrong patient.

As a result of this automated process, a basis has been created for forwarding accurate data to INEK for payment of hospital services.



Payment by InEK GmbH for hospital services is therefore also incorporated in the overall analysis:

Table 6: Payment based on DRG calculation

|          | Number of cases p.a. | Total revenue p.a. (€2.03 per case) |
|----------|----------------------|-------------------------------------|
| Before   | 0                    | €0.00                               |
| After    | 942                  | €1,912.26                           |
| Revenues |                      | €1,912.26                           |

An analysis of the documentation process as a whole gives the following result:

Table 7: Time saved in the Herz-Zentrum Bad Krozingen

| Process                                     | Time saved p.a. |
|---|-----------------|
| Documentation in the functional departments | 51:48:00        |
| Entry by the accounting department          | 29:45:00        |
| Controlling the allocation of materials     | 15:36:00        |
| Total                                       | 96:39:00        |

## Greater transparency, safety and quality

In addition to the cost savings, there are also qualitative benefits of scanner systems and uniform standards, such as greater data transparency, safety and quality.

Since the continuous entry of consumed material provides up-to-date figures of the articles in stock, the entire ordering process can be automated. When stock falls below a predefined amount, an order is automatically triggered. This does away with stock planning, leading to yet another enormous saving of time. If required, the purchasing department can also monitor stocks in real time.

The Herz-Zentrum Bad Krozingen has established that stocktaking takes only around 1.5 hours instead of the

previous six to seven hours. The available data is reliable and the hardware can be used flexibly for a wide range of processes.

The data scanned in by the functional departments is available to other departments for downstream process steps. Transparency is increased since every area works with the same information. Additionally, it is now possible to simplify medical documentation, since the scanned product data, including batch numbers, can be transferred into medical documentation. This not only reduces the time spent on entering data but also avoids potential sources of error that can result from data that is classified or entered incorrectly.

With the transparency that is created, products can also be traced within the organisation, since consumption and movement of goods can be documented automatically. In the event of recalls, the products in question can be located and returned quickly and systematically. Not only does the use of automatic data entry systems make sense for products where documentation is mandatory, but in the long term all medical goods are likely to factor in such considerations for the sake of increased efficiency and patient safety.

In the hospital, the project encountered extremely positive reactions, resulting in the gradual inclusion of other operational areas. With the support of management and staff in the various departments, it will not be long before the hospital sees this project become part of daily practice.

Since parallel processes lead to unnecessary expenditure of time and the benefits speak for themselves, the hospital's message to its suppliers is unmistakable: products need to be identified with GS1 barcodes across all packaging sizes, enabling universal use from production to patient.

## AUTHOR

**Holger Klein** is Head of Inventory Management and Logistics at Herz-Zentrum Bad Krozingen in Germany, a health service centre specialised in cardiology, heart surgery, vascular surgery and angiology. Having finished his apprenticeship in international business successfully, Mr. Klein studied business management at VWA (business college) in Freiburg. Afterwards he started his

career at Herz-Zentrum Bad Krozingen within the procurement- and materials-management-department. Mr. Klein has extensive experience within the healthcare sector and has been leading various standardisation projects. He was responsible for optimising logistic processes in Bad Krozingen, including the roll-out of a scanner-based ERP system.

# Efficiency models in the Andalusian Health Service supply chain

## ABSTRACT

The Andalusian Health Service (SAS) is setting as their strategic objective the integration of the available logistics resources under a common operating model to enable their effective and efficient coordination. One of the initiatives adopted by SAS includes the definition and establishment of coding and symbol requirements by means of GS1 standards for products purchased by the Andalusian Health Service. The aim of this initiative is to promote the effective use of automatic product identification systems within the supply chain of health centres, in order to maximise the reliability of identification of the product and of its characteristics during use and during the management of its logistics movements.



Article by **Jesus Gavira**

## Background

The Servicio Andaluz de Salud / Andalusian Health Service (SAS) is an autonomous body affiliated to the Ministry of Health of the Autonomous Regional Government of Andalusia. Its aim is to provide public health services to the citizens of Andalusia.

Serving an area of 87,268 km<sup>2</sup> and a resident population of over 8 million inhabitants, the Andalusian Health Service provides its primary and specialised health care via 1,491 primary care centres, 29 hospitals and 8 blood transfusion centres.

It is equipped with 83,132 health care professionals (2007 data) and a budget of 8,751,387,000 Euros (2008 data) for the purposes of providing these services.

These figures give a clear idea of the magnitude of the challenge of equipping this organisation with a corporate logistics solution that meets the supply chain requirements of all its preventive care, medical assistance and health promotion systems and services.

