GS1 Healthcare
Reference Book
**2010/2011**

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Welcome to the second edition of the GS1 Healthcare Reference Book (Edition 2010/2011)! After its successful 'premiere' in 2009, we are proud to present another compendium of information on the adoption and implementation of GS1 global Standards in the Healthcare supply chain. Experts from different countries and different backgrounds share their insights on important regulatory and industry developments, adoption initiatives, lessons learnt from implementation projects and more. We hope that you gain valuable information from this publication and we extend our appreciation to all the contributors that have made this possible.

# Acknowledgements

## Five years of advancing GS1 global standards in the Healthcare supply chain

GS1 Healthcare would like to extend its thanks to the hundreds of people worldwide who have contributed to the voluntary global and local Healthcare user group activities, especially in the development and implementation of global standards. With your engagement and commitment, improvements to patient safety and supply chain efficiency continues to advance worldwide, with the ever increasing recognition and adoption of GS1 global standards in Healthcare.

# GS1 Standards in Healthcare: Making a difference in the Healthcare supply chain

## ABSTRACT

GS1 Healthcare envisions a future where the Healthcare sector utilises GS1 global Standards for all items, locations, people and processes, to drive patient safety and supply chain efficiency improvements – starting with the manufacturer and ending with procedures or treatments for a specific patient.

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

In light of a variety of concerns about patient safety and rapidly escalating Healthcare costs, governments worldwide are taking action and important policy changes are on the way. Some of them will have a direct impact on the Healthcare supply chain. Various authorities worldwide have developed, or are developing, regulations requiring automatic identification, serialisation and traceability systems in Healthcare to improve patient safety, including the European Commission, the US Food and Drug Administration (FDA), the National Health Surveillance Agency in Brazil (ANVISA), the Ministry of Health of Turkey and the India Ministry of Health and Family Welfare (MoHFW).

GS1 Standards provide a global framework that takes into account all these types of specific requirements for medical products (pharmaceutical and medical devices).

In light of the same requirements, Healthcare providers, group purchasing organisations and associations worldwide have also announced that they will take action to drive adoption and implementation of GS1 global Standards in the Healthcare supply chain, including; Australia, Brazil, Canada, Chile, Columbia, France, Germany, Hong Kong, India, Japan, the Netherlands, Spain, Switzerland, Turkey, UK and USA.

## GS1 in Healthcare – global reach

GS1 has been working with the global Healthcare community for more than 5 years via its voluntary, global Healthcare user group: GS1 Healthcare. This group is leading the Healthcare sector to the successful development and deployment of GS1 global Standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

Countless hours of vetting, offline discussions, brainstorming and more than 10,000 contact hours (conference calls and physical meetings) have now resulted in some important milestones with the publication of a set of ratified global standards for the Healthcare sector including; GTIN Allocation Rules for Healthcare, AIDC Application Standards for Healthcare and the Global Traceability Standard for Healthcare.

## GS1 in Healthcare – local reach

The main focus of GS1 Healthcare is now on standards adoption and implementation. Standards' development work will continue, but now we have reached a point where local Healthcare user groups and GS1 Member Organisations are driving adoption in their local communities and support the implementation of these standards throughout Healthcare. The global and local Healthcare user groups provide a neutral platform for Healthcare supply chain stakeholders to exchange experiences and best practices, to enhance future standards development and adoption.

For more information about GS1 Healthcare, visit www.gs1.org/healthcare.

# U.S. FDA to establish unique identification system for medical devices

## ABSTRACT

On September 27, 2007, the president signed into law the Food and Drug Administration (FDA) Amendments Act of 2007. This act includes language related to the establishment of a Unique Device Identification (UDI) System (section 226). This new system when implemented will require:

- The label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices.
- The unique identifier to be able to identify the device through distribution and use.
- The unique identifier to include the lot or serial number if specified by FDA.

If used by all healthcare stakeholders, UDI can improve visibility of device movement, recalls, post-market surveillance, adverse-event reporting, and anti-counterfeiting, among other benefits. A properly implemented UDI will also facilitate the integration of medical device data across disparate IT systems, including those that support the supply chain, clinical and reimbursement functions.

By **Jay Crowley**

## Introduction

Over the last few years, the U.S. healthcare industry has rallied around establishing a unique device identification (UDI) system that will provide a platform for communicating accurate, reliable information about medical devices to stakeholders who need information about the device. A UDI system will enable many benefits, including faster and easier recalls, improved traceability, more effective counterfeit detection and abatement, increased accuracy in electronic transactions and information sharing, reduced costs and, most importantly in the healthcare industry, improved patient safety. For patient safety reasons, the U.S. Food and Drug Administration (FDA) is not only interested in developing a UDI system in the U.S., but would like to see the adoption of such a system globally for the healthcare industry.

## Challenges in medical device identification

The U.S. medical device industry is diverse, and devices vary dramatically in size, complexity, packaging and use. Medical devices cover a wide range of products – everything from complex imaging systems, implants, hospital equipment and supplies, clinical lab products, dental care, home care and over the counter devices. Some items are packaged individually, others in boxes, and some are not "packaged" at all. They may be implanted in patients, used once and thrown away, used and reprocessed, or used for many years until next generation models are launched.

Sharing information about a device is inherently complex. From the time a device is manufactured to the time it is used in patient care, information about the device is passed up and down the healthcare supply chain many times with all of the distributors, group purchasing organizations, hospitals and users in between. The lack of data standardization adds further complexities to these interactions, as the information shared is oftentimes inaccurate, duplicative, out of date or confusing.

Today, hospitals and their suppliers use thousands of different numbers to electronically track devices. The U.S. Healthcare information systems are filled with inaccurate and manually created item and company names, and self-created numbering systems that differ from user-to-user and vendor-to-vendor, creating an environment for data exchange that is fraught with errors and inconsistencies which creates both inefficiencies throughout the supply chain and potential impact on patient safety.

Lack of consistent device identifiers in healthcare has been a long-standing problem, yet is one that can be solved with the industry-wide adoption of consistent global identification standards across the industry and the implementation of systems to provide accurate data throughout the healthcare system. After many years of research and industry input, hospitals, distributors, manufacturers and other key stakeholders are now coming together to collaborate on the use of data standards to improve patient safety.

## The solution: Critical visibility through UDI

The FDA's Sentinel Initiative is intended to strengthen FDA's ability to query data systems for relevant device information after a device is on the market. In today's environment, with no UDI system in place, there are many challenges in doing so. UDI will vastly improve our understanding of medical device use, post-market surveillance, and adverse event reporting. UDI will facilitate the ability to identify and locate medical devices, whether physically in route to a hospital or recorded in a patient's EHR, or in hospital information systems.

Inaccurate and inconsistent data about medical devices plague the healthcare system today, with potential serious consequences. For example, in 2007, the FDA received more than 100,000 reports of adverse events associated with medical/surgical devices: 15% of the reports lacked model or catalog numbers, 50% of the reports lacked lot numbers or other production identifiers, and more than 10% lacked needed information in both categories. Because there is no consistent, systematic way to gather information about these devices, the FDA receives information that varies widely from one reporter to the next. With a UDI system in place, the reporting of adverse events would be more seamless, with more complete information, so that the FDA can strengthen its ability to monitor the safety and effectiveness of device use and adverse events and take action when needed.

Also in 2007, manufacturers issued more than 1,000 recalls. A single recall can represent thousands to hundreds-of-thousands of individual items, ranging from disposable devices to testing strips to implantable devices. In a recall situation, limited information causes delays in identifying and removing recalled items from the shelf. The problem is further compounded if the device is an implantable, as tracing it to the patient can be extremely difficult and time-consuming. As shown in Figure 1 *Future Information Cycle* with UDI in place, the use of UDI will allow improvements in the ability to identify medical devices.

Once a device is on the market, the FDA uses post-market surveillance tools to monitor patient safety and quality related to the use of the medical device. The UDI will also help improve the ability to find medical devices, wherever that item may be – an important ability when considering recalls, for example. Consistent, accurate information about medical devices communicated in a language all players can understand has an important role in improving patient safety. In addition, it is important that the implemented UDI system will address needs beyond the U.S., serving as a basis for accurate and sharable information globally.



Figure1: **Future Information Lifecycle**
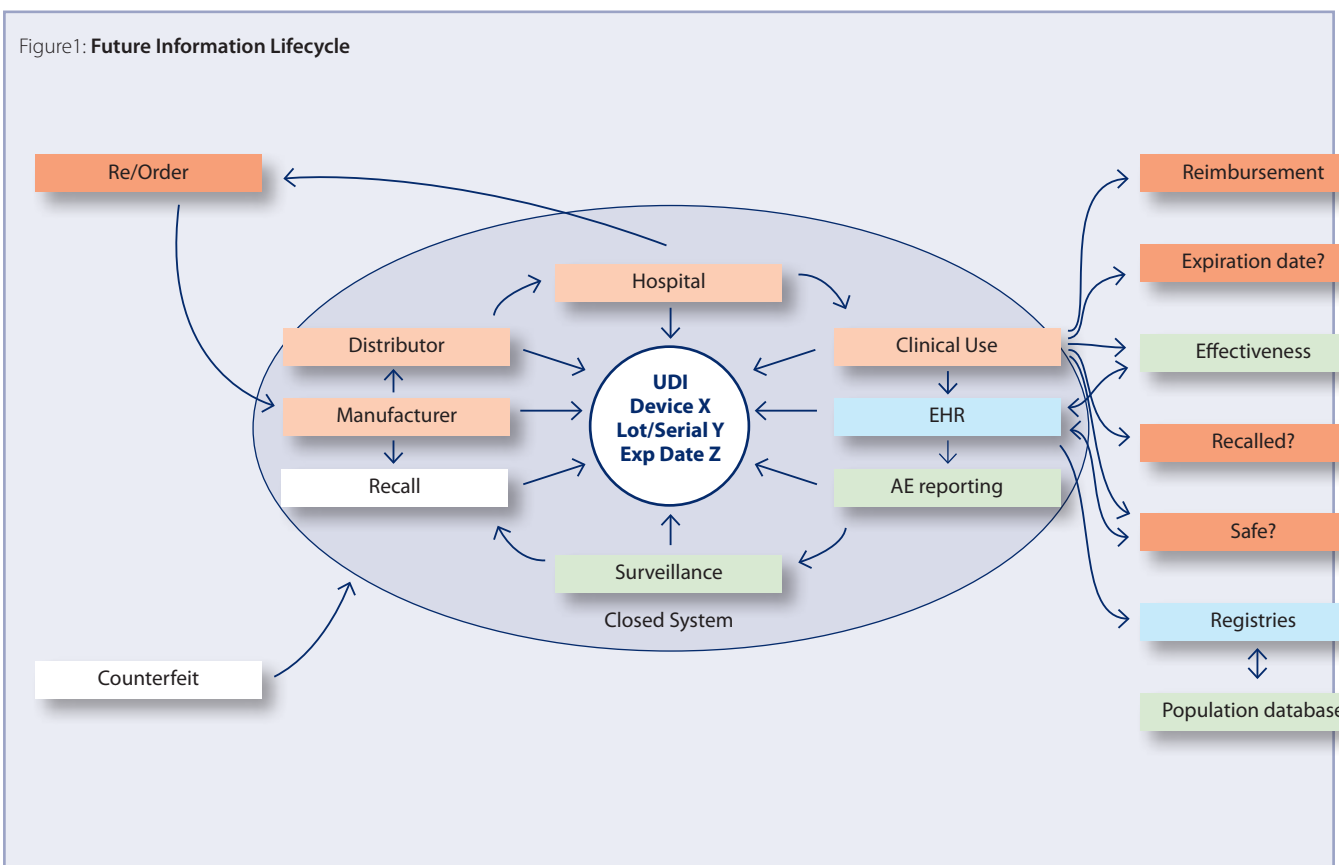
**Advantages of UDI**

UDI Can Improve... Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anticounterfeiting/diversion
- Comparative effectiveness (e.g. registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative – strengthening FDA's ability to query data systems for relevant device information

## The long road to UDI

In 1999, the Institute of Medicine published a study that revealed as many as 98,000 people die each year as a result of medical errors1. Automation of many of the key processes involved in patient care delivery could help prevent many of the mistakes that happen in the hospital setting. As such, the FDA issued its Pharmaceutical Bar Code Rule in 2004, which applies to certain human drugs and biological products and requires that a linear bar code containing the National Drug Code (NDC) number be placed on these product labels. The Bar Code Rule helps facilitate systems to ensure the "five rights " of medication delivery by enabling healthcare professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time.

Realizing that the same potential for error exists when using medical devices, in 2005 the FDA began to look at the possibilities for bar code standards for medical devices. The FDA issued calls for comments, held workshops and public meetings. The FDA Amendments Act of 2007 includes language requiring the FDA to establish a UDI system (section 226). This new system requires:

- The label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices.
- The unique identifier to be able to identify the device through distribution and use.
- The unique identifier to include the lot or serial number if specified by FDA.

The FDA is interested in adopting global standards in an unambiguous way, with an understanding that the promised benefits of UDI can only be realized if used by all stakeholders.

In 2008, the Global Harmonization Task Force (GHTF), an international partnership between regulatory authorities and industry, established an ad-hoc unique device identification working group to facilitate a global approach to UDI.

## Creating an "implementable" UDI system

Only a few people will actually physically touch a medical device, but many more constituents will need to know information about that item, including patients, clinicians and researchers.

The FDA would like to create a UDI system that is:

- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally

The FDA sees the establishment of a UDI system taking place in four distinct steps:

- Create a standardized UDI, it must use globally accepted standards for device identification.
- Require the UDI to be placed in human readable and/or AutoID format, directly on the device, its label, or both. It is important to remain technology neutral in this area and will not establish a rule defining which data carrier (i.e. linear bar code, 2D data matrix bar code) to use.
- Create and maintain a UDI Database that facilitates the storage, exchange, and integration of data and systems.
- Drive adoption and implementation. The entire industry must work together to make UDI work.

**The UDI System: Making useful information available**

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique identifiers (UDI)
2. Place the UDI in human redable and/or Auto ID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation

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1    To Err Is Human: Building a Safer Health System. Institute of Medicine (1999). The National Academies Press.

In order to implement a UDI system, we need to be able to make information about medical devices available to people who need it. The UDI code will include product "static" information (device identifier) and may also include "dynamic" information (production identifiers). The static part of the UDI code identifies the specific device. A significant change to any of the device characteristics would require that a new UDI code be allocated to the device. The dynamic part of the UDI code identifies production information about a particular device (i.e. the lot number, serial number or expiration date).

The UDI code is developed and maintained by the manufacturer. It should be both human readable and encoded in a form of automatic identification technology (such as a bar code). Some devices may have direct part marking (DPM), such as implants and those that require reprocessing, cleaning, or sterilization between patients' use.

A UDI Database (UDID) will contain certain identifying attributes for each device. It will not include dynamic information, pricing or other manufacturer-proprietary information. Recently, the GHTF released a call for comments for guidelines for the development of a global UDI system including attributes that might be included in a global UDI database[2] (See Figure 2).

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2    GHTF Discussion Paper (in view of preparation of a draft guidance on) UDI for Medical Devices: Unique Device Identification (UDI) System, GHTF, 2009



Figure 2: **GHTF's recommendations for "core identification attributes" are[3]:**

- Unique Device Identification Code
  – This is the static part (device identifier) of UDI code.
- Manufacturer Name
- Manufacturer Contact Information
  – Address, including Country Name and Contact Point information.
- Nomenclature
  – Global Nomenclature code (e.g. GMDN).
- Device Name (generic name)
- Trade Name (brand name)
- Device model number (or reference number)
- Controlled by serial and/or lot/batch number and/or manufacturing and/or expiration date - check box [ ]
- Quantity and Packaging level
  – E.g. Box of ten items, kit of 100 tests
- Size including units of measures (volume / …)
  – Device size when it is needed clinically, (e.g. 8F catheter).
- Storage conditions (as labeled on the product and/or the IFU) (e.g. needs to be refrigerated)
- Labeled as single use – check box [ ]

- Sterility
  – Package Sterile – Yes/No
  – If Yes: Sustainability of the sterile package ()
- Need to be sterilized before use – Yes/No
- Restricted number of use (number)
  – Only if the device's label indicates a limited number of use.
- Labeled and /or IFU (Instructions for Use) as containing allergens/materials of concern – Yes/No
  – If YES
  – Indicate the name of the allergens/materials of concern (e.g. Latex) (limited list to be defined and managed by the GHTF)
- Regional authorised representatives as labelled (list of countries)
  – Information about the regional representatives information such as the address or telephone number, when applicable.
- URL for additional information – Web address
- Special Instruction for use – If it is necessary to inform to the user about special indication for the device, such as: "Contraindications", "Intended Use or Part of Use," etc.

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3    Draft attributes as of March 31, 2010.

The FDA recently completed a pilot test of a prototype UDID. The goal of the pilot was to assess the feasibility of collecting, storing and retrieving UDI data from device creation (manufacturer) to point of use (hospital). Hospitals viewed the concepts for the UDID favorably, as the UDID prototype provided the data hospitals regularly need. Some manufacturers experienced difficulties during the pilot and are currently working through challenges they experienced in the pilot with data definitions, the ability to obtain data from various sources and working with the data formats for the UDI upload.

### Looking to the future: The time is right – now!

Looking down the road, a fully actualized UDI system will provide the foundation for improved patient safety, as it will enable more efficient and effective device recalls, improved post-market surveillance, better adverse event reporting, and better device identification in registries. UDI will give us the ability to document specific device use in patients and to track devices in patient's electronic health records. The FDA will be able to conduct better population-based results from device usage. The safety benefits of a UDI system however can only be realized if the UDI is captured, stored, integrated and exchanged by ALL stakeholders.

In addition, UDI will facilitate better information sharing, as data will be integrated across disparate systems. With this integration comes insight and visibility to assess the effectiveness of devices in certain patient populations or in particular environments. This is especially important when investigating ways to reduce medical errors.

Exposure to the allergen latex is a significant concern in the healthcare setting. The UDI database will help to identify which devices contain latex and, as such, will help prevent exposure to latex in the future. UDI will help the healthcare community understand and determine the role medical devices play in medical errors across patient populations.

After many years of industry mobilization around establishing a UDI in the U.S., the time is right for a UDI system. An increased focus on the benefits of information technology in healthcare (the U.S. government's investing more than $19 billion to improve IT infrastructure in the U.S. healthcare system) and greater attention to reducing medical errors are adding to the urgency. The FDA's vision is a UDI system that is integrated and harmonized with global efforts to ensure patient safety benefits are realized worldwide.

## The Global Harmonization Task Force (GHTF)

The Global Harmonization Task Force was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This is being done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world.

A partnership between regulatory authorities and regulated industry, the GHTF is comprised of five Founding Members: European Union, United States, Canada, Australia and Japan. The chairmanship is rotated among the Founding Members and presently resides with Canada. For more information, go to www.ghtf.org

## ABOUT THE AUTHOR

**Jay Crowley**, Senior Advisor for Patient Safety, U.S. Food and Drug Administration

Jay Crowley is Senior Advisor for Patient Safety in FDA's Center for Devices and Radiological Health. Jay is interested in developing new methods and techniques to identify, analyze, and understand problems occurring from medical device use within the healthcare environment. He has been working at FDA for nearly 20 years in a variety of positions. Jay holds degrees in Risk Analysis and Engineering.

# Pharmaceutical products traceability system pilot project in Brazil

## ABSTRACT

In order to break the vicious circle in the pharmaceutical market in which illegalities imply serious risks to public health, ETCO (Instituto Brasileiro de Ético Concorrencial, the Brazilian Institute of Ethical Competition) and the companies linked to the Pharmaceutical Chamber have entered in a partnership with the government. And, in a combined effort, we tested a simple and efficient mechanism, which can electronically track the course of any and every drug sold in Brazil. This article describes the new legislation establishing the obligation of such traceability system, and the lessons learned of the pilot organised by ETCO in collaboration with ANVISA (National Agency of Sanitary Surveillance).

By **André Franco Montoro Filho**, **Patrícia Blanco**, and **Luiz Emílio Ferreira**, ETCO

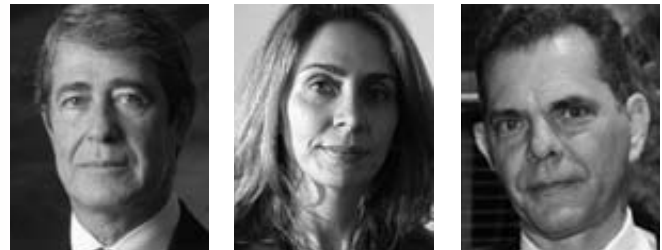## The pharmaceutical market in Brazil

A study of the pharmaceutical market in Brazil conducted in 2005 by the McKinsey consultancy office and the Pinheiro Neto law firm, by ETCO's request, showed that the high degree of the existing informality severely damages the industry and society as a whole.

The study conclusion was that informality must be fought with a set of specific actions, including the implementation of a traceability and authentication system, which aims at allowing a follow-up of each step of the pharmaceutical products, from the plant to the final consumer.

In accordance with information provided by IMS Health (December 2008), the Brazilian pharmaceutical market accounts for more than one billion units of Ethical products and 600 million OTC drugs. According to companies' estimates, 500 million drugs are directly sold to hospitals. The whole pharmaceutical chain comprises approximately 450 companies, over 2,000 wholesalers and a huge chain of 56,000 retail pharmacies and drugstores.

## Fighting counterfeiting in Brazil: legislative developments

The risks to the Public Health and the losses resulting from drugs manufactured in non-compliance with the norms and procedures adopted present incalculable dimensions. Brazilian authorities and companies have been long seeking for mechanisms to restrain illegality.

In July 2nd, 1998, the National Congress qualified the counterfeiting of pharmaceutical products and raw materials as hideous crimes against public health, as defined in the Law no. 9,677/98. In this same year, the Secretary of Sanitary Surveillance of the Ministry of Health enacted the Administrative Rule no. 802/98, which instituted the Control and Inspection System for the whole chain of pharmaceutical products. The popular raspadinha (a scratch-off label with a reactive ink that helps in the verification of the authenticity of the drugs), the inviolability of the packages and the identification of the batch number in commercial transactions are some of the innovations established by that norm.

In 2002, the Administrative Act RDC no. 320 established that the wholesalers of pharmaceutical products should start to execute the commercial transactions and circulation operations with sale bills that presented, mandatorily, the product's batch number.

In spite of those measures, the level of informality in the Brazilian pharmaceutical industry is still alarming. Along the whole year of 2008, ANVISA seized approximately 45 tons of unregistered, smuggled and counterfeited products. According to ANVISA, in the first semester of 2009, 316 tons of fake medicines were seized. Another important issue is the cargoes thefts in the Brazilian cities and highways. In 2007, approximately 11,700 cargoes were stolen across the whole country, according to information provided by NTC & Logística (National Association of Cargo Transportation and Logistics). The estimated figure for 2008 is even higher: 12,400.

In March 4th, 2008, ANVISA published the Public Consultation no. 8. aiming at receiving reviews and suggestions associated to the minimum requirements for the definition of mechanisms to track the pharmaceutical products chain and to guarantee their authenticity. The purpose was to identify solutions that could allow the implementation of systems of drug tracking and authentication in the whole chain of pharmaceutical products.

## Pharmaceutical products traceability system pilot project in Brazil

In January 14, 2009, the Law no. 11,903 was issued, which created the National System of Drug Control. The Bill was initially submitted by the Congresswoman Vanessa Grazziotin and carried out in the House of Representatives during two years.

The Law establishes the tracking of all kinds of drugs existing in the country, from their manufacture to their sale to the final consumer. The control will be performed by means of technologies for electronic capture, storage and transmission of data. Each product will have to display an exclusive identification code.

The law establishes that the system will have to be totally implemented within a period of three years. At the end of this period, the drug control in Brazil should reach levels of excellence, ensuring, in addition to the traceability, an effective monitoring about the drugs' use and prescription.

## Enabling pharma traceability in Brazil: the pilot project

With the purpose of collaborating with ANVISA in the implementation of a tracking and authentication system, the ETCO's Pharmaceutical Chamber has submitted to the regulatory agency the proposition of developing a pilot project. The consolidation of efforts was discussed and the final agreement was signed in December 18, 2008.

From January to July 2009, ETCO conducted the pilot test of the Traceability System Pilot Project, supported by technicians from ANVISA. According to the Technical Cooperation Protocol, the Institute's work aimed at helping the regulating agency to define the best technological solution to effectively fight informality in the pharmaceutical industry.

### System design



**Surveillance**
The Traceability System will ensure that inspection agents have access to traceability data for all drugs, from the point of manufacturing to the point of sales or point of dispense.

**Industry**
The manufacturer will be responsible for printing the Unique Drug Identifier (UDI) both on the secondary packages of its medicines and on logistic units (cases or pallets) – inference labels.[1] The code will contain the following information, initially sent to a private database and then to a central database:
- Product identification (GTIN);
- Batch number;

**Warehouse**
In case the manufacturer possesses its own warehouse, a product movement will occur previous to the billing, whose registration should be present in the database. A similar situation occurs when the company counts on an outsourced logistics operator. In this case, the following additional information should be sent to the central database:

**Wholesalers**
As of receipt of the goods, the wholesaler will be accountable for transmitting other information, associated to the commercial transactions, to the central database:
- Date of the drugs arrival;
- Name of the retail pharmacy or drugstore.

**Retail Pharmacy**
The retailers will have to forward the following information to the central database:
- Data associated to the purchase of the goods;
- Data of sale to the final

[1] The working definition of "inference" as it applies here is that it refers to the ability to "infer", based on tracking and validation of a unique identifier attached to an aggregate package (e.g., pallet, case, tote) which has a hierarchicak relationship with unique

**Pilot participants and operational flow**

## Pilot planning

The pilot test was established in different stages, in order to evaluate a significant representation of the industry's reality. In the first stage of the project ETCO´s group detected and mapped needs and expectations of its partners: companies, wholesalers and retailers. In the second stage, the practical section of the pilot test, which was put into operation in June 2nd, 2009, was executed. In the course of approximately 40 days, the processes of printing and scanning the identification codes on the secondary packages were assessed, and the collection and transmission of all information generated by the companies participating in the initiative was equally evaluated.

## Pilot participants and operational flow

For the test an adequate volume of drugs was adopted (approximately 75 thousand) in order to support improvements and changes of route in the processes.

| COMPANY | PRODUCT | AMOUNT |
|---|---|---|
| Aché (Biosintética) | BROMOPRIDE 1 mg/ml bottle w/ 120 ml | 3,333 |
| Bayer | ADALAT RETARD 10 mg w/ 30 tablets | 29,800 |
| Eurofarma | ASTRO 500 mg display w/ 60 tablets | 1,650 |
| Mantecorp | CELESTAMINE syrup 120 ml | 9,600 |
| Nycomed | RIOPAN suspension 240 ml | 14,350 |
| Pfizer | PONSTAN 500 mg w/ 24 tablets | 14,000 |
| Sanofi-Aventis | DORFLEX box w/ 30 tablets | 3,000 |
| | TOTAL | 75,733 |

GS1 Brazil was responsible for the definition of international standards of coding, the entity acted as a certifier of the quality of the codes printed on the packages.

Open technological solutions of public domain were adopted to allow the required technical flexibility to meet the specificities of each company's processes.

- Adoption of several technologies for item marking: continuous ink-jet, laser and thermal ink-jet printers.
- Availability and flexibility so that the pharmaceutical chain's agents could select the equipment for the electronic capture of data (DataMatrix scanners) that was more compatible with their industrial and commercial processes.
- Equipment with low, medium and high speed and complexity, usually utilised by the whole pharmaceutical chain, was tested.
- Adaptation of the information technology systems of the pharmaceutical chain companies, so that the whole tracking process was put into operation in a validated form.

Adoption of an identification system, so that all essential information required for the tracking can be captured from each medicine package.

- The two-dimensional barcode, internationally accepted - GS1 DataMatrix (ECC 200), was adopted and printed on the secondary packages. The barcode included the following information about the product: GTIN, batch number, expiry date, and serial number.
- Usage of GS1-128 bar code with SSCC key on the logistic unit (case) to ensure the link with the content (secondary packs).

The data obtained during the test, from the manufacture to the point of purchase, were stored in a central database, allocated in a data center, in order to reflect what should occur in the real model. Every change of establishment was informed to the system in all of the tested stages: reception, incorporation to the inventory and sorting for the dispatch. The UDI lifecycle begins with the generation of a serial number and its storage in a database.

## Lessons learned

- During the tests, no insoluble technical difficulty was detected in the implementation of the unitary coding technology in the manufacturers' packing lines.
- The choice of the adequate technology was based on the type of the manufactured products, the boxes' layout, the packing lines' speed, and the packing process, among other aspects.
- The available packing materials were used and some parameters of printing quality of the DataMatrix codes did not integrally comply with the GS1's recommendations. The tests showed, however, that occasional problems in the processes of code application and scanning are solvable.
- Regarding to the required equipment and software solutions, there are several companies in the market that can provide technologies complying with the specific demands of each link of the pharmaceutical chain.
- Investments on equipment, training courses and infrastructure should also be taken into consideration. Every professional directly involved in the production, storage and dispatching process should be trained in the traceability concept. They should understand that each box will be dealt with as a single package by the whole pharmaceutical chain.
- Important aspects were identified, which should be taken into consideration by the agents of the pharmaceutical chain and the regulatory authorities in order to ensure a greater efficiency in the implementation of the system.
- The mobilisation and gathering of forces of all of the key stakeholders, besides the support and availability for discussion from the federal government, are crucial for the definition of the best possible system, to be executed within the period established by law.
- The DataMatrix printing process was also tested in a logistics operator, where ink-jet printers and scanners were installed in a conveyor belt, out of the packing line, in which over 10 thousand boxes were printed and scanned. The test evidenced that, in a controlled environment, it is possible to obtain a printing level in the same standard found in the manufacturers' packing lines, taking into consideration the "Good Manufacturing Practices".

## Conclusion

The purpose of ETCO's Pharmaceutical Chamber was to test a traceability system as close as possible to the reality of the pharmaceutical chain and to demonstrate its feasibility. The pilot project totally fulfilled its purpose of providing guidelines to all agents in the pharmaceutical chain for the implementation of the National System of Drug Control. The system can be implemented with the adoption of open technological solutions, of public domain, with characteristics and flexibility to be used by the companies regardless of their size. The pilot test showed the advantages of the direct printing model with open technologies.

The major paradigm change is the introduction of the "unitary codification", which is crucial for the achievement of the required tracking level for compliance with the Law.

## About ETCO

Created in 2003 as a public interest entity of the civil society, ETCO's basic mission is to foster an ethics-based competition, fighting the competition unbalances generated by counterfeiting, tax evasion, smuggling and other business conduct deviations. Such practices result in illicit advantages for the transgressors, harming the companies that comply with the laws. Thus, the ethical companies find themselves discouraged to invest, to innovate and to grow, opening more room for illegalities.

### ABOUT THE AUTHORS

**André Franco Montoro Filho** is Chairman of the Brazilian Institute of Ethical Competition – ETCO, a non-profit organisation that congregates non-government and entrepreneurial that aims to establish ethical parameters for competition. Mr. Montoro is Ph.D. in Economics from Yale University (USA), is full professor of the Economics and Administration College of the University of São Paulo (Brazil). He was Secretary of Economy and Planning of the State of São Paulo and President of the Brazilian Economic and Social Development Bank (BNDES) from 1985 to 1988.

**Patrícia Blanco** was Executive Director of ETCO – Brazilian Institute of Ethical Competition. Patricia was responsible for the management of the ETCO's project pilot of the pharmaceutical products traceability system.

**Luiz Emílio Ferreira** is Coordinator of the Pharmaceutical Chamber of ETCO – Brazilian Institute of Ethical Competition, which has worked with associated companies on the traceability system. Prior to joining ETCO, Luiz Emilio worked for more than 16 years in GlaxoSmithkline.

# "Coding for success" Automatic Identity and Data Capture programme within the National Health Service

## ABSTRACT

In February 2007, the Department of Health published a best practice guidance document titled "Coding for success" (*Simple technology for safer patient care*) which advised that, in order to address patient safety issues, the National Health Service (NHS) should adopt GS1 coding standards provided to help eradicate patient safety issues in the NHS. This work has been adopted and driven by NHS Connecting for Health (CFH), the Department of Health's agency which is responsible for delivery of the NHS's "National Programme for IT". The Automatic Identity and Data Capture (AIDC) programme has since driven adoption of GS1 UK standards by over 250 English Trusts operating in many different facets of healthcare.

Article by **Neil Lawrence**, Programme Leader for AIDC technologies, NHS

## Introduction

The Department of Health (DH) conducted a review of patient safety within the NHS in 2006 and some of the findings were of great concern to parliament, the NHS and the permanent secretary of the Department. The main finding of the report was that 1 in 10 patient admissions into the NHS results in some kind of error, thus costing the NHS an estimated £2billion per year in additional, avoidable hospital days. (C. Vincent, G Neale, M Woloshynowych (2001) "Adverse events in British hospitals.) The report also found that at least half of these errors were preventable. These findings led to the development of the vision within the DH that the patient should have 5 safety rights

The 5 Patient Rights
- Ensuring that the **right patient**
- Is given the **right treatment**
- In the **right dose**
- Through the **right route**
- At the **right time**

This was reinforced by the Darzi report which reviewed the safety of the NHS, and stated that

*"Our vision should be an NHS that is safe, as safe as it possibly can be, giving patients and public the confidence they need in the care they receive."*

Lord Darzi

In 2007, the Department of Health published the guidance document "Coding for Success". The document had been written in partnership with The Department of Health, The National Patient Safety Agency, The Medicines and Healthcare Regulatory Authority (MHRA), NHS Connecting for Health and The Purchasing and Supplies Agency. It strongly recommended that both industry and the NHS should adopt the GS1 System of Standards and set out an action plan to support both the NHS and healthcare industry sector.

Shortly after the publication of the document, NHS Connecting for Health entered into an agreement with GS1 UK, to lead a programme of work for the NHS to drive adoption and use of the coding standards to reduce patient safety risk.

After the announcement that NHS CFH were entering into an agreement with GS1 UK, Lord Hunt (the then Minister for Health) issued a statement to parliament advocating the programme and the adoption of GS1 coding standards in healthcare.

By focusing on key areas of healthcare, and working with other healthcare agencies and liaising with the industry and manufacturing side of healthcare, CFH has been able to make a huge success of the programme and to influence healthcare end to end, from manufacturer to patient to after care.

## Connecting for Health and GS1 UK

The contractual agreement that is in place between CFH and GS1 UK provides the NHS with professional standards services allowing for the easiest and best led implementation of AIDC.

NHS CFH provides vital governmental liaison expertise while working with manufacturers, solution providers, suppliers

and - most importantly - the NHS to drive adoption of the GS1 Standards. NHS CFH also provides NHS organisations with membership to GS1 UK at no cost to the NHS.

GS1 UK provides support, expertise, facilitation, project and standards documentation and a dedicated service desk to the NHS.

This joint approach has reaped great rewards over the past 3 years and should ensure continued success into 2010.

## Key Focus areas

To make the programme manageable and achievable, the adoption was broken down into focus areas allowing the expertise of GS1 UK to be more "Genre specific." Below are some examples of these areas.

## Sterile services

Errors in the decontamination cycle have been well publicised. NHS CFH, GS1 UK and the DH "national decontamination programme" are all working to solve lost instruments, lack of track and trace, loss of revenue due to poor availability, postponed procedures and other issues .

The ability to track and trace instrumentation across the NHS is invaluable and coding solutions have been progressing well over the last few years. Tray level tracking is now available, through loan sets and in-house equipment. Direct part marking is also progressing and that would bring a full track and traceability across the NHS. The development of the super centres for the decontamination cycle has presented an ideal opportunity to



### The National Health Service

- The National Health Service was formed in 1948 as a public health service in Britain.
- The NHS is the 2nd largest employer in the world and has some 1.3million staff, of which 77% are female.
- Nursing staff make up over 30% of the  workforce
- The NHS serves more than 1.5million patients everyday and 23 million people visit their general practitioner each month
- 1.4million people receive care in their homes every week.
- Community pharmacies process more than 745 million prescriptions every year
- Since the NHS was established in 1948, men and women in England live an average of 10 years longer.

The main benefit of the programme is the improvement of patient safety in the NHS. There are also other benefits that have been realised:

- Cost reduction
- Time and effort saving
- Removal of paper processes
- Greater data usage
- Reduction of human intervention
- Service is more patient-centered
- Opportunity to inline NHS with Industry
- Anti-counterfeiting benefit
- Great increase in track and trace
- Single data set leads to greater efficiency in processing

introduce coding standards to surgical devices of all kinds. With NHS CFH, the NHS supply chain, the DH, GS1 UK and the solution provider community involved, coding in sterile services and theatre management will continue to improve.

## Pharmacy and medicines manufacturing

Coding in the pharmaceutical world is being adopted to reduce errors in prescription, and to assist with administering, validation, dispensary issues, packaging issues and waste management.

Coding solutions are being adopted throughout the pharmacy sector from manufacturers, to suppliers to repackaging and over labelling units, manufacturing units in trusts and hospital dispensaries. Robotic dispensing which is being used in some trusts also works with GS1 UK standards.

Legislation stating that all outer packaging of pharmaceuticals must carry unique identification codes may come into effect in the next 6 months. The MHRA is currently working with the other regulatory bodies across Europe to take this forward. This move is a counter measure to the counterfeiting of drugs which is a huge problem in the medicines world, but one that can be addressed through unique coding.

## Patient Identification

*"A study carried out at Charing Cross hospital, as part of Coding for Success found that patient ID checks were only being undertaken 17% of the time. When bar-coded wrist bands were implemented they were checked 81% of the time"*

Through simply issuing a unique NHS Number, bar-coded

wristband to every in-patient in a hospital, we can greatly increase the positive identification of patients before, during and after care. The unique nature of this NHS CFH identifier also enables cross referencing to treatment and ensures direct access to patient records.