## Transformation of purchasing and logistics services

The organisation of purchasing and logistics services has evolved significantly over the last decade. The “multicentric”

focus which is based on each Primary Health Care Hospital or District being equipped with a budget, a logistics system and the decision-making capacity to manage it, has been replaced by a systemic and integration-centred focus; a collective corporate vision based on the intensive use of information and communication technologies (ICT).

The inefficiencies resulting from a “multicentric” focus, which requires the provision of logistics resources in each institution without taking into account the possibility of sharing organisational facilities or systems, and which is the dominant model in public health systems and in some private health networks, can and must come to an end by means of establishing integrated networks of logistics resources.

At the beginning of this transformation process, the Andalusian Health Service is setting as their strategic objective the integration of the available logistics resources under a common operating model to enable their effective and efficient coordination.

Two central lines of analysis are distinguished under this approach: the first of these is to examine and assess the logistics resources available in the Andalusian Health Service. The second is to outline their integration strategy.

The development of these initiatives takes two different forms: firstly, the concept of the Corporate Logistics System, defined as the collection of facilities, material and professional resources and organisational means aimed at meeting needs in this regard in the Centres. Secondly, the Integral Logistics Management System – Spanish initials: SIGLO®, set up as the group of IT applications used for the management of the logistics procedures carried out via the Corporate Logistics System, and which, in turn, takes the form of two main lines of analysis, one of which concerns goods, and the other dealing with issues regarding information and business messaging.

From this point on, the Andalusian Health Service is to embark on the following courses of action:

### **1. Establishing infrastructures to enable traceability and efficient logistics management.**

The initiatives that come under this heading aim to introduce those basic elements of infrastructure into the supply chain on which a secure and efficient logistics management model will subsequently be built. The initiatives adopted by the Andalusian Health Service include the following notable examples:

- Definition and establishment of coding and symbol requirements by means of GS1 standards for products purchased by the Andalusian Health Service.  
The aim of this initiative is to promote the effective use of automatic product identification systems within the supply chain of health centres, in order to maximise the reliability of identification of the product and of its characteristics during use and during the management of its logistics movements.  
The level of establishment achieved has greatly improved the outlook for this sector.
- Alignment of files with suppliers. Product catalogue  
The product catalogue of the Andalusian Health Service is supported by an IT platform which the suppliers of our organisation can access via the Internet Portal of the Andalusian Health Service ([www.juntadeandalucia.es/servicioandaluzdesalud](http://www.juntadeandalucia.es/servicioandaluzdesalud)) in order to provide information on the technical, identification and logistics characteristics of the products that they wish to market to our organisation's centres. It is the channel for aligning the product catalogue required by the Andalusian Health Service with those products available on the market (with each of the companies that sell them)



that match the specifications of the buyer, once the corresponding validations have been carried out on the product and on the information provided on the product. It is an essential step for becoming a supplier of the registered product.

- Validation of the coding structure and the symbols used.  
The validation of the logistics information provided by the supplier is critical for the correct identification process of goods in the logistics chain. The guarantee of accuracy of the information provided via the product catalogue and of basic quality of representation of the symbols on the containers and packaging of the goods supplied is essential for the establishment of efficient models of logistics management. To this end, the Andalusian Health Service has drawn up two courses of action: the first aims to guarantee the consistency and validity of the logistics information provided; the second aims to examine the technical adaptation of the symbols (bar codes) used by the suppliers on their containers and packaging and their consistency with the logistics information provided, both on the samples requested and on the goods supplied to the Centres.
- Purchasing policy based on the prior approval of suppliers and products.  
A corporate purchasing policy must be drawn up and implemented, which, in addition to improving the efficiency of the Centres as purchasing agents, and therefore the global position of the organisation in the market, will direct and encourage the supply companies toward the points of interest of the corporate operations. This is the case with the identification of products using GS1 standards or the conditions of transfer of the goods from the supplier to the buyer via Logistics Development Agreements and Logistics Specifications Forms as elements incorporated into the supply contract, which shall be dealt with later in the text.
- Policy of maximum information for purchases.

Corporate policies which are based on the decentralisation of the purchasing function, such as that developed by the Andalusian Health Service, require the implementation of strategies of maximisation of information for purchases, especially with regard to the technical information concerning the characteristics of the product and the approval fees and actual purchase prices.

## **2. Normalisation and generalisation of requirements in relation to logistics services for purchases. Logistics Development Agreements. Logistics Specifications Forms. Deposit Management Agreements.**

The need to include a number of clauses in a systematic and homogeneous form in supply contracts to govern the transfer process of goods from the supplier to the buyer, as indicated above, has brought about the normalisation and systematic use of a number of logistics practices that due to their nature must be the result of a consensus between the parties involved. The nature of the supply chain requires this. The Andalusian Health Service has developed and sought a consensus with the main representative organisations of its suppliers on the conditions that ought to govern these practices, both in the case of storable goods (Logistics Development Agreements) and in the case of goods supplied under an assisted storage arrangement, such as surgical implants (Storage Management Agreements). The prior and specific knowledge of the logistics aspects that must be implemented in order to fulfil the contract are essential for the subsequent monitoring of their performance and for the correction of any potential deviations.