NHS CFH has been working with the National Patient Safety Agency (NPSA) and GS1 UK to have Safer Practice Notice (SPN) No. 24 published to try to ensure that the benefits associated with bar-coded wristbands. This stated that, by September 18th 2009, all Trusts should have taken action towards using the NHS number bar code on patient wristbands.

The NPSA Safer Practice Notice No. 24 (3 July 07) 'Standardizing wristbands improves patient safety' can be found at www.npsa. nhs.uk/nrls/alerts-and-directives/notices/wristbands.

The standard for encoding the NHS number is ratified by the Information Standards Board and backed by NPSA Chief Executive Officer, Martin Fletcher.
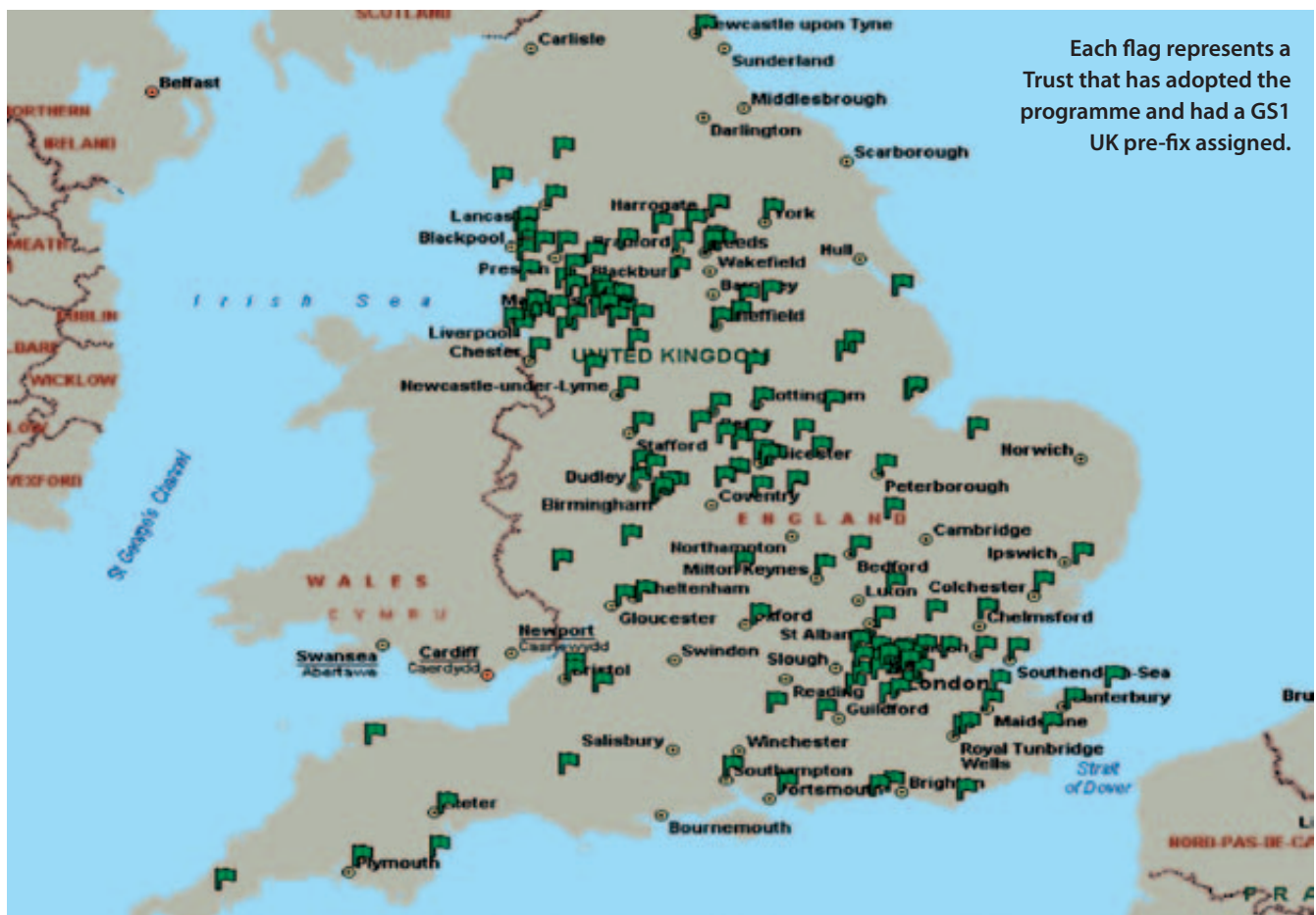
Through working with the NPSA, DH and ISB agencies and the NHS Number programme, holding workshops and collaborating with the procurement hubs and the OGC, we have enabled widespread adoption of wristband technologies.



**Each flag represents a Trust that has adopted the programme and had a GS1 UK pre-fix assigned.**

Since the publication of SPN 24, the Information Standards Board for the NHS has also published guidance that all Trusts must be compliant with the SPN24 guidelines by June 2011, this has led to an increase in adoption by trusts.

## Document tracking

Many clinical appointments in the NHS have to be re-scheduled, as patient's notes cannot be located. This causes a significant loss in terms of cost and wasted effort as many staff hours are lost by records staff, nurses and clinicians looking for notes and records.

Through the adoption of GS1 coding, either in bar code or Radio Frequency Identification (RFID) format, these problems can be vastly reduced. The ability to locate a set of patients' records almost instantly within the library or to know exactly which of a hospital's various department the notes have gone to, greatly increases efficiency and improves organisation. There is considerable evidence that implementation of the system has led to swifter response times, improved staff morale and reduced cost.

Pilots are being run currently to test two different RFID systems in the document tracking environment, and there are early indications that one of has already generated fantastic benefits.

While these key focus areas are the large focus areas within the project we have many, many instantiations which are also being developed such as Healthcare GLNs, Real time tracking, Newborn baby screening, Blood tracking and supplies and materials management projects.

## Current status

The significant extent to which the programme has been adopted across England can be seen from the map below.

In summary the programme has been one of great success and under the guidance of NHS CFH will continue to drive adoption and encourage new ways of adopting the standards across the NHS. Through the selection of the key focus areas and the development of them, a great number of health care professionals have become advocates of the programme and many more can see the direct benefits it brings. Through workshops, seminars, conferences and hospital site visits along with the issuing of policy and guidance documents the adoption of AIDC in the NHS will continue to grow.

### ABOUT THE AUTHOR

**Neil Lawrence** is the programme leader for AIDC technologies in the NHS. Before working for Connecting for Health, he worked for many years in the financial sector for companies Capital One and GE Money. Neil is greatly involved with GS1 UK, and sits on the global regulators' body as well as the UK HUG and UK Technical Committees.

The Coding for Success programme has been driving adoption with the NHS for 3 years with great success. Some examples of this are:

- Over 260 trusts signed up to the programme
- National backing of the programme from government agencies
- Parliamentary backing of the programme
- Positive media coverage of all aspects of the programme
- E-learning and internet tools delivered by NHS CFH to help Trusts adopt the standards
- AIDC documentation written and available to the NHS to assist adoption
- 5 key focus areas established and piloted
- Use cases published to European audience
- UK Healthcare user group established
- Positive coverage of the programme worldwide
- Joint approach to wristband programme with the National Patient Safety Agency has led to mandated standards in the NHS

**Lord Hunt's statement to parliament:**

*"Auto identification is not a new technology – we've all been used to bar codes in supermarkets for years. But to reap the benefits in healthcare everyone needs to work to agreed standards. We are recommending that both industry and the NHS should use the GS1 UK System for coding, and I am delighted to be able to announce that GS1 UK will be providing membership and support to NHS organisations who want to move forward on this."*

REFERENCES
- Coding for success:
  http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_066082
- NHS Connecting for health E-learning
  http://www.connectingforhealth.nhs.uk/systemsandservices/etd/elearning
- The Darzi Report
  http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825
- "Nurses waste an hour a shift"
  http://www.nursingtimes.net/nurses-waste-an-hour-a-shift-finding-equipment/1987381.article
- Case studies can be found at
  http://www.gs1uk.org/solutions/health/Further_information.asp

# Automating the medication use process: North York General Hospital Pharmacy Services

## ABSTRACT

North York General Hospital in Toronto, Ontario, Canada is a 434-bed healthcare facility with approximately 2200 medications listed on its hospital formulary. In the later part of 2005, the hospital began research to develop a bar coding strategy to reduce potential medication errors at the point of care, and to streamline their pharmacy operation processes. The outcome of research performed by North York General Hospital, Pharmacy Services has resulted in its endorsement of GS1 standards for its bar coding strategy and leveraging their established criteria of using "unique, static data" that defines the Global Trade Item Number (GTIN) – helping to move the healthcare sector to an increasingly e-driven global supply chain.

By **Doris Nessim**, Director of Pharmacy Services, North York General Hospital

## Background

In Canada, the federal government's healthcare arm – Health Canada – does not mandate bar coding of pharmaceutical (Rx) drugs. However, manufacturers are required to mark the product packaging with the drug's unique Drug Identification Number (DIN). DINs are assigned by Health Canada to a pharmaceutical product prior to it being marketed. The DIN is a computer-generated eight-digit number that uniquely identifies all prescriptions and over-the-counter (OTC) drug products sold in Canada.

However, the attributes associated with the DIN are limited; the DIN is not unique to the drug package hierarchy and does not enable globally unique identification of a product. This poses challenges in the implementation supply chain improvements. As well, the DIN does not support automatic identification technologies, which inhibits implementation of improved patient safety measures that would enable a healthcare provider to more effectively confirm that a particular medication is being administered to the right patient, at the right time, and in the right dosage.

With these circumstances in mind, North York General Hospital, Pharmacy Services set about on a journey to identify patients and drugs effectively and correctly, seeking a method to track and trace medications from the point they enter the hospital, to when they are administered to patients. The goal was to do so by augmenting the capabilities provided by Health Canada's DIN and by meeting the hospital's Pharmacy Services bar coding criteria of unique and static information.

## First steps

Medication error literature consistently documents that approximately 39% of potentially serious medication errors occur at the point of administration. This is due to the fact that, after a medicine is administered to a patient, it cannot retracted. Types of medication errors that may occur include:

- Wrong patient
- Wrong drug
- Wrong dose
- Wrong dosage form
- Wrong strength
- Wrong time

Most significantly, literature reports that only 2% of administration errors are actually caught prior to administration.

The hospital's Pharmacy Services was determined in its goal to find alternatives to the processes and solutions already in place in order to improve safety at the point of care, thereby preventing the types of errors reported in the literature. North York General Hospital has a culture of safety and believes that errors reflect failures in processes. No healthcare provider comes to work wanting to make a mistake. And while some errors simply cannot be identified by bar coding, the majority will be.

The hospital's first step was to take a systematic look at what it needed to do to improve its own medication error rates. This was completed by methodically assessing the touch points of the hospital's medication-use process as a whole, which led to the identification of approximately three dozen touch points in all. As with any hospital, the medication-use process begins with procurement and inventory management, followed by dispensing the medication – enabling the drug to be available at the point of administration for nursing units.

As a result of its research of point of administration errors and its medication-use process, North York General Hospital, Pharmacy Services determined that their bar coding strategy had to be able to identify preventable errors by triggering the healthcare provider at the point of care to re-evaluate the patient, the medication, the dose and the dosage prior to administration. Following this determination, the pharmacy was set to identify the following:

- Its preferred bar code;
- How bar codes could be affixed to each of its medications as a unit dose entity;
- How medications are provided to the nurse; and
- How the bar coded medication is administered to the patient.

In the absence of a national standard for a bar code strategy in healthcare, Pharmacy Services developed its own criteria for a bar coding solution. The criteria included ensuring that the bar code would be unique, specific and static, enabling Pharmacy Services to identify the pharmaceutical product at every level of packaging. This endeavor included strong collaboration with internal and external stakeholders in order to arrive at the right bar code strategy.

The only solution that met all of the criteria was the GS1 standard GTIN.

## The GTIN

North York General Hospital, Pharmacy Services first approached GS1 Canada for additional information on the Universal Product Code (UPC) in the later part of 2005. There were just a handful of GS1 Canada members at this time in the hospital sector, meaning the GTIN was not leveraged beyond the point of the manufacturer and therefore placing a lot of responsibility on hospital pharmacies to effectively track and trace their products.

Pharmacies, specifically hospital pharmacies, face the challenge of managing the organization of medications received in bulk. For example, hospital pharmacies will obtain medication packages containing 100 doses and the only bar code that appears is placed on the secondary packaging (e.g. the container). The hospital pharmacy is therefore obligated to repackage each unit dose within that larger package, repackaging each dose with a hospital-generated, bar code identifier.

Following the determination that the GTIN was the hospital's preferred standard, North York General Hospital, Pharmacy Services prepared a spreadsheet that contained all of the different pharmaceutical manufacturers from whom they purchased medications. From there, the pharmacy determined which manufacturers were already using the GTIN and which were not.

With 2200 medication types on the hospital's formulary, and only a small percentage of those containing a unit dose GTIN bar code at the time, the pharmacy – along with every other hospital pharmacy in Canada – faced a lot of work in regards to tracking and tracing its medications safely and effectively.

## The bar coding strategy: The process

In order to meet the needs of the hospital and ensure that each medication unit dose could be tracked and traced to support the hospital's commitment to a culture of patient safety, the North York General Hospital, Pharmacy Services developed the following processes as part of its strategy in order to identify each unit dose with a bar code.

## Point of procurement

When a formulary medication comes into Pharmacy Services' locale, it is recorded on the previously mentioned spreadsheet whereby each pharmaceutical manufacturer is noted as being GS1 GTIN-compliant or not.

Virtually all pharmaceutical (Rx) and OTC products are marked with a GTIN at the bulk level, as well as those medications that come into Pharmacy Services already packaged as unit doses for patients. Products at patient-level that are administered in the manufacturer's original packaging or that are stocked at nursing stations are also identified with GTINs.

However, for those products a part of bulk medication shipments requiring repackaging as unit doses, a proprietary bar code is affixed as an identifier until all hospital suppliers become GS1 GTIN compliant.

## Affixing bar codes to unit doses

It is crucial for the infrastructure of a hospital pharmacy matches its medication-use process – which means that a hospital's already stringent budget needs to be stretched to meet the necessary requirements that come with implementing a bar coding strategy.

North York General Hospital therefore purchased an automated repackaging machine to provide unit dose dispensing – removing manual processes to help Pharmacy Services realise operational efficiencies with unit dose packaging, as well as prevent potential errors that occur by prepackaging medications. The capital for this system is extensive – priced at approximately $300,000CAD.

In order to affix proprietary bar codes to those unit dose packages that the hospital creates via its automated repackager, a bar coding station was established by purchasing a machine that would create and generate bar codes – this system is approximately $30,000CAD. With the bar coding station, North York General Hospital Pharmacy is enabled to input bar code numbers and print off bar code labels to be affixed to unit doses.



*Bar coding station, including test scanner*

As an added layer of safety, medications identified with either a GTIN or proprietary bar code are validated at the bar coding station before being added to the pharmacy's inventory. The pharmacy retains a hand-held device that tests unit dose bar

codes to ensure they are identifiable and readable, thereby preventing them from being rejected when they are scanned at the point of administration.



*Testing bar codes*

Only after a unit dose is bar coded and tested can it make its way into inventory for eventual administration to a patient.

## Cost savings

Despite the costs, North York General Hospital's executive committee supported the hospital pharmacy's proposal to purchase the above systems and implement the bar coding processes proposed – a direct reflection of the hospital's dedication to patient safety. This encouraging decision was largely due to Pharmacy Services' awareness presentation, given to the hospital executive committee in 2005 to identify areas of breakdown leading to medication errors and highlighting errors occurring at the point of administration. Through this presentation, the hospital pharmacy enhanced overall knowledge internally and leveraged executive support to proactively prevent errors.

As a result, the bar coding station and automated repackager have already enabled North York General Hospital to realize a cost savings of 7-8% each year in terms of its medication purchasing and packaging activities.

## Mandating the GTIN

With the hospital's executive support, a logical next step would be to attain support from the supplier community to assist all Canadian hospitals to wholly implement the GS1 standard GTIN, which would enable interoperability on a national scale and remove the need to affix proprietary bar codes to medication unit doses.

North York General Hospital, Pharmacy Services has unarguably identified the need to include GS1 bar code adoption as a factor when procurement groups are evaluating drug products

during the contract process. However, individual hospitals are not in a position to mandate bar coding standards; this is a government decision.

To this end, GS1 Canada is collaborating with leading Canadianpharmacy supply chain stakeholders, the Institute for Safe Medication Practices (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), having launched a national project to promote automated drug identification in Canada using global GS1 bar coding standards. The goal of both ISMP Canada and CPSI, along with all healthcare partners, is to reduce preventable medication errors affecting patients in both institutional and community settings. The collaborative efforts of ISMP Canada, CPSI, GS1 Canada and healthcare industry stakeholders resulted in a national consensus in 2010 to use GS1 bar codes as the standard format for labeling medication packaging in Canada.

## Next steps

Approximately four years have passed since the North York General Hospital, Pharmacy Services began taking steps to augment its medication-use processes and improve patient safety at the point of care. The hospital pharmacy's bar coding strategy will officially roll-out to all hospital departments in early November of 2010, when anticipated additional benefits and cost savings will be realized.

Due to the anticipated success of this initial undertaking, the hospital pharmacy is moving forward with implementing bar coding strategies for all medication dosage forms, including oral, injectibles, topical, and other dosage forms dispensed through North York General Hospital, Pharmacy Services. In addition, Pharmacy Services has also engaged in discussions with GS1 Canada to leverage additional GS1 standards in the future, namely the GS1 Company Prefix Licence. A Prefix will enable the pharmacy

to create GS1-compliant bar codes, streamlining their bar coding process by removing the need for proprietary identifiers.

Today, there is increasing momentum in the Canadian healthcare sector to reach consensus on business processes that support GS1 standards. With collaborative efforts and community management initiatives, such as North York General Hospital's representation on the GS1 Canada Healthcare Pharmacy Sector Board – multiple industry sectors across Canada are working together to make enhanced patient safety a reality with critical mass adoption of a standardized and automated medication use process.

## ABOUT THE AUTHOR

**Doris Nessim** has over 15 years of experience in healthcare and pharmacy leadership positions, including project management in implementing healthcare technologies, as well as pharmacy practice, education and research experience.

Currently, Ms. Nessim is the Director of Pharmacy Services at North York General Hospital, a large community teaching hospital located in Toronto, Ontario, Canada. In addition to providing overall strategic leadership, fiscal planning, and managing acute and ambulatory care pharmacy services, Ms. Nessim's visionary leadership is advancing safe medication practices at each stage of the medication use process.

Ms. Nessim received her MA in Higher Education from the Ontario Institute for Studies in Education, University of Toronto, and is a graduate of the Faculty of Pharmacy, University of Toronto.  She completed her residency in Hospital Pharmacy Practice at Toronto General Hospital.

# Keeping an eye on the big picture: Mayo Clinic's integrated supply chain management

## ABSTRACT

The U.S. supply chain has advanced in other industries (retail, grocery, general merchandise), but the healthcare industry as a whole is just now learning the benefits of electronic commerce, vendor-managed inventory (consignment), evaluated receipts settlement, and just-in-time replenishment. Some suggest the primary reason we struggle in healthcare is due to the lack of a solid, underlying infrastructure, one that facilitates the integration of the supply chain with clinical systems through interfaces and data standards. For one Integrated Delivery Network (IDN), Mayo Clinic, integration is beginning to show the promised benefits and allowing the industry to finally see the big picture – the role data standards play in improving supply chain performance.

By **Joe Dudas**,
Director of Accounting and Supply Chain Informatics, Mayo Clinic

## Here a system, there a system: piecing it all together

Mayo Clinic has in place many systems and processes that help its healthcare professionals understand, manage and track the movement of medical products throughout its facilities. Mayo has an Electronic Medical Record system and to support our business functions, such as human resources, accounting and supply chain management, we use an Enterprise Resource Planning (ERP) system. Mayo has also developed its own software to manage supplies at the point of patient care that we call SIMS (Surgery Information Management System, although use is beyond surgeries).

The ERP system contains the source data for suppliers, products and pricing for the entire enterprise. SIMS contains an item master file for point-of-care sites within our hospitals, including the operating room (OR), Catheter Lab, Interventional Radiology (IR) and Gastroenterology (GI). These SIMS files are synchronized with our ERP system, mainly using the product item number stored in the materials management module. Integration between SIMS and the ERP has been built (both process and automation) over the past 10 years. Our integration with the revenue cycle (billing) has evolved similarly and it, too, utilizes the ERP Item number in the Charge Master.

As we work diligently to cut costs while delivering high quality patient care, a focus area for us has been the OR. We use an automated physician preference card system, which helps to automate the functions of the OR. Preference cards make it easier for nurses to provide the correct supplies and equipment for each surgery, reducing the number of supplies opened unnecessarily. Preference cards also help in streamlining the billing process,

limiting mistakes and making the entire process more efficient. With our SIMS system, we scan and document exceptions that are not on the preference card or items that require serial tracking. The goal is to make everything as simple as possible for those doing the scanning, in most cases our nurses. All items arrive in the OR (from our centralized OR Inventory Core) with a barcode for scanning. For supplies, approximately 30% of barcodes need to be created "in house" and 70% can be scanned exactly as they arrive from the vendor. We also use grocery style bar-coded catalogues for items that are not practical to barcode.

For implants, all items must have an internally generated barcode, because the vendors currently lack standardized barcodes which can be used for this purpose. The barcode for

implants is generated internally by entering the serial number, lot number and expiration date. Consigned items and tissue are also stored in SIMS. The system has an indicator for consigned verses owned items which is reconciled monthly with the "official" consignment contracts.

Using our current system and processes, Mayo has been able to obtain accurate data on implant and supply use in the OR and other points of care. The data is then used to drive standardization and areas of possible expense reduction which ultimately leads to higher value for our patients.

## Information drives value

By integrating our supply chain management systems and processes with other critical business and clinical functions within the hospital, we have come a long way in terms of driving efficiencies and gaining insight into our supply use. We are employing best practices to accomplish these goals, including:

### Using very few non-contract items
Frequently used items, inventory and serially tracked items (implants) are all kept on the ERP Item Master file. Non-contract supplies can be procured by either adding the item to the file or ordering as a "special/non-file" item. Special/non-file items are managed very closely as are any non-contracted purchase. Data regarding the use of non-contract items is collated and reviewed by a centralized Value Analysis Team for Mayo's hospitals. When this centralized team sees a particular non-contract item ordered multiple times, they move forward in discussions with the hospital(s) that is ordering the non-contract item to better understand the item, and to evaluate whether the item should be placed on contract. The committee may also research whether there are already acceptable substitute products already under contract and used in other Mayo facilities. Mayo works very collaboratively as a team and we are data driven in our decision making (often using Six Sigma – DMAIC (Define, Measure, Analyze, Improve, Control)/Lean as our quality/efficiency framework). We also have been discussing alternative strategies pertaining to our Item Master Strategy that would further close gaps and enhance our processes (Called Category Management, used in the Retail Industry today) but are only at the beginning stages of scoping and designing.

### Ensuring the accuracy of preference cards
With accurate preference cards, the correct items are pulled from inventory up-front, items are not wasted, and there is little rework on the part of those doing the stocking in returning items to the stock room. This level of preference card accuracy has been achieved through multiple avenues.

- There is a team leader for each service's preference cards at each hospital. OR nurses maintain electronic communication with the team leader, so that items which are incorrectly "on" or "not on" the preference card are easily communicated to the Team Leader for updating.

- As supplies are pulled for a given case, they are put into a "pending" mode electronically. The case cart goes into OR. As OR staff opens supplies they increment inventory if they are not going to use something and decrement inventory if they add something. All supplies decremented and incremented are done via barcode scanning. Both these tasks are completed before the items used during a surgical procedure are "finalized" and sent to the ERP central back office system. Once the supplies/implants used are finalized, the implant information is entered into the patient's electronic medical record as well.
- As the patient records are being finalized a small subgroup that reads surgeon dictations and checks dictations against supplies/implants entered into the electronic medical record as used. For example, if the dictation shows that hernia with mesh procedure was done, mesh shows up in the "used" supply/implant area.

### Managing point-of-care restocking processes to allow for "right item, timely availability"
Restocking management is a process that eliminates overstocking and potential expiration of supplies. It requires buy-in on the part of the nurses for rigorous documentation of supplies, because if nurses do not scan added supplies, the computer system does not know the item needs to be re-ordered. The point of use SIMS system is a real-time system that feeds the central ERP system. The central ERP system is a batch system, which then replenishes supplies when items are noted to have dropped below a PAR level (the previously determined order point). Cycle counts are done regularly and back-orders are monitored and managed daily.

### Collaborating with physicians to reduce one-shot, non-contract item ordering
With input from key Mayo physician groups, Mayo's Supply Chain Management and Clinical workgroups gather and collate data about contract/non-contract use of implants and supplies and report the findings back to physicians. This process allows the physicians to drive toward consolidation of use for both implants and supplies. Physicians are interested in providing high quality care for the best price for the patients and so engage in this work readily. Our Finance department also collates "cost per case" data and presents this to the physician groups as well.

### Ensuring that rebates are captured
Mayo's contract management staff enters supply contracts into a centrally housed and managed database. Any contracts with rebate features are set up with a receivable based on the payment schedule and assumed amount (based on projections). The receivable is then managed closely like any other significant receivable. Disputes are handled through the contracting team if there are issues or delinquent payments.

### Ensuring billing is accurate and complete.
Cost changes are electronically updated as received and authorized into the ERP central files at Mayo. We closely manage

pricing, and only accept the price if it is within our terms and conditions (we hold pricing firm for the term or allow for updates on a defined calendar). SIMS as well as our Billing System is fed any applicable updates and accepted "as is" from the ERP. The only thing the barcode is used for is to identify the item. The rest of the information about that item is kept in the item master file. The ERP 3-way (purchase order, receipt and invoice) match ensures payment accuracy. The ERP can handle site specific prices for the same item (although our goal is to have one price for the enterprise).

## Support of suppliers paramount

Like other hospitals in the U.S., Mayo uses thousands of supplies from thousands of manufacturer partners. While many of the supplies come through a distributor many also come through direct relationships with the manufacturer. As we strive for ultimate efficiency in our supply chain, we recognize that the journey is more of a marathon than a sprint, and as such, we need the complete support and partnership of our vendors. Key developments in these relationships include:

### Vendor control
To manage which vendor may be permitted in a surgical suite, we are using a vendor registration system. All vendors must go through the OR nurse manager before they are allowed in the surgical suite. The vendor and surgeon use products that are identified on the surgeon case request before surgery. If the surgeon wants to use a new product, the surgeon formally requests the "new" item through the OR Manager. Compliance is managed through reporting and basic compliance management protocol.

### Data standards
Mayo Clinic is on the Leadership Team of GS1 Healthcare US to assist the healthcare industry in standardizing our numbering system with the GS1 System of standards. We are working with the U.S. Food and Drug Administration and GS1 US to move

initiatives forward. While suppliers are not denied access to Mayo if they are not GS1 standards compliant, we are requesting that our supplier partners convert their ascribed account numbers and product descriptions to the GS1 GTIN and GLN standards consistent with 2010 GLN Sunrise and 2012 GTIN Sunrise dates. Mayo Clinic considers our suppliers as partners and we work collaboratively with them. However, at some point in the future we may need to take stronger actions due to either regulation, safety or cost concerns (or all three).

Mayo Clinic is asking suppliers to standardize first for locations (GLN) (see Mayo Clinic/Cardinal Health case study summary in this article). Under this system Mayo will do all contracting and purchasing through the standard facility identifiers (one set of identifiers at the Mayo Ship to level) as opposed to each supplier providing account numbers representing the supplier's unique view of Mayo locations. Later, we will ask vendors to standardize by having a unique product identifier for each product, using the GTIN, as well as contributing product data to a common registry in a shared data utility via the GDSN (see Figure 1).

Figure 1: **GS1 standards included in the U.S. Healthcare Industry Sunrise Dates**

The foundational standards of the GS1 System:

**Global Trade Item Number® (GTIN)®** – a 14-digit code assigned to each individual manufactured product as well as to each different packaging configuration

**Global Location Number (GLN)** – a 13-digit code used to uniquely identify healthcare supplier and provider locations

**Global Data Synchronization Network® (GDSN®)** – a network of certified data pools enabling the standardization and synchronization of supply chain product data between trading partners

## Conclusion: benefits come into view

Open communication lines, both internally and externally, have helped to ensure smooth integration of our systems and processes along our 10-year journey. Mayo has participated in industry initiatives to better educate ourselves and to share our insights with others. We've recruited partners that share our vision of a better way of doing things, and we have selected suppliers who have a proven track record working with us collaboratively. Executive leadership is also important in terms of prioritizing the multiple and sometimes competing healthcare IT initiatives and providing resources and support across supply chain management at Mayo.

Based on our experiences to date we are confident the rewards of standards adoption and complete supply chain management systems integration will be realized industry wide. Organizations that go through this process will learn the skills needed to excel in the healthcare industry of the future, including unprecedented collaboration, systems thinking utilization of high quality information, innovation, improvement and change management. Keeping an eye on this big picture can serve as a powerful motivator to get through implementation challenges.

Mayo Clinic has automated much of the Supply Chain and the results are unquestionable. Over the past 10 years, our IDN has achieved documented Supply Chain savings approaching half a billion dollars all while reducing staffing levels and achieving charge capture improvements. What is really exciting is what is to come. The systems are not fully developed, processes have not been fully optimized and implementation of data standards has just begun. The next 10 years represent a huge opportunity as opposed to a healthcare crisis. Mayo Clinic remains steadfast in its commitment to their patients where "the needs of the patient always come first".

## About Mayo

Mayo Clinic is a not-for-profit medical practice dedicated to the diagnosis and treatment of virtually every type of complex illness. The needs of the patient come first. A patient will see as many doctors, specialists and other health care professionals as needed to provide comprehensive diagnosis, understandable answers and effective treatment.

## ABOUT THE AUTHOR

**Joe Dudas** is Director of Accounting and Supply Chain Informatics at the Mayo Clinic, where he is responsible for implementing and optimizing technology and business best practices. He leads forums across Mayo organizations to drive strategic supply chain, accounting and research IT direction, standardization and best practices.

Mr. Dudas is currently a member of the GS1 Healthcare US leadership team. He participates in many other industry efforts to improve the healthcare supply chain. Mr. Dudas brings more than 20 years of information systems experience in IT outsourcing, telecommunications, retail and healthcare.

**Contributors** to the article included Tom Loukes, Surgical Process Analyst, and Donada Reimer, RN, BSN, SCM Clinical Support Services Manager

## Mayo Clinic and Cardinal Health partner to implement GLNs for patient safety and supply chain efficiency

In the past there have been numerous discussions about the value of standards, and which standards to use in the healthcare industry. Today, the discussion has shifted to how to implement standards, the first steps to take, and timing.

Many of the healthcare industry's supply chain partners, including Mayo Clinic, have voluntarily established the end of 2010 as the date by which they will adopt GS1 GLNs to replace custom account numbers in order to reduce costs and improve patient safety. Mayo Clinic firmly believes that supply chain data standards will greatly improve healthcare safety and efficiency, supporting their primary value that "the needs of patients come first."

In July 2008, Mayo Clinic and Cardinal Health collaborated to implement the GS1 GLN as their sole account/location identifier. Both organizations agreed that this GLN project would be an innovative first step toward the 2010 GLN Sunrise.

**Implementation results**
Mayo Clinic and Cardinal Health are among the first organizations in U.S. healthcare to implement GLNs in supply chain transactions. The results were as follows:

*   Mayo Clinic converted 58 custom account numbers to GLNs.
*   Mayo Clinic was able to convert approximately 60,000 order lines to the GLN in November 2009 – which accounted for 85% of total EDI orders.
*   $8 million of product was transacted with Cardinal Health using the GLN in November 2009, and over $70M of product was purchased with the GLN over the course of the 2009 year as a result of this implementation.

**Implementation benefits**
Price accuracy improves with location identification accuracy. Location identification errors can cause loss of discount eligibility as well as tier qualification and rebate disputes. Price accuracy for Mayo Clinic and Cardinal Health is currently 99.5%, whereas the average supplier accuracy is 95%. Superior price accuracy is attributed to not only GLN, but also to the commitment that both organizations make to price integrity and associated improvement efforts.

The use of GLNs improves supply chain management performance, and GLNs used in conjunction with other GS1 standards promise even greater performance. Similarly, the more supply chain partners that adopt GS1 standards, the greater the benefits for the entire industry.

Visit **www.gs1us.org/healthcare** to read the full case study.

# Hong Kong Hospital Authority improves procurement process and asset management through EDI and RFID

## ABSTRACT

The Hong Kong Hospital Authority (HA) – a statutory body responsible for managing all Hong Kong public hospitals – continuously seeks to enhance patient safety through increased operational efficiency, data security and traceability. In conjunction with its modernisation plans, the HA enlisted GS1 Hong Kong's EDI platform, ezTRADE, to improve its procurement process and initiated a pilot study on the feasibility of RFID technology to enhance asset management. This article outlines case studies on how the adoption of EDI and RFID technology has improved the HA's procurement process and asset management system.

Article by Hong Kong Hospital Authority

## Background

Established in December 1990, the HA is accountable to the Hong Kong Special Administrative Region Government. HA currently manages a portfolio of 41 public hospitals and institutions, 48 specialist outpatient clinics and 74 general outpatient clinics. In total, these operations comprise around 53,000 staff and more than 27,600 hospital beds. Budget-wise, the HA manages an ever-growing public healthcare expenditure, projected to grow from HK$32.7 billion (or US$4.2 billion) in 2007/8 to $78 billion (or US$10 billion) by 2015 and $127 billion (or US$16.4 billion) by 2025.

In keeping with the mission to enhance patient safety through closer collaboration with the global healthcare sector, the HA joined the global GS1 Healthcare user group, as a voting member in 2008. Aiming to deliver a win-win-win worldwide environment for consumers, providers and suppliers, it is beyond doubt that the global healthcare supply chains should work closely together to achieve optimal efficiency, increase necessary transparency and build traceability.

With this goal in mind, the HA has set several key targets as part of its modernisation plans for procurement and materials management. These targets include the establishment of an integrated supply chain data and information platform and the enhancement of risk management tools and processes. The vision is to establish a value-for-money seamless supply chain operation with maximum risk management.

## Case 1: Streamlining procurement process for over 160 hospitals and clinics with B2B platform – ezTRADE

To maintain supply continuity and appropriate technology adoption at the frontline, HA has to secure a smooth supply of all the necessary medical consumables through bulk procurement from global suppliers. The procurement processes involve a large network of vendors, including pharmaceutical companies, medical consumables suppliers, as well as third-party equipment maintenance service providers. Managing all these suppliers requires thorough planning, detailed policy formulation, as well as a transparent system of risk and information management at both the head office and cluster/hospital levels. Head office functions include policies and guidelines formulation, standards setting, risk management and system development, while individual hospitals would focus on vendor performance monitoring, inventory control, logistics support, bulk contracting and so on.

**Hong Kong Hospital Authority improves procurement process and asset management through EDI and RFID**

Like all healthcare service providers around the world, soaring healthcare expenditure is a constant pressure area. In the face of this challenge, coupled with issues such as accuracy of information on spending, reported discrepancies in product quality, as well as the constant need to manage change, the HA decided in 2002 to modernise its procurement and supply chain management processes. This strategic move is also found to be consistent with the HA's new initiative of continuous healthcare technology assessment and adoption. The modernisation plan aimed to achieve three goals to improve:

- efficiency by reducing operational costs and procurement lead time while raising product safety
- security, especially with regard to process control, accountability and data security
- traceability with greater information sharing and integrated data management down to the consumption level.

### Enlisting GS1 Hong Kong to implement ezTRADE

Earlier on, in 1996, in a bid to modernise procurement and supplies management through the implementation of an e-procurement system, the HA had enlisted GS1 Hong Kong and adopted GS1 service by implementing ezTRADE – a business to business EDI platform using standard-based interface for automatic identification and communication in the healthcare supply chain. As of December 2009, a total of 48 HA suppliers have joined ezTRADE with over 18,000 EDI Purchase Order transactions throughout the year.

### ezTRADE facilitates information flow and increases operational efficiency

Traditional manual order processing involved a complicated workflow; and this process was compounded by non-value-added tasks such as duplication of efforts on data entry and information dispatch subjected to slow modes of communication i.e. sending orders through fax. Not only was it time consuming and manpower intensive, there was a high risk of human error in the communication process, which in turn incurred hidden administrative and operational costs.

ezTRADE – designed to allow businesses to conduct trading activities with full electronic data interchange (EDI) and extensible markup language (XML) support – provided the ideal standards-based platform for the HA and its suppliers to do business with greater efficiency. With this platform service, all product categories, prices and quantities are itemised in detail on each Purchase Order, allowing the buyers in HA and the suppliers to extract accurate and timely trade information using a common business language in a standardised electronic

format. In short, all data transmission can be conducted over the ezTRADE network in a simple and efficient manner. The system also automated the payment process and could be used to facilitate management of recalls, in the case of a product defect.

ezTRADE assisted us to improve the business transaction flow for medical consumables. The specific benefits included improved effectiveness of operation flow in the communication with suppliers; elimination of duplication of non-value-added work, especially in the administration processes, fewer human data entry errors and improved inventory management.

### Case 2: Harnessing RFID technology to achieve traceability for enhanced patient care

The rapid development of wireless technology (e.g. RFID) in enabling more effective asset management in hospitals is closely associated with the rising concern of enhancing healthcare quality and containing healthcare costs. Overseas pilots and implementation projects have revealed that effective fixed asset management with the help of technology leads to better asset utilisation, thus facilitating frontline medical staff to better focus on patient care.

As equipment for treating patients becomes increasingly sophisticated and expensive, the prevention of equipment loss takes on greater importance. Besides potential economic losses, inefficient asset management in a hospital can lead to other adverse issues, such as disruption of medical services and lost productivity of health professionals. As one overseas study has shown, some hospital staff can spend as much as 30% of their time looking for equipment needed for use.