## **3. Identification and inventory of facilities, material and professional resources and organisational means used for logistics purposes. Logistics Accreditation System. Configuration of the Corporate Logistics System.**

Addressing the “logistics issue” in an organisation of the size and complexity of the Andalusian Health Service requires several methods of approach. The analysis of the material resources used for this purpose, which the initiatives described in this section refer to, is essential as they represent a direct source of costs in the system that must be managed.

Therefore, the examination and inventory of the facilities, material and professional resources and organisational means used for maintaining the logistics systems in the centres forms part of an internal accreditation process that requires



an internal examination of the organisation’s centres by means of an information collection protocol supported by a corporate-wide IT application (Logistics Accreditation System). Completion of this process allows, among other objectives, the accreditation of conditions for the future establishment of the SIGLO® platform, referred to below.

This accreditation process, in which all the Centres of the Andalusian Health Service are involved, enables the actual magnitudes and descriptive characteristics of the Corporate Logistics System to be determined.

## **4. Identification and normalisation of management processes and procedures.**

The second of the aspects addressed in the accreditation process focuses on the identification of the principal processes and procedures, in other words, those which form part of the common nucleus of operations taking place in all the Centres (entering into transactions, order management, reception of goods, storage, etc.).

Having identified these processes and indicated the units responsible for carrying them out, the next step is the normalisation and standardisation of these procedures in order to incorporate them into the collection of utilities that make up the management system contained in the SIGLO® platform. In this way, a standardised group of procedures is established which must incorporate all the users of the platform.

## **5. Design of the SIGLO® platform.**

For the management of the Corporate Logistics System, understood as the material and tangible component of the logistics resources, as well as of the management processes and procedures, this platform focuses its course of action in two directions: the management of goods and their

traceability, and the management of business messaging which, as an Electronic Data Interchange (EDI), drives and intervenes in the supply chain.

- **Management of goods. Traceability.**  
The procedures incorporated into the functional design of this platform have been based on the full implementation of the GS1 identification standard, thereby completing the course of action described in the preceding paragraphs.  
This set of initiatives aims to improve the control and logistics management of the goods moving through the supply chain, as well as their traceability.  
The automation of the process of receiving orders and their validation, the elimination of errors and incidents during processing, the accurate knowledge of the levels of stocks in storage, the correct preparation and management of orders for restocking and distribution, and the monitoring of consumption, among other factors, are benefits that are hoped to be obtained in each of the Centres following the implementation of this system, thereby considerably improving the efficiency of certain processes that currently involve a significant administrative workload. In addition, we must consider the possibility of integrating resources so as to favour their shared use, given that the management tools and the organisational bases are shared. We shall address this matter in the final section.
- **Management of business messaging (EDI)**  
The automation of the goods identification process by means of the systematic use of bar codes must be completed with the establishment of a standard protocol of communication of business messages between the agents involved in the logistics chain. The Andalusian Health Service has, as an initial step, integrated the following into the functional structure of the SIGLO® platform: use of the order messages (ORDER), delivery note (DESADV), confirmation of reception (RECADV) and invoice (INVOIC), so that close monitoring can be established for each step as of the

prior verification of fulfilment of the former.

The generalisation of this strategy shall entail a far-reaching transformation of both the management of goods and the management of messages that drive their movement through the supply chain, thereby resulting in considerable improvements in the efficiency of the internal processes and a considerable reduction in the costs of management of goods.

## 6. Improving the efficiency of the logistics system: redesign strategies.

As has already been emphasised, the SIGLO® management platform must enable all its users to operate under the same operation model, given that its management procedures are shared.

This condition enables us to understand the Corporate Logistics System as a network in which each node (Centre), which until now has functioned in an autonomous and unconnected manner, is integrated into a coordinated and interactive structure. This evolution is only possible with the establishment of a common “intelligence”, a logical system which harmonises and coordinates the operation of all its nodes.

Irrespective of the direct improvements in the internal efficiency of each node that this entails, this measure enables us to establish a new analysis and redesign approach for the Corporate Logistics System. We must not forget that a logistics system currently exists for each Centre within this network.

A significant reservoir of improvement initiatives therefore exists for the global efficiency of the logistics system, which must explore the standardisation and the shared use of logistics resources on the basis of an efficient distribution system.

We shall devote our attention to this issue in the future.

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