Recognising all these issues and challenges, the HA decided to conduct a pilot study using RFID technology as a means to facilitate asset tracking and management of medical devices at the point of care, and ultimately, to improve patient safety and service quality.

## RFID asset tracking system to streamline utilisation of high-value equipment

In 2007, the RFID Asset Management Task Force was set up with GS1 Hong Kong to conduct a study involving the Prince of Wales Hospital and North District Hospital.

The study was aimed at identifying the best way to streamline stocktaking processes and enable faster stocktaking of assets. In addition, it sought to compare whether the selected technology outperformed the bar code technology currently in use. It was also intended that a business case could be prepared to build a system that would enable real-time location tracking of medical assets and streamline the utilisation data capture process for high-value medical equipment.

The study designed three systems for trials using mostly matured RFID technology:

- Passive RFID to further facilitate stocktaking of equipment in operation theatres
- Active RFID to enable real-time tracking of medical devices in wards
- Active RFID to streamline utilisation capturing and reporting of high-value assets in hospitals

Safety measures for protecting sensitive medical devices such as EMI assurance testing were performed; and it was found that there was no interference generated on the active RFID tags. Of the three applications, the use of active RFID technology for real-time asset tracking proved to be most helpful to the frontline nurses by eliminating the time spent in locating or counting the frequently-used devices and also enabling them to better utilise their time for enhancing patient care. In this pilot study, 15 devices were tagged, including blood pressure monitors, electrocardiograms, syringe pumps, infusion pumps and bladder scanners. A nurse would only spend 12 seconds to locate a tagged medical device in the ward, as compared to a much longer duration ranging from half an hour to even several hours and days through searching the paper record system and the manual searching for the equipment. Active RFID was also preferred for its proven user-friendliness and tag capability.
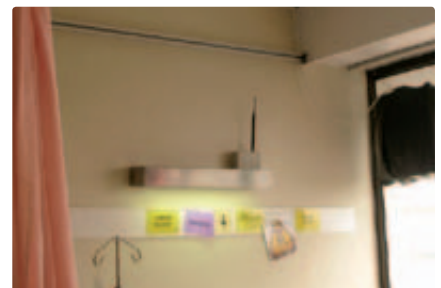
The study provided conclusive proof that RFID asset tracking systems can address many key objectives of asset management, including maximizing the utilization of assets, reducing asset losses and improving asset maintenance.



*EMI Assurance Test Setup*



*Active RFID tag affixed onto a medical device for its location tracking*



*Installation of Fixed Readers at the Pilot Ward*

# Improving quality of care and patient safety in Chile: Servicio de Salud Metropolitano Occidente

## ABSTRACT

The *Servicio de Salud Metropolitano Occidente* (Western Metropolitan Healthcare Network) has embarked upon an ambitious process to modernise administrative and clinical management. It is therefore implementing GS1 Standards to monitor stock and to enable traceability of drugs and medical supplies. This is "*an important step toward quality and safety for patients*" according to the responsible parties.

By **Dr. Carolina Cerón Reyes**, Director of the Servicio de Salud Metropolitano Occidente

## About SSMOCC

The Western Metropolitan Health Service (SSMOCC) is an agency of the Chilean Health Ministry managing and coordinating a healthcare network including six hospitals, a Diagnostic and Treatment Center, a Health Reference Center, 33 Primary Healthcare Centers and 23 Rural Healthcare Centers. A population of 1,200,000 people of fifteen municipalities in the west area of the Chilean capital (Santiago) are assigned to the network.

## "Más Salud Occidente"

The SSMOCC aims to improve quality of care and to increase access and opportunity to healthcare. A strategic decision was therefore made to implement a system on hospital management, focused on the clinical care of patients. In 2008, after an exhaustive process to define requirements and analyse possible solutions, a comprehensive, world-class system in healthcare information (HIS) was established. It is a pioneer in the Chilean public healthcare system.

The project is called *Más Salud Occidente* and creates an Electronic Health Record (EHR) system.

The system is aimed at patient management within the healthcare network (waiting lists, scheduling, referral and counter-referral between centres, etc.), management of available resources (availability of beds, optimisation of stocks of medicinal products and medical supplies, optimisation of the use of operating rooms and diagnostic and therapeutic equipment, etc.), quality assurance and opportunity to receive care (access to clinical guidelines, treatment protocols, follow-up of explicit guarantees to health, safety in drug use, etc.) and management information (includes real-time reports on how the centres in the network are operating, management of indicators, information regarding compliance with goals, etc.).

## Drug traceability

Important challenges have arisen within the framework of this project. Specifically, in the case of handling medicinal products, to achieve drug traceability, from the time of acquisition until a given dose is administered to the patient. This was made a priority to improve the safety and quality of clinical procedures. The need to monitor the entire flow of medicinal products, with reliable records throughout every stage and in every centre in the network, set the challenge of creating a standardised coding system for drugs, using product characteristics and logistical information.

This was a serious challenge, given that no system of the kind existed in Chile to code and track medicines. Therefore, the first task the team undertook was to analyse the existing alternatives on the market. The main criteria were to use universal, recognisable, shared standards, which allow for the exchange of information with parameters that suppliers, institutions within the sector, logistics companies, etc. have in common.

GS1 Standards were considered to be the best option for the Department's requirements. It is an international coding system, widely used by supplier companies, which can be integrated into the *Red Occidente* (Western Network) information system. It primarily allows for the precise tracking of medicinal products. Furthermore, the Chilean Ministry of Health's *Central Nacional de Abastecimiento* (CENABAST) [National Supply Centre], which is the Department's main supplier of drugs and consumables,

had already started to use this same coding system, making the standard requisite for its providers.

## Preliminary steps

The preliminary steps were not easy. A detailed study was required to standardise and approve the drugs used by the various hospitals in the network. Then a "master list" was drawn up to which every hospital in the network had to conform. At the same time, the procedures of each hospital were analysed with an end to defining a common flow, including warehouse receipt, delivery to pharmacy, dispatch to clinical services and dose administration to the patient.

This flow chart was developed in the field, alongside local teams in each centre, thereby facilitating a standard procedure to be applied to all the centres.

Meanwhile, another essential piece was being developed: a clinical table was created containing information concerning each medicinal product (active substance, pharmaceutical form, strength, route of administration, etc.). To this end, a review was carried out regarding the existing available information. It was determined that a study developed by the *Instituto de Salud Pública* (ISP) [Public Health Institute] could be used, which had a base of clinical information for each drug on the market.

The GS1 System enabled the information from the ISP to be collected, while adding to it the logistical data for each product (origin, storage conditions, lots, expiry dates, etc).

Nevertheless, the implementation of the project required a serious amount of work, being primarily focused on creating and updating the "supplies master list" and establishing a logic to the network to be offered by the system. In this way the information can be shared and the use of resources between all the centres can be optimised, contributing to the *Red Occidente* joint management.

In this context, efforts were concentrated not only on standardising the process, but also on the approval of drug-associated terms, thereby creating a common glossary for their characteristics.

## Implementation and start-up

The implementation process was designed in stages, starting with Hospital San Juan de Dios, the most complex centre in the *Red Occidente* network. From there, progressive installation was foreseen for each of the other centres.

Today, with the registration and monitoring system installed in warehouse receipt, the goods are checked using a barcode reader. This allows for the integration of the clinical information for the product and the logistical information regarding origin, characteristics and forms of storage. If the goods carry the code EAN128, the lot and expiry date information are also included. If they carry the generic code EAN13, this information is added to the system locally, re-labelling the product.



In every stage following receipt –dispatch to pharmacy, delivery to clinical services and administration to the patient– the code is used again and again. Information about the drug can be recovered and traced throughout the entire flow.

Start-up of the system has entailed a serious change in the way things are done, not to mention the change in mentality, technology and infrastructure which first had to be developed.

The supply centres were the first to experience the transformation. In addition to installing the required hardware (more computers, barcode readers, etc.), spaces were redesigned and changes in infrastructure were made for the storage of the products, bearing in mind their particular conditions. This is because by having a record of information on lots, they can

be separated in the warehouse, establishing different physical spaces. The pharmacies are undergoing similar changes, with an end to adapt processes and infrastructure to the new working dynamics.

Training has also played a key role in defining and implementing the system, both in terms of management of the changes and technical know-how. All parties involved have worked closely to coordinate the changes: pharmacists, doctors, heads of supply, administrative assistants etc.



## Challenges

Considering the magnitude of the project, the teams have had to handle a series of challenges during the start-up phase. The main problem has to do with the fact that some goods arrive at the warehouse without a barcode. Although the international standard has been partially put in place, there is still a large gap between those products that are labelled and those that are not; currently the Health Service suppliers are not obliged to provide this. Given the volume of products normally received by a hospital warehouse, the additional task of creating a provisional internal code and re-labelling goods has been painstaking.

The same can occur when a coded item cannot be traced in the range of pharmacological goods. In such a case, after consulting the updated GS1 Master List, a provisional code is supplied. Thanks to the GS1 web service, the information can be updated directly, incorporating new products (new suppliers, new presentations, etc.).

Furthermore, in this phase, there is currently a need for the additional task of manually repackaging drug presentations into unit-dose packaging. Each new dose must then be relabelled to maintain the information associated with the medicinal product. Coverage is currently only partial, but there are hopes of including 100% of drugs in unit-dose packaging for hospitalised patients.

## Next steps

The SSMOCC plans to use the GS1 coding system for more than just drugs. Our goal is to integrate all goods into the system. This would achieve better large-scale logistics, which would no doubt influence the planning, programming and organisation of procedures relating to supply and storage and the Network pharmacies.

The records and monitoring systems in place help to optimise stock levels and rotation. This has a clear effect on costs, and in the case of medicinal products, the computerised monitoring of expiry dates implies fewer losses as a result.

In any event, the greatest progress brought about in terms of safety and quality is by far drug traceability, which is a huge step forward in the history of public health in Chile.

There are still great challenges ahead for the SSMOCC and for all related institutions – health services, pharmaceutical companies, CENABAST, etc. An integrated national system must be put in place, with common standards that allow for the exchange and monitoring of information regarding drugs and healthcare products.

The Red Occidente has made the first steps in this direction, placing the institution in the forefront of modernization in healthcare management.

### ABOUT THE AUTHOR

**Dr. Carolina Cerón Reyes**, Director of the Servicio de Salud Metropolitano Occidente, joined the institution in 2007 as Assistant Medical Director. This year she assumed the position of director of the Department. In both posts she has played a leading role in the implementation of the HIS project.

As a surgeon with a diploma in Healthcare Institutions Management, an MBA specialising in Health and a diploma in Public Policy and Social Management, Dr Cerón has extensive experience in public health management.

# Medical information support system using Personal Digital Assistants (PDAs)

## ABSTRACT

Kyoto Second Red Cross Hospital in Japan has introduced a medical information support system using Personal Digital Assistants (PDAs). This system, which is connected to the Electronic Medical Record (EMR) system, enables clinical staff to easily verify and record that the right medication is administered to the right patient. Currently, seven types of PDAs are in operation for the purpose of risk management and to provide service support to nursing staff; the use of PDAs contributes to reducing risks and to streamlining the work of the medical office.

By **Dr. Kiyohito Tanaka**, Project Manager Hospital Distribution, Kyoto Second Red Cross Hospital

## Background

Medical safety issues have been coming under increasingly intensive public scrutiny in Japan, with many critical eyes being turned on medical institutions. Any case of medical malpractice in a medical institution could lead to liability for massive financial compensation to the affected patient and/or their family, including damages and legal costs. Furthermore, such a case would seriously impair patient/user trust in the medical institution concerned and rebuilding that relationship could take a long time. The potential for such situations to arise further underscores the importance of risk management in medical practice.

Kyoto Second Red Cross Hospital in Japan is fully committed to risk management aided by use of Personal Digital Assistants (PDAs).

## Overview of Kyoto Second Red Cross Hospital

The hospital is a 640-bed, acute tertiary care facility with a medical emergency centre. Since June 2006, it has been implementing a fixed amount payment system based on the "Diagnosis Procedure Combination" (DPC). An Electronic Medical Record (EMR) system was introduced in January 2004 and some 700 desktop terminals are currently in operation.

With the introduction of EMR, the hospital also introduced a risk management system for medications using PDAs. Through the PDAs, the system records and verifies all the data relating to infusions, thus making it possible to reduce risks and mistakes. Based on the result of the operation of this system in 13 wards, the use of PDAs has been extended to other hospital information systems such as a system for operating room support, endoscopic operations and in-hospital distribution.

## System overview

Currently, seven types of PDA units are in operation at the hospital. These fall into two broad categories: risk management and service support (recording by nursing staff).

### 1. PDAs for risk management

#### (1) PDAs used for identifying IV medications

As part of the system for identifying IV medications in hospital wards, the following checkpoints should normally be observed:

- Verifying the identity of the patient when administering an IV medication
- Ensuring that the prepared IV solution is in line with the doctor's prescription.

In order to achieve this, the hospital has implemented the "Solemio NURSE" system and provided its clinical staff with PDAs. This system enables the pharmaceutical department to prepare the medication according to a doctor's prescription as shown in the EMR, and to issue a barcode label for the IV fluid bottle. In the wards, nurses scan, with a barcode scanner, the barcode on each vial/ampoule of medicine to be mixed; the barcode contains its Global Trade Item Number (GTIN). This process verifies that the details of the mixed medication match those in the doctor's prescription (Fig. 1). In addition, nurses use PDAs equipped with a barcode scanner to verify the identity of the patient and the fluid bottle upon giving an IV infusion and removing a needle. This data is transferred to the EMR system via wireless Local Area Network (LAN). Thus control of every single aspect of "6W1H" (when, who, whom, what, where, why, and how) can be attained (Fig. 2).

## Medical information support system using Personal Digital Assistants (PDAs)
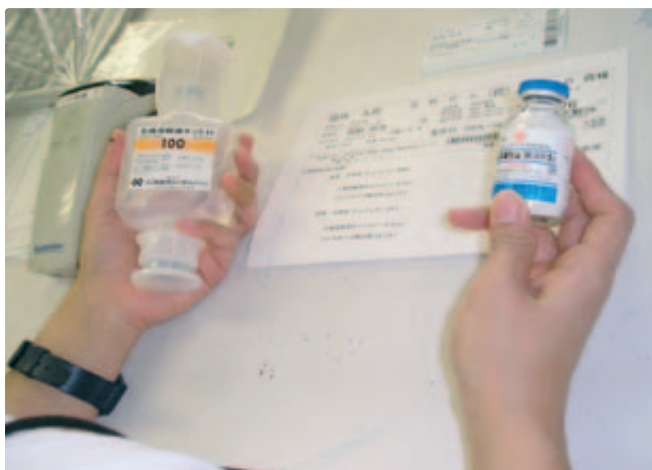


Fig. 1 Barcode for IV fluid bottle and mixing medications

This system is extremely effective in ensuring that the IV infusion given to a patient conforms to the doctor's prescription and, as it holds 6W1H data for each given IV infusion, it can be queried at any time.

Most PDA-based systems offered by other manufacturers cannot provide doctors' instructions in real time, this means that a time limit has to be set when issuing an IV instruction. Such an operational shortcoming can sometimes seriously reduce the advantages of electronic systems.

### (2) PDAs used for Endoscopy Support System

"Solemio ENDO" system, which is in use for endoscopic examinations in the hospital, fully embodies the concept of "entry upon implementation" which refers to data entry at the time of examination. In addition, it enables data entry and data management of details of pre-exam procedures and treatment devices used. In the examination room, the PDAs display a list of examinations to be conducted on that day and the patients that are to be prepared for pre-treatment are confirmed. The barcode scanner PDA is used to scan the drugs used for pre-treatment. A GS1-128 barcode can be scanned from a list issued by the hospital distribution system for medical materials that are used but are not marked with a bar code. The GS1-128 barcodes use a standardised system with application identifiers, enabling not only internal ordering within the hospitals but also external ordering from suppliers.

### 2. PDAs for service support purposes

### (1) PDAs as media for recording nursing care in hospital wards

Due to their simplicity and portability, this is the most common usage of PDAs, recording a patient's conditions right at the bedside. In contrast, there has been a similar identification system using mobile notebook PCs. However, in the event of an emergency, it may be more likely that the notebook PCs be left in a patient's room.
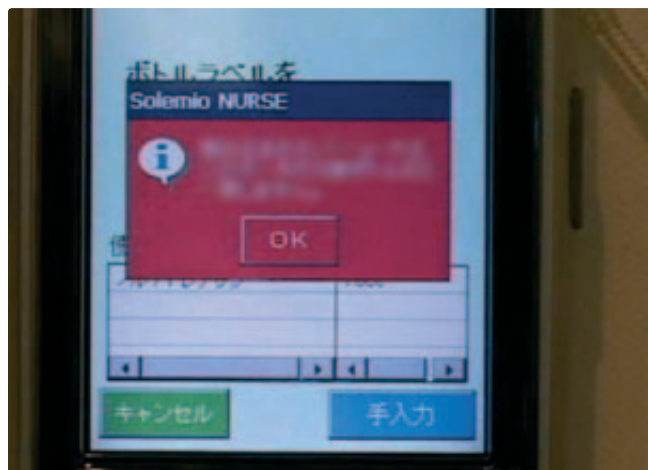


Fig. 2 Patient identity verification upon IV injection

### (2) PDAs used for operating room support system

The operating room support system is also adopting PDAs. The function of "Time Stamp" of PDA is fully utilized to record all the data of the treatment during operations.

The scheduled operations for that day are transmitted to the PDAs. This information is checked against the barcode on a patient's wristband to verify those who are scheduled for surgery. Barcodes for medications and medical/surgical materials are internally integrated GS1-128 barcodes issued from the distribution system. During the operation, scrub nurses record implementation information by scanning each barcode of every medication and medical/surgical material used (Fig. 3).



Fig. 3 Operating Room Support System

## (3) Application for endoscope disinfection (RFID-based PDAs)

PDAs equipped with IC-tag readers are used in endoscope cleansing and disinfection. This has enabled the establishment and implementation of an endoscope disinfection management system whereby every endoscope that has an IC-tag showing its type and serial number is linked to the disinfection machine and the disinfection personnel (Fig. 4).

## (4) PDAs used for distribution system

In the case of emergencies, when medication is used from ward stock rather than dispensing from the pharmaceutical department, PDAs on the ward are used to scan and record the dosages. Thus, the system not only holds usage history but also facilitates order management (Fig. 5).

## (5) PDA operation in ECG system

Many commercially available electrocardiograph monitors are huge in size, which can sometimes lead to significant difficulties in shifting the equipment in the event of an emergency or in using it in a cramped environment. Therefore, the hospital has introduced a system where a PCI card with electrode cables is inserted into PDA slot this enables 12-lead electrocardiograms. The cardio graphic record once stored in the PDA can easily be transferred to the EMR system. The physiological laboratory operates a system where patients' electrocardiograms when at rest can be easily viewed and compared to those taken during an attack via the Web server.

## Barcode use with other than PDAs

Currently, sterilisation is performed in the Central Sterilisation Room. To manage instruments by set and by unit, the hospital places barcodes on the set tray or the unit after sterilization. When the instruments are used in the Operating Room or Treatment Room, data on whom they were used and for what treatment is captured and held in the hospital system. In the case of insufficient sterilization or an infection outbreak this information can be retrieved and appropriate action taken.

## Secondary use of data

In addition to preventing errors themselves, analysis of "warning" occurrences that happened at the time scanning can lead to measures for reducing risks. Here, "warning" means alert messages given in the event of misidentification, thereby successfully averting or preventing a potential malpractice situation. The hospital analyses nurses' work details, total workload and "warning" information at the time of, for example, an injection (all of this data is obtained using PDAs), demonstrating the facility's total commitment to improving operating processes. To cite an example, it was found that warnings frequently occur in wards where certain medical practices (e.g., chemotherapy) involve frequent changing of doctor's orders due to changes in patients'



*Fig. 4 IC tag attached to endoscope*



*Fig. 5 Application of PDA for distribution system*

conditions or blood test results. Based on such results, doctors are instructed to ensure the notification of order changes, and this has proven to be effective.

## Conclusion

Use of PDAs within the hospital has resulted in a system that allows data management in every aspect, regardless of time or location. In terms of establishing a "ubiquitous environment," use of PDAs appears to meet medical institutions' needs. From the perspectives of achieving medical safety, ensuring patient safety, developing traceability, and streamlining medical office work, Kyoto Second Red Cross Hospital has certainly proved that PDAs can be used as effective tools.

### ABOUT THE AUTHOR

Dr. Kiyohito Tanaka is Vice-Director of the department of Gastroenterology and Project Manager of hospital distribution in Kyoto Second Red Cross Hospital (K2RC). He leads four projects: optimization of Purchase for Medical Material Project, safety management for injection and infusion, business improvement for operation room and sterilization centre, and business support for endoscopic centre.

# Project Prometheus: Electronic administration within the blood transfusion chain

## ABSTRACT

The implementation of an electronic blood transfusion administration record, utilising Bar code Point of Care technology (BPOC) in the blood transfusion process can dramatically improve patient safety and prevent the wrong blood products from being administered to a patient. The way this solution is designed and developed is crucial for the acceptance and implementation in our healthcare organisation. This article outlines how we used the principles of Agile Software development and Lean Thinking to build a software system based on a root cause analysis of the blood transfusion process.

Article by **Erik Zwarter**, Project Manager Healthcare Logistics, Erasmus Medical Centre

## Background

In 2008, Erasmus Medical Centre, Rotterdam (the Netherlands) started this initiative to improve patient safety and reduce the "wrong patient" events. Based on information from the nursing staff and the risk management system, the BPOC implementation was considered crucial for the blood transfusion process.

The Dutch TRIP foundation (Transfusion Reactions in Patients) reported 190 events in 2008 for the 11 participating hospitals.

|                            | 2008 |
| -------------------------- | ---- |
| Wrong Patient Event        | 190  |
| Blood to wrong patient     | 57   |
| Near accident              | 53   |
| Incident                   | 80   |

Source: ISBN/EAN: 978-90-78631-07-1 TRIP report 2008 – Hemovigilantie.

The utilisation of a BPOC system is based on six components:

- The Information System (IS)
- The healthcare processes
- The interface between IS and device
- The objects
- The scanning device
- The identification technique

## Information system and healthcare processes

Erasmus MC's longstanding relationship with Bodégro, their module LabTrain blood transfusion software, made implementing very easy and flexible. System development and implementation based on Agile Software Development guarantied maximum input from nursing staff and an expected outcome of the software. The system provided supply chain data and information that was never captured before. We provide data about the reservation process within the transfusion lab, the distribution process to the clinic and the administered blood products to the patients. The system was built and tested in a period of 2 months and implemented in mid of 2009.
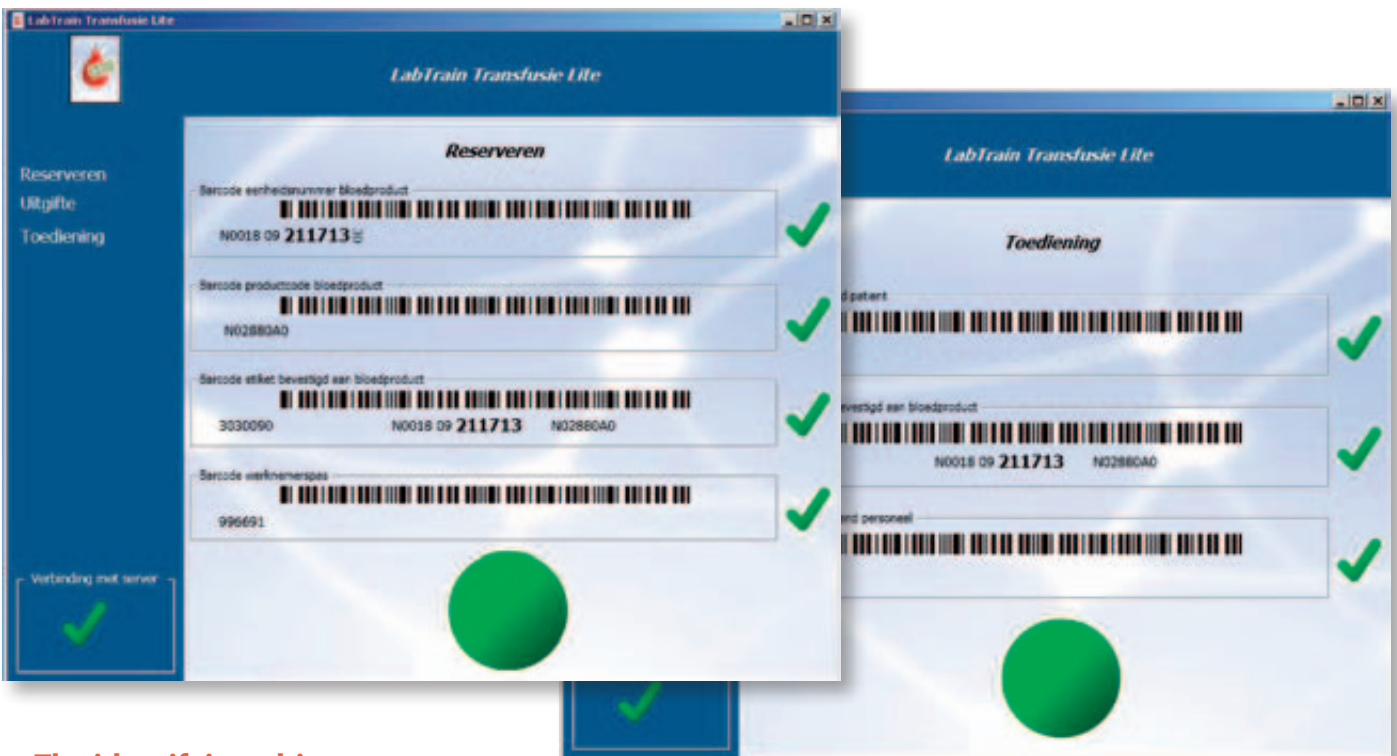
## The identifying objects

The blood products are all compliant with the standard ISBT-128. Since the patient is one of the other identifying objects, one of the preconditions for this project is a patient identification wristband based on standard specifications. The GS1 Standard provided the GSRN in combination with the GS1 DataMatrix two dimensional (2D) bar code with several Application Identifiers. Quality improvements in Lean Thinking are managed by Small Group Activities (SGA). With the SGA we started the vendor selection for the identification of wristbands and printers and several vendors were tested. Within the specifications, the SGA was flexible to determine the outcome. By the end of 2008 the vendor was selected for this project. The identification wristband was such a success for this project; in October 2009 it was implemented throughout Erasmus MC.

## The interface and the scanning devices

With the SGA the healthcare processes were visual mapped, both inside the transfusion lab and ward. These processes and the SGA specified the solutions. In several iterations the project team delivered the prototypes to be tested by the SGA. For the success of this project we chose to be independent from wireless data communication. This interface will be introduced in a later stage. Several scanners and devices were tested and a few "solutions" failed horribly.

## The identifying technique

At this stage the Erasmus MC followed the international GS1 Standards in healthcare. The GS1-128 symbology provided the necessary identifiers for matching several items (e.g. patient

ID, Unique Device (Product) Identifier…). The benefit of the 2D DataMatrix code is that all this information is contained in a very small bar code (approximately 1cm by 1cm).

The benefit of breaking down this project in modular components is the possibility to experiment with different devices, ID techniques and interfaces, through time. The main goal is constant improvement of patient safety and as long as the current solution is the best we will stick to that solution. But as wireless data communication or RFID improves, patient safety will be discussed again within the SGA.

## Post-Prometheus implementation: Small Group Activities

By monitoring and analysing our process data, and through direct observations (Gemba), we are able to identify the root cause of adverse events. We are able to monitor the amount of mismatches in the three stages of the blood transfusion process. If other steps are necessary to improve patient safety we are also able to base these steps on qualitative process data.

It was imperative, as part of the transfusion process, to ensure each blood product is matched with a patient by BPOC. This strategy is supported by the medical staff and the hemovigilance officer. This new process will make the current labour-intensive process of the four-eye principle redundant. The hemovigilance officer is currently rewriting the procedure. Based on 37,000 transfusions per year we will increase quality and save time of the overloaded nursing staff.

**Project Prometheus: Electronic administration within the blood transfusion chain**

## The importance of a standardised automatic identification system

A standardised system for the identification of medical devices consisting of implants and disposables is very important. Eramsus MC has checked the availability of bar codes on the medical devices according to the GS1 Standards and the outcome of the research shows the following results:

*   2004 - 60% have a bar code of which 20% are GS1 (33% overall)
*   2006 - 85% have a bar code of which 34% are GS1 (40% overall)
*   2008 - 90% have a bar code of which 42% are GS1 (47% overall)

In cooperation with GS1 Netherlands, the quality of the existing bar code was verified. Of the medical devices, which have a bar code, the quality was below acceptance level. A lot of them do not meet the requirements of the GS1-128 Standard. These suppliers have been notified and a substantial amount of them have improved their quality significantly.

A few other results:

*   Only 18 % of the bar codes have a Lot Number and Expiry Date
*   28% have a bar code with an E-F qualification according to the CEN-ANSI standard
*   27% do not have bar codes or use an internal code

Suppliers who don't use GS1 Standards (for healthcare) should be encouraged to do so. Only then can the healthcare community benefit from the patient safety improvements that the system has to offer, not to mention the logistic efficiency and cost savings this implies. Looking at the results mentioned above, we have a long way to go, nevertheless on a train that has already left the station. Please get onboard now!

REFERENCES
*   Patient wristbands requirements by the United Kingdom National Patient Safety Agency
*   Patient wristbands requirements by Australian Commission for Safety and Quality in Healthcare
*   www.youtube.com/ezwarter

### ABOUT THE AUTHOR

**Erik Zwarter** is the project manager Healthcare Logistics in the Erasmus Medisch Centrum. He has been active for several years in process optimalisation, based on Lean Thinking. Zwarter led several EPD implementations and project teams. He is now responsible for implementing BPOC and an automatic identification standard within Erasmus MC for domains such as Logistics, Pharmacy and Healthcare.

He is active in GS1 Healthcare and chairman for the GDSN work team Netherlands and member of the steering committee of ZorgDAS. He has spoken nationally and internationally on bedside scanning, bar coding of medical devices and BPOC, amongst others.

http://nl.linkedin.com/pub/erik-zwarter/0/5a8/230

# Stock management of implants through RFID technology

## ABSTRACT

The Complexo Hospitalario de Ourense [Ourense Hospital Complex] has carried out a proof of concept for an innovative system, based on the use of Radio Frequency Identification (RFID) technology, to optimise stock managements of implants. This case study describes its scope and results.

By **Benjamín Rodriguez Nespereira**, Galician Health ServiceHospital

## Background

Stock management of implants consigned to hospitals through a supplier is considered to be a task for hospital purchasing managers. However, there are other parties involved to whom the functional and financial importance is of interest. These include: the supplier, who has a business relationship with the hospital and over time keeps track of restocking the material used, and continually reconciles stock and invoicing; the surgeon and nursing staff, who need information regarding stock to plan operations and who after using said materials are responsible for entering the information in the patient's medical records; the purchasing staff, who must keep track of the stock, its use and the allocation of a product, to validate payment and close the circuit of traceability which is required for implants by law.

## Proof of concept

The *Complexo Hospitalario de Ourense* [Ourense Hospital Complex] has carried out a proof of concept for an innovative system which satisfies the abovementioned requirements. This trial is based on the use of Radio Frequency Identification (RFID) technology. Now completed, it is a good time to discuss its scope and results. The Chinese proverb "*The longest journey beings with the first step*" is perhaps more appropriate than the technical and commercial disclosure of its achievements.

The system is based on two fundamental points: the development of the *Servizo Galego de Saude* [Galician Health Service] management system and the recurrent monitoring that this Hospital Complex in particular carries out of third party warehouses. Without these premises, developing this type of application would have an infinity of needs leading up to its implementation, demanding more urgent, less comprehensive solutions. The test carried out is a reflection of the attitudes adopted by the organisations which aspire toward improvement insofar as their basic needs have been covered.

## Optimising stock management processes

The project provides a systemic approach to all the processes it covers. Although it can be improved in terms of efficiency and information requirements, the test carried out ensures that, from a technological standpoint, all the technologies involved have been successfully integrated.

When an item with these characteristics is received by the hospital, the warehouse management system enters the products into the specified database assigning a unique code to each product which serves as a unique key for the rest of its attributes (GS1 Identification Key, expiry date, lot number, serial number, etc.). There are three ways of entering this information: by manually entering all the item's data and variables into the system; using a barcode reader capturing the GS1-128 bar code; or by way of an EDI DESADV message (Electronic Data Interchange – Despatch Advice). Once that data interchange is defined, the management application sends it to the RFID unit where a label is printed, a Smart Tag, and is stored in its memory, entering it into the database as a product stored in the warehouse in an intelligent closet, which as far as the system is concerned, is seen as another sub-warehouse.
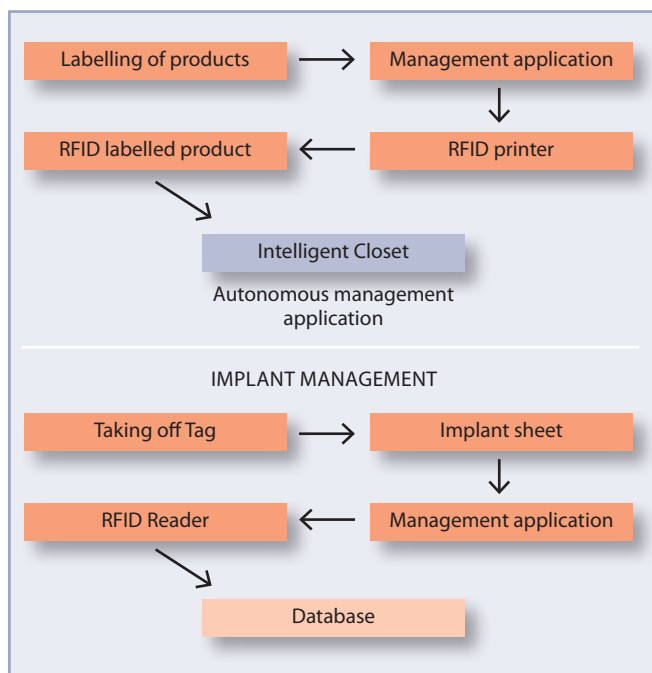
## The intelligent closet

The intelligent closet is a clinical cupboard, made of stainless steel and managed by controlled-access RFID technology in which more than 230 articles can be stored.

Inside, 6 antennas have been suitably placed, which are run by an RFID reader through a multiplexer. The application that manages the closet also allows it to be accessed with a personal ID card, read by a RFID proximity reader, and once access has been validated, the closet opens. The access is recorded. Once the doors close again, a switch activates the Smart Tag reader which identifies each item through a reading cycle using the antennas.

## Stock management of implants through RFID technology

The information obtained is compared with the previous reading, and the replacements or removals made are recorded and stored in a temporary file for the person who entered the closet, including the date, time, movement of items, etc. Each time the closet is closed, it performs a complete inventory in 30 seconds, updating the stock.





### Surgical procedures and medical records

At the same time, if an operation is planned which will involve devices stored in the warehouse, the clinical database is accessed and the patient's details and medical record number are imported and recorded using RFID in another Smart Tag. This is attached to the implant sheet and brought into the operating room with the rest of the patient's documentation.

Once the surgical procedure has been completed, the Smart Tags of the articles used are attached to the implant sheet and using a desktop computer RFID reader, all the products used during the surgical procedure are entered. The information is then stored in another temporary file which must be reconciled with the file containing the information about the items taken from the closet.

Immediately after an item has been entered into a set of medical records with an RFID label reader, the product is considered "consumed" and the tables that reflect this movement are updated in the purchasing department.

### Reconciliation

Once a day, outside of working hours, the system launches a reconciliation and inventory process, performing several

readings of the items stored in the closet to thereby obtain a 100% accurate count of stock. Using this information, it updates the quantities on which the next movements will be based and reconciles the removal of goods against the information from the implant sheet readings. The differences are then dumped into another file allowing the management systems to validate their use and pinpoint their origin.

When the whole process has been completed, the supplier has a list of items to be restocked and the current stock in the closet. This information is available within 24 hours, by way of EDI, which can be accessed on the Internet. With this information, the entire cycle of replenishing, invoicing and restocking can be started.

### Conclusion

As the current project stands, it would be premature to call this a pilot test, let alone a successful case study. Nevertheless, this trial has demonstrated that RFID technology is reliable enough to consider solutions of this scope, and that integrating management systems and technology does not requite great effort. Accurate, trustworthy information can be obtained without the decisive intervention of the user.

It is important for this project to continue, due to the financial value of the resources it watches over and the challenge it involves. The aesthetic and design elements of the closet should be improved mechanically, minimising reading times and costs. One RFID reader should be able to control several closets. A display should be added, so the surgeon does not have to open the closet to find out what is in stock. A "0 series" should be achieved, both in its production and in the application that manages the process, so it can become an industrial product.

### ABOUT THE AUTHOR

Benjamín Rodríguez Nespereira (Industrial Technical Engineer) is Assistant Director of Financial Resources of the Ourense Hospital Complex and Manager in the Galician Health Service Logistics for an Innovation Project based on the use of automatic identification technology and electronic transmission ( Barcodes  and EDI messages). He is Professor of Health Logistics at the Galician Health Public School Foundation. Mr. Nespereira is currently the president of the Health Sector Committee of GS1 Spain.

# Supporting the implementation of a traceability system for the healthcare sector in Colombia

## ABSTRACT

In view of new government regulations requiring the different stakeholders of the supply chain in the healthcare sector to develop traceability systems for medications, Colombian organisations have been left with the need to find the least disruptive solution possible to adapt current processes. This solution needs to be functional and adaptable by the different types of organisations. GS1 Colombia designed CABASnet STL (Online Traceability System), a tool based on the GS1 System of Standards that enables organisations to find product flow and information online and in real time. Cafam and Wyeth Consumer Healthcare (now Pfizer Consumer Healthcare), two of the main organisation's in the Colombian healthcare sector, have lead the implementation of this solution by undertaking a pilot. In mid-2010, it is anticipated that all other suppliers will be invited to begin using the solution.

By **Luis Gonzalo Giraldo Marin**, CEO Cafam

## Background

For the last two years, various stakeholders from the healthcare sector in Colombia have identified the development of a traceability system for medications and medical supplies as a top priority. The system should improve the wellbeing of patients and ensure the complete traceability of products throughout a more efficient supply chain.

New regulations issued in 2007 by the National Government increased the need for a traceability system. Therefore, Colombian healthcare sector organisations were invited to explore solutions that could provide them with full traceability of medications and medical supplies.

The solution selected contains a large number of local requirements (in terms of processes and operations). The consensus of the community was critical as traceability is a process that calls for a joint, synchronised effort throughout the entire supply chain as it involves considerable time, resources and technological development and needs to follow a structured implementation plan.

Cafam, one of the key stakeholders in the Colombian healthcare sector supply chain, has an extensive network of pharmacies nationwide, provides healthcare services and is currently one of the shareholders of the country's largest Healthcare Management Organisations, Nueva EPS (previously the Social Security Institute). Cafam's executives recognised that the regulation set a significant milestone for the healthcare sector and led them to pay special attention to the solutions available that could optimise healthcare services and improve patient wellbeing.

To comply with government regulations and improve their services, Cafam participated in numerous meetings with key associations and organisations from the healthcare sector. In these meetings, one of the issues with achieving traceability was that capture, storage and access to data on medications in real time was poor or non-existent. In many cases, while manufacturers have powerful internal solutions, wholesalers do not have an information system robust enough to store and manage such data.

Therefore, Cafam decided to approach GS1 Colombia. "*Our previous experience with GS1 Colombia as regards product coding and synchronisation, as well as developing solutions on a standard system for both chains and suppliers, made us think that it would be less complex to develop and implement a traceability solution created by GS1 Colombia*", a Cafam spokesman said.

Due to the interests they shared with GS1 Colombia, in regards to the development of a simple solution to solve the traceability challenge efficiently, Cafam decided to play an active role in the traceability pilot proposed by GS1 Colombia. For the pilot, GS1 Colombia's eCom team developed CABASnet STL (Online Traceability System), a tool that could be used by the different stakeholders to trace medications and medical supplies across the supply chain.

CABASnet STL allows the various supply chain stakeholders to check the information on a product at anytime, anywhere using mobile devices or the internet. It is supported by the use of other GS1 Colombia applications, such as CABASnet synchronisation, and is available for use by GS1 Colombia members without the need for any major technological investments.

**Supporting the implementation of a traceability system for the healthcare sector in Colombia**



CABASnet STL supports GTIN, GS1 DataBar, GS1 DataMatrix, and EPC/RFID and, in addition to logistics data and updated images (lot, shipment date, addressee, etc.) from the CABASnet data pool, it is capable of holding and providing product information related to physical characteristics.

## Main challenges

Once the national government had issued the resolution, the organisations in the healthcare sector began to face a series of challenges that put their capacity to work collaboratively with other business partners to the test:

1. Information systems were not ready to handle traceability information: even though manufacturers identify products with barcodes to enable traceability, data was not being captured or used.

2. The awareness of manufacturers and other stakeholders in the healthcare sector supply chain of the importance of participating in an initiative that could provide visibility of medication all the way through to the end user. As many of the manufacturers already had robust internal traceability systems, the idea of having to adjust to a new system operating based on the GS1 System of Standards was not an easy sell. It would be important that lot number and expiration date already marked on product packaging by the manufacturer, be captured automatically by using GS1 standard symbols, such as GS1 DataBar, GS1 DataMatrix or GS1-128,

3. Another interesting challenge faced local subsidiaries of multinational manufacturers, where the parent company determines organisational processes – how to build on what was already in place. Therefore, working with a solution based on international standards became increasingly interesting.

4. It was important also to develop a standard ship notice that would satisfy the needs of the supply chain and the supplier. The ship notices being used contained just one expiration date and lot/batch per product, when in reality, a shipment of just one product may have several lot/batch numbers and different expiration dates.

## Project commissioning

In the end, the development of a two-phase pilot was suggested:

The first phase, "Traceability with bar code without serialisation – sales unit level using CABASnet STL – Online Traceability System", consisted of a pilot test carried out with Wyeth Consumer Healthcare in an effort to provide a short-term solution that would allow the Cafam Distribution Centre, as well as its pharmacy and point of sale staff, to access information online about a GTIN, lots/batches and expiration dates of the products shipped by the supplier.

The objective of the first phase was to connect product flow and information flow (a fundamental enabler for traceability), making use of the GTINs used by the supplier to identify its products.

One additional operational control introduced for the pilot was that the products being received for the pilot was stored in a different location.



Figure 1. PHASE I Work Methodology

TRAINING and RAISING AWARENESS

13 weeks

| Defining the Value Network (Product Flow and Information Flow) | CABASnet Synchronisation Status | Definition of the Product Portfolio Susceptible to Tracing | Defining Locations | Defining Message and Media | Process to Store and Inquire Information on CABASnet STL | Information Storage Frequency on CABASnet STL-PRODUCTION |

Supplier    Client

Figure 2 illustrates how the traceability information was centralised on CABASnet STL during the first phase, with a simple scheme connecting product flow to information flow through the Ship Notice message, based on the active use of the Data Synchronisation process also through CABASnet.

This methodology also required the identification of critical points of sales and the selection of a group of products with similar characteristics; these were treated in a special manner throughout Phase I. On behalf of Cafam and Wyeth Consumer Healthcare, GS1 Colombia played a very important role in training the personnel that were going to participate in this phase of the project.

Product and information flow can be diagrammed as follows:

1. Product Shipment from Supplier DC to Client DC
2. Information Report (SHIP NOTICE) to CABASnet STL
3. Product Shipment from Client DC to Points of Sale / Dispensing
4. Information Report (SHIP NOTICE) to CABASnet STL
5. Information Inquiry by Users (Wyeth Consumer and Cafam) using the Internet and/or a mobile device, upon request or with the permission of a regulating authority.

For this first phase, it was crucial that the solution operated without affecting the existing processes of the supplier or the supply chain.

The pilot was carried out between April and May 2009 and, in the words of Luis Tapias, Administrative Sales Manager of Wyeth Consumer Healthcare "*The objective of this pilot will enable us*

*to establish, based on the different technologies evaluated, in the context of the infrastructure available in Colombia and the horizon of the worldwide pharmaceutical industry development, the implementation of traceability among business partners; it provides a response for the regulatory requirements, generates added value with secondary results and has less impact on product costs for the main benefit of guaranteeing the specific medication for the end user".*

Phase II of the project is currently underway. Its objective is to extend the scope to other stakeholders. The pilot was undertaken with Wyeth Consumer Healthcare, but now has the participation of other suppliers including Novartis and Tecnofarma. A work plan has been designed with these manufacturers with the support of GS1 Colombia, identifying the parties responsible at each stage of the process.

In addition, important decisions have been made, such as using GS1 DataMatrix, taking advantage of the fact that products are already identified with this symbol, thus facilitating the receiving, storage and shipping process from Cafam's Distribution Centre to its pharmacies and points of sales. GS1 DataMatrix was chosen as it can hold more product information than a linear barcode. In addition, several medications are already identified with GS1 DataMatrix by the head office and other countries worldwide use the same technology for similar purposes. The decision was taken together with the supplier in recognition of the mutual benefits obtainable.

In this regard, it is important to point out that the receiving process at the Cafam Distribution Centre included a visual inspection of the expiration date of each lot/batch of products received, pursuant to certain corporate parameters (products
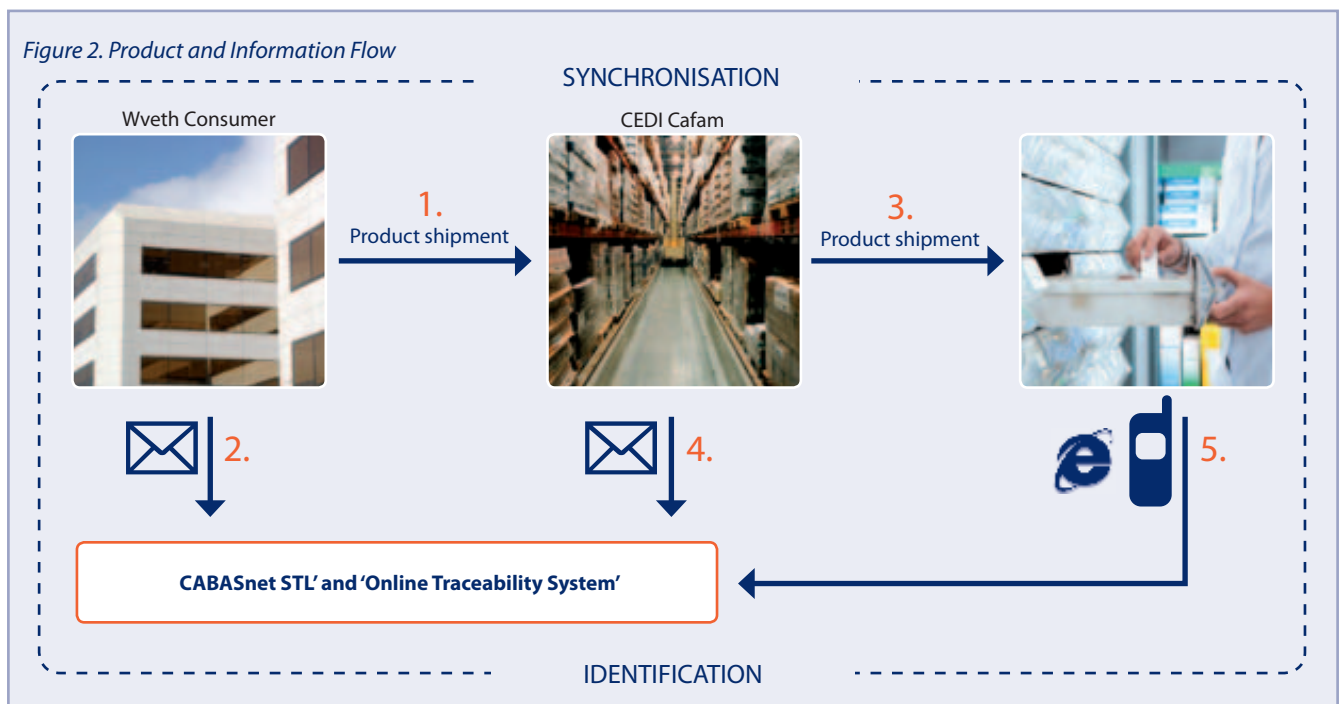


*Figure 2. Product and Information Flow*

**Supporting the implementation of a traceability system for the healthcare sector in Colombia**

with expiry date less than one year could not be received). It was a completely manual process.

In addition, the use of Electronic Product Code (EPC/RFID) on the product insert sent out by manufacturers (box identification) was established. To this end, reading portals were installed at the receiving docks of Cafam's Distribution Centre.

At the same time, work began on a pilot for identification of high-cost medicinal products (sales unit) using EPC/RFID, to understand how the technology would work in this context. In order to manage these products, GS1 Colombia provided cabinets equipped with RFID readers, which were installed at Cafam's Distribution Centre and at selected points of sale.

The second phase is expected to be fully implemented by mid-January 2010 and, by mid-year, a larger number of suppliers is expected to be involved and identifying the range of products selected for full traceability.

In the case of Wyeth Consumer Healthcare, the products identified with GS1 DataMatrix from the head office were selected, but product margin and turnover will also be taken into consideration.

## Benefits

At Cafam, the broadcasting process is expected to begin in mid-2010 once the ship notice with the modifications necessary is approved by GS1 Colombia's e-commerce committee. Thus, Cafam is asking its suppliers implement and achieve total traceability using CABASnet STL. GS1 Colombia fully supports the process of reaching an agreement with all the stakeholders of the healthcare sector.

Although the benefits obtained up to now are more qualitative than quantitative, it is important to point out the impact of using a traceability solution in key processes such as:

1. Specific control by product and lot/batch
2. Visibility of inventory expiration dates
3. Support for decision making and return management
4. Efficient monitoring of products
5. Visualisation of specific points of filtration
6. Increased product safety for the benefit of the end user
7. Better relationships between supplier and supply chain
8. Less product aging
9. Increased level of satisfaction in patients
10. Supply chain efficiency
11. Patient safety (right patient, right medication, right administration, right product, right time)
12. Increased visibility in regard to counterfeits
13. Information regarding the final destination of the product
14. Compliance with government traceability regulations
15. Elimination of manual operating processes to reduce errors
16. Client claims elimination and control.

## Special thanks

We would like to thank the following organisations that have made this project possible:

- Techpoint, our technology ally, who supported us in the process of identifying the requirements for the Distribution Centre and points of sale, and provided the equipment.
- GS1 Colombia for the structuring and commitment to the success of the project
- At Cafam, our special thanks to its executives and the areas of operation administration, information technology and electronic maintenance.
- The Logistics Management Committee of the GS1 Colombia pharmaceutical industry, the roundtable where the different alternatives to establish the best practices of the category are analysed, debated and suggested.
- Wyeth Consumer Healthcare Colombia, for its role and assistance at all the stages of the project.

## ABOUT THE AUTHOR

**Luis Gonzalo Giraldo Marin** is the CEO of the Caja de Compensación Familiar Cafam [Cafam Family Compensation Bureau]. He has held the post since 2005. From the beginning, he has managed to consolidate Cafam as one of the most solid family compensation bureaus in the country, strengthening services in the areas of housing, education, healthcare, recreation, promotion and marketing. Over the last few years, he has promoted new culture and sports-related products and services, in addition to the construction of the Bogotá Fine Arts Theater at Cafam Floresta. Moreover, under his administration, Cafam has developed a large number of solutions focused on optimising services, particularly for the healthcare sector, which is one of top priorities of this compensation bureau.

One of his most important achievements has been the creation of the member and user defence unit, which plays a role in guaranteeing the timely, qualified care of its users, in addition to being a spokesman and making his best efforts to protect members' rights.

# Bar codes and Co.

## ABSTRACT

Today, we are facing an alarming array of bar codes on the packaging of implantable medical devices. Some packages have up to five different bar codes with quite different information and even different symbologies. In the Consumer Goods sector, global standards are enforced by the retail chains; in Healthcare, we see hospitals and suppliers beginning to take action and working together. We are working towards a uniformly usable system, whereby all relevant data will be made safe and readable by scanner. GS1 DataMatrix bar codes appears to fulfil the requirements most favourably.

By **Dr. Thomas Rothe**, University Hospital of Dresden (Germany)

## Background

Vast rows of shelves with screws, bolts, nails, plates, clamps – in hundreds, no, thousands of different sizes, shapes and materials. Add to this bizarre-looking mechanical parts in the strangest forms made out of various metals or plastics, neatly lined up in large cabinets behind glass doors. We are in the operating theatre preparation rooms of the Orthopaedic Clinic at the University Hospital in Dresden. We watch as nurses pull out a gigantic assortment of implant parts and place them on metal screens or roller tables. All parts are clearly marked, and yet now and again we see that where items have long names, only a letter or a digit serves to distinguish a slightly different part in terms of its shape or make-up. It takes someone with considerable expertise to be able to distinguish between these items and understand their medical purpose. And we are not talking about the assembly of inanimate machines; a mistake could have disastrous consequences for a human being's health, as doctors and nurses well know. This is a place where experts work in shifts in several operating rooms at a time; 60 operations per week are the norm, sometimes many more. And in the neighbouring accident and reconstructive surgery, as well as in the neurosurgery just next door, the situation is scarcely different. And this is not just the case at the University Hospital in Dresden.

## Automatic identification of implants

After a successful operation, all implants must be clearly documented with coherent descriptions for the medical records and, of course, they must be reordered from the manufacturer, ready for the next operation. The manufacturer delivers the correct supplies for the shelves within the next 24 hours – provided the right one out of thousands of items was ordered from them – worldwide. A vast network is required in order to do this, a network of information and logistics.

But who is keeping track of all this? Which theatre nurse will be able to distinguish between the items in the future when the cabinets grow even bigger, the shelves even longer? Bar codes on the implant packaging, at least on most of them, remind us of being at the supermarket. So we begin our search, is there a kind of "scanner checkout" here, too?

No, we don't find one; none of the implants are scanned.

Let us take a closer look at the labels on the implants. We quickly realise that all bar codes are not created equal. What at first looked similar, upon closer inspection shows that the manufacturers use very different systems. The system of machine-readable labels is almost fifty years old and there are many different systems around the world. People talk about different "symbologies". We also see that some packages have up to five different bar codes with quite different information and even different symbologies. What should a scanner read here and what shouldn't it read? We even find implants from one and the same manufacturer with different bar code symbologies. How can that be?


*Rows of cabinets with implants*

## Bar codes and Co.



*That's a very long bar code*



*Five different bar codes on one package?*

Let us first attempt to compare with the retail sector. Why does a system that works there, not work for implants (and, unfortunately, not just for implants)? In global terms, the everyday items in retail are often much easier to replace than very specialised medical products. Retail chains exert high pressure on manufacturers to include the goods in their range, or even not to. For these retailers the logistics are the crucial cost element, as every minute in the warehouse and at the checkout counts. So retailers agreed long ago on a globally uniform bar code system and anyone who wants to be in it must participate. When it comes to implants, as a rule, sales do not go through retail chains: manufacturers normally supply consumers directly, that is, the hospitals. For production and sales, manufacturers have built and optimised their own systems, but each manufacturer for himself. This has contributed to the fact that implants cannot yet be scanned in hospitals using a simple system like the one used in the supermarket.

Not yet, but this is beginning to change!

Hospitals operate under cost constraints with more and more responsibility falling upon medical staff. There is no room for error. Making sure that people receive the correct treatment is always paramount. Should an implant be fitted incorrectly, it would not only be a personal tragedy for the patient but there would also be an additional and therefore extremely high financial burden on the company due to the necessary follow-up treatments, For all these reasons, these errors must be avoided.

### Future outlook: GS1 DataMatrix

And in the case of labelling implants with bar codes, there are now proposals to solve the problem. For example, the standards organisation GS1 developed the GS1 DataMatrix. With the GS1 DataMatrix a system is defined which allows all necessary information such as article identification (GTIN), serial numbers, lot numbers, expiry dates and much more to be encoded within very small spaces and to be machine-readable. This is based on a small square graphic pattern in conjunction with a so-called data identification system. This 2D bar code is also regarded as particularly easy to read, due to the "Reed-Solomon error

correction", it is even recognisable if it is partially damaged or covered. The problem of scanners for implants in the operating room is therefore not insurmountable.

The GS1 DataMatrix: extremely small, a lot of information, very easily read by camera scanners.

UNICO and GS1 Germany have already discussed bar code identification of implants with 13 university hospitals from Germany and the Netherlands and the 10 largest manufacturers of implants. The manufacturers were both interested and willing to invest in modern methods of machine-readable labels that followed a uniform standard in the future – so long as the hospitals also pressed for a globally consistent system. Because of its special properties, the GS1 DataMatrix appears to fulfil the requirements most favourably.

Also the providers of hardware and software for the bar code scanners need to come on board, because integration with the existing major HIS and ERP healthcare systems is the hospitals' primary objective. Eventually a global recommendation for the machine-readable identification of implants will be published, offering both manufacturers and hospitals a uniformly usable system, whereby all relevant data will be made safe and readable by scanner.

### ABOUT THE AUTHOR

**Dr. Thomas Rothe** studied at and obtained a doctorate from the Technical University of Dresden. From 1992 to 2003, he has worked in a large German pharmaceutical company in various positions, where he had already initiated a number of organisational and IT projects. In 2003 he became Project Manager at the University Hospital Carl Gustav Carus, Dresden, where he was responsible for the introduction of SAP. Since that time, he has worked on various IT projects as a management staff member. Within the UNICO purchasing group (of which the University Hospital of Dresden is also a member), he does committee work in GS1 and other organisations.

# Cytostatic treatment and bedside scanning: Improving patient healthcare at Geneva University Hospitals

## ABSTRACT

Treatment of patients suffering from cancer requires the use of special medication, customised for the individual patient. At Hôpitaux Universitaires de Genève [Geneva University Hospitals] (HUG) in Switzerland, the high number of patients, who need such a specialised treatment, results in the preparation of over 14,000 cytostatic drugs per year. To improve patient care processes, HUG has developed tools to support this very critical medication process. The overall objective, from the beginning, was to provide safer care as well as responding to security concerns for the technicians and nurses, who have to prepare and administer these potentially hazardous drugs.

Article by **Prof. Pascal Bonnabry** and **Christian Hay**

## Process enhancements

Cytostatics are high-risk medications, proportional to their efficiency against combating the disease. Risk management for cancer chemotherapy has evolved over time at HUG:

First of all, since 2005, cytostatics are electronically prescribed by physicians, by integrating a number of factors and patient information, allowing them to select the best protocol to apply. The amount of available clinical data has increased over the last decade, which has allowed prescriptions to be more specific and medication to be increasingly customised. Physicians have to be able to efficiently manage all this data. Considering the high-risk of prescription errors, a template 'order-set' and an 'electronic prescription system' was developed, integrating medication schemas based on the best evidence. This first step has allowed HUG to leverage collective experiences and to reduce the potential of prescription errors.

Secondly, between 1999 and 2002 all the drug compounding processes in the hospital pharmacy were centralised. Thirdly, a computerised solution was implemented to support the production of cytostatics, bridging the electronic prescription to the computer-supported manufacturing process.

Last, but not least, information is now automatically captured at the point-of-care. Cytostatics have a potentially very short lifecycle, in addition to other characteristics, which make them unique in the medication process. The need to capture that the right medication (in its right dosage) is going to be administered to the right patient at the right time by the right route of administration (the so called "5 patient rights") is crucial. This step required the bags, containing the cytostatics, to be specifically labelled and for the patient and the caregiver to be identified in such a way that automatic data capture can be processed.

## Risk analysis to support solution choice

Administering cytostatics to patients has been analysed carefully to select the best and most efficient solution. The strategic approach was built on the three pillars proposed by the Joint Commission International (JCI, 2001):

- Prevention - based on a risk analyses, processes are formalised, staff are trained;
- Diagnosis - based on the incident reported, root incident causes are analysed;
- Treatment - corrective measures are put in place.

Because of the low rate of incidents, and therefore the difficulty to measure improvement, a prospective risk analysis has been conducted. Several methodologies for risk analysis have been explored; FMECA (Failure Mode Effect and Criticality Analysis) was selected as the most appropriate. FMECA has been used for various high-risk care processes, including parenteral nutrition or chemotherapy.

The analysis was used to provide evidence about enhancements of the initial actions (prescription protocols and centralisation of production), and to anticipate the benefit of information technologies in the prescription, production and administration processes.

**Cytostatic treatment and bedside scanning: Improving patient healthcare at Geneva University Hospitals**



## Implementation of IT at the point-of-care

A multidisciplinary team has been set up to conduct the risk analysis. The team determined the potential failures in the processes (split into 5 phases) and their criticality. Looking at the point-of-care, the risk analysis has identified how the final check, at the point-of-care, is complex.

It includes the following control points:

- Control Patient ID: Patient – Protocol – Product
- Control Product ID: Protocol – Product
- Control Dose: Protocol – Product
- Control Route: Patient – Protocol – Product
- Control Day: Protocol – Product – Calendar
- Control Expiration: Product – Calendar
- Control Conservation: Product – Conservation

Automatic Identification and Data Capture (AIDC) provides more efficiency than check lists, by documenting the processes at the same time. The reduction of the criticality at the patient's bedside with bedside scanning, provided the following estimates:

- wrong patient: 75% reduction
- wrong administration route: 50% reduction
- wrong flow rate: 50% reduction
- wrong administration day/time: 50% reduction
- wrong drug or drug expired: 50% reduction

To enable the AIDC solution, it was decided to use GS1 Identification Keys and the GS1 Application Identifier (AI) System.

The latter did not provide an AI to capture expiry date and time, and therefore – together with the Hospital of Dijon in France, HUG submitted a Change Request to GS1, which was approved in 2005. Cytostatics are now labelled with a single GTIN (Global Trade Item Number), a serial number (which is a sequential number, delivered by the software managing the manufacturing processes) and an expiration date and time.

In a first stage, RFID tags have been tested because of the ease in capturing information they carry, and because staff identification badges already included an RFID tag. At the time of the first tests, technology raised unexpected barriers; tags on the staff badges were on a different frequency to the tags on the cytostatics' label. As the hospital uses a large number of PDAs, it provided the opportunity to use them for data capture. The RFID reader, plugged into the existing PDAs, only read one frequency. Additionally, PDAs were at that time very insensitive in their wireless connection, which caused connectivity disruptions.

Tests made, with voluntary staff, demonstrated that the new processes were meeting their expectations, when used in optimal conditions. In the wards, the connectivity issues were of concern and lead to a reconsideration of the hardware solution.

After this learning, it was decided to implement a system using bar codes, marking the bags with a GS1 DataMatrix (2D bar code) as well as marking the patient wristbands. Staff are recognised with their log-in. Instead of PDAs, laptops are used on trolleys, as their robustness in wireless connection is stronger, compared to PDAs.

## Conclusions

To ensure end-user buy in, the implementation of bedside scanning for cytostatics took many months. Nurses were involved in several trials to measure and monitor their satisfaction level and understand their expectations. Currently a project addresses the impact of ergonomic and acceptance to process compliance in the cancer chemotherapy process at the patient bedside.

Learning by doing has been one of the key benefits of the project. Safer, and better documented, processes provide the patients with the care services they expect from a leading hospital. Learning by doing is also the tagline of HUG's communication with its suppliers, as it has now demonstrated that GS1 bar codes can be read in hospitals when care processes present a certain level of risk. Suppliers understand this as well as health authorities; recently a recommendation for the labelling of injectables has been adopted by both manufacturers and hospital pharmacists, with the support of Swissmedic (the Swiss surveillance authority for medicines and medical devices). At HUG, cost effectiveness of point-of-care bar code verification has been demonstrated in the domain of the cytostatics. Further projects are planned, using GS1 Standards, for example controlled products (narcotics). Other hospitals visit HUG to see how the loop has been closed for the benefit of the patients.

## ABOUT THE AUTHORS

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**Christian Hay** currently works for GS1 Switzerland and GS1 Global Office. Educated as 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. Christian is board member of the Swiss Medical Informatics Association and has recently been elected Chair of IHE-Suisse.

# Health procurement leader turns to Australia's National Product Catalogue to improve tendering

## ABSTRACT

The 'single source' of item master data for health institutions in Australia, the National Product Catalogue (NPC), has been used successfully by one of the state health jurisdictions to improve the quality of data sourced for its pharmaceutical tendering process. In 2009 Health Purchasing Victoria (HPV) requested suppliers who wished to tender to supply pharmaceutical products, to provide tender data in the format of the NPC Browser Template. For current NPC Ready / NPC Populated companies (loading validated data to the NPC), this provided a simplified process for tender submission. For HPV, this resulted in a 60% improvement in data matching with items from the current contract. The NPC is an initiative of the National E-Health Transition Authority (NEHTA) and hosted on GS1net, GS1 Australia's data synchronisation service.

By **Tom Truman**, Manager Tenders and Contracts, Health Purchasing Victoria

## About Health Purchasing Victoria

Health Purchasing Victoria (HPV) was established in 2001 by the Victorian State Government to facilitate access by public hospitals and other health related services to goods and services on best-value terms. HPV contracts can be accessed by 76 public hospitals and healthcare services that provide healthcare to more than 5 million Victorians. HPV achieves optimal collective procurement outcomes through innovative practices and collaborative partnerships and by engaging public health service providers, consumers, funders, regulators and suppliers.

The organisation's vision is to be a health procurement leader in Australia, acknowledged for innovation, ethical procurement practices and transformation of the health supply chain. HPV's strategy is aligned with the Federal Government's National eHealth Strategy which is being implemented by the National eHealth Transition Authority (NEHTA). The Strategy outlines four strategic priorities:

- Urgently develop the essential foundations required to enable eHealth.
- Coordinate the progression of the priority eHealth solutions and processes.
- Accelerate the adoption of eHealth.
- Lead the progression of eHealth in Australia.

## The National Product Catalogue

In consultation with the Australian states and territories, as well as the federal government, NEHTA initiated the National Product Catalogue (NPC) as the 'single source' of item master data for health institutions seeking to purchase medicines, medical devices and other necessary healthcare items.

The NPC, which has been endorsed by all state, territory and federal health departments in Australia, is a single repository of product, pricing and healthcare data for all health industry product categories for the purpose of data synchronisation. These categories include pharmaceuticals and medical devices (such as orthopedics, implants, dental products, etc.).

The NPC is hosted by GS1 Australia on GS1net, a GDSN-certified data pool used in Australia and New Zealand by more than 1,400 companies across a number of industry sectors. This platform enables the secure sharing of item master information such as product identifiers and descriptions, units of measure, package contents, product classification, pricing and related healthcare information.

For suppliers in the Australian healthcare sector to become 'NPC Ready', all of their product and price data must be loaded to the NPC, the data validated, and published to the NPC data recipients (i.e., health jurisdictions and private healthcare organisations). Some organisations take a phased approach and achieve NPC Populated status as they load segments of their product range. The validation step in the process, performed by GS1 Australia, is crucial as it ensures the quality of the data provided which will assist all jurisdictions such as Victoria to overcome difficulties in validating tender outcomes.

## Health Purchasing Victoria tenders

Every year HPV is required to consult with public hospitals and health services to develop its Confirmed Annual Tender Program. HPV then publishes Requests for Tenders to establish best-rate prices per product and/or pricing benchmarking.

To assist with tender development and viability assessment, hospitals and health services are requested to supply data and information to HPV about their current purchasing habits and usage volumes. HPV then uses this data to form valid judgments concerning pricing viability of tenders and to perform evaluation of tender outcomes.

For a number of years, HPV has had an established policy of preference for tenderers who demonstrate the highest level of compliance with the requirements of the NPC as well as use of other aspects of the GS1 System, such as GTIN allocation, bar coding and eMessaging capabilities.

Flagging supply chain efficiency as a priority, HPV has also encouraged tenderers to offer and describe any current or proposed supply chain solutions that could provide a demonstrated improvement to the efficiency and effectiveness of delivery.

HPV asked the tenderers to outline the anticipated benefits to all Victorian public hospitals and other health and related services arising from the implementation of solutions, including how the success of each solution would be measured.

## The 2009 pharmaceutical products tender

Working collaboratively, the Victorian Department of Health and HPV recognised the need to improve the data integrity within the Pharmacy supply chain. HPV resolved to integrate the utilisation of NPC data into the tendering process. The steps taken were:

1.  Tenderers were to submit the item and price data relating to products they were tendering in the 'GS1net / NPC browser template format'. The browser template is a csv file format that can be used by suppliers to load data to the NPC and also read data output from the NPC. Prior tenders had requested suppliers enter data into a proprietary HPV spreadsheet, which created additional work for suppliers.

    For existing NPC Ready / NPC Populated companies, this meant that provision of product data for the tender simply meant downloading information from the NPC and adding appropriate tender pricing. Non-NPC Ready / NPC Populated companies were required to get familiar with the data requirements and prepare their data. However, these companies then had data ready to load to the NPC.

2.  HPV stipulated that it would prefer to enter into an agreement with tenderers who would load and publish all product information and pricing for products selected as part of the contract on to the NPC prior to execution of the contract. Loading of this data is required at least one month prior to the anticipated commencement of the contract on April 1 2010, or as otherwise determined by HPV. Data must be published to both Victoria Health (as a data recipient) and also any wholesalers / distributors nominated in the tender submission as authorised suppliers on behalf of the tenderer.

3.  Tenderers would be required to maintain in a timely fashion, all product data loaded to the NPC for contracted products, for the life of the Agreement. Should a contractor fail to load all product and price data to the NPC for any deliverable, HPV also reserved the right to contract with an alternative tenderer for supply of those products.

## Tender submissions

The Request for Tender was issued on August 20, 2009 and the tender closing date was October 2, 2009. Significant supplier education and engagement was undertaken prior to the tender. This took the form of two supplier seminars (tender briefings), help desk support provided by GS1 Australia, and face to face supplier meetings.

Using data from past tenders, HPV was able to assess if the new tender data provision process had any impact on the rate of response to the tender.

HPV received 35 tender responses, including responses from all but two incumbent suppliers. Twelve responses were from tenderers not currently on contract, and approximately 3000 product lines were tendered. All distributors responded to the tender and all have now published GTINs to the NPC. Of the currently contracted suppliers who responded, all but three have published to the NPC. Overall, the number of tenderers and number of items tendered has not changed appreciably since previous pharmaceutical tenders, which indicates the new process has not discouraged participation in the tender. Refer to Figure 1.
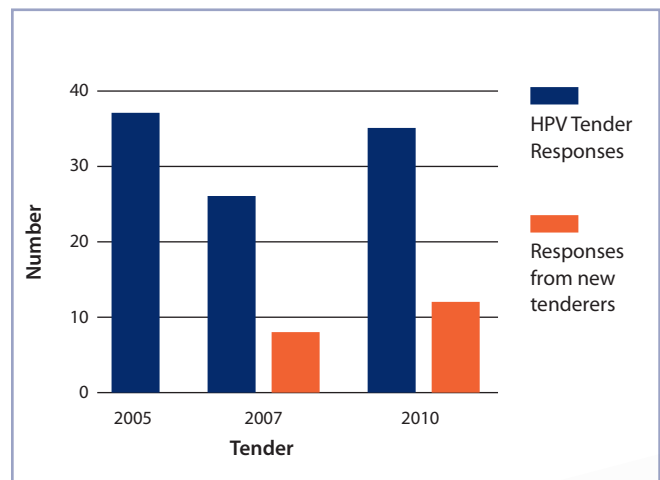


*Figure 1: Number of tender responses by tender*

By September 2009, the number of GTINs published to the NPC by HPV's incumbent suppliers increased from less than 8,000 to more than 10,000, an increase of 25 per cent. Refer to Figure 2. By January 2010, the number of GTINs loaded to the NPC by incumbent suppliers had exceeded 11,000. This indicates that use of the NPC for the tender process had a direct impact on the number of companies loading data to the system.
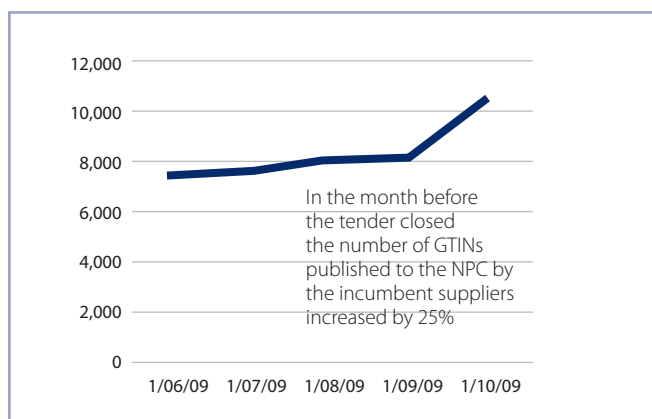


*Figure 2: Number of GTINs loaded to the NPC per month*

## Tender data quality analysis

Using data from the current tender and as well as the previous tenders, HPV was able to undertake two key comparative analyses:

1. Identify if there was a difference in quality of data provided for the current tender when compared between suppliers who had previously achieved NPC Ready / NPC Populated status versus those who became familiar with the NPC data requirements for the tender and did not complete the strict NPC data validation process.

Accuracy of selected data elements were quantified for all tenderers and a comparison made between those who had published data to Victorian Health (i.e., were NPC Ready / NPC Populated) and those who hadn't. The results of the data quality analysis showed that information provided by companies who were NPC Ready / NPC Populated was of much higher quality than that from other companies, as outlined in Figure 3.

Errors included wrong supplier code, full text used rather than a code value, and fields left blank. These errors would normally be detected and rectified through the GS1net validation process.
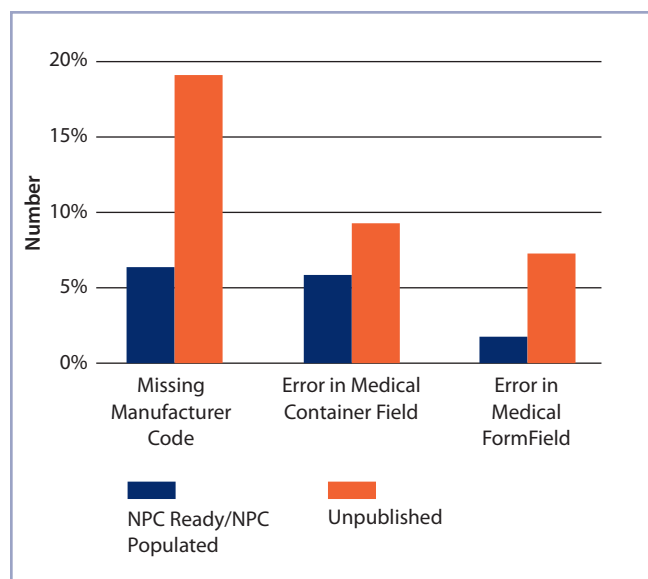


*Figure 3: Error rates for common fields*

Other data issues revolved around the familiarity of the tenderers with the browser template and inconsistent data typing.

- Not all tenderers installed the template for healthcare specific application and this led to additional columns being present in many submissions.
- Data entered directly into the template (rather than downloaded) was sometimes entered as text rather then numeric values, creating difficulty in manipulation.

Generally, these problems were avoided by tenderers who downloaded published data from the NPC to populate the template.

2. Assess the impact of the improved data quality on the financial evaluation of the tender outcome.

There was a 60% improvement in data matching with items from the the current contract, significantly increasing the confidence in financial impact statements for the Victorian Hospitals' pharmaceutical costs.

## Benefits and next steps

For HPV access to accurate and validated data from the NPC made tender analysis and evaluation significantly easier when submissions were from NPC Ready / NPC Populated companies. More companies becoming NPC Ready will further streamline the tender process.

HPV also intends to utilize the NPC for ongoing contract management as a single source for validating, communicating and promulgating data updates. This eliminates the use of multiple spreadsheets and manual data communication and manipulation, and the attendant opportunity for error.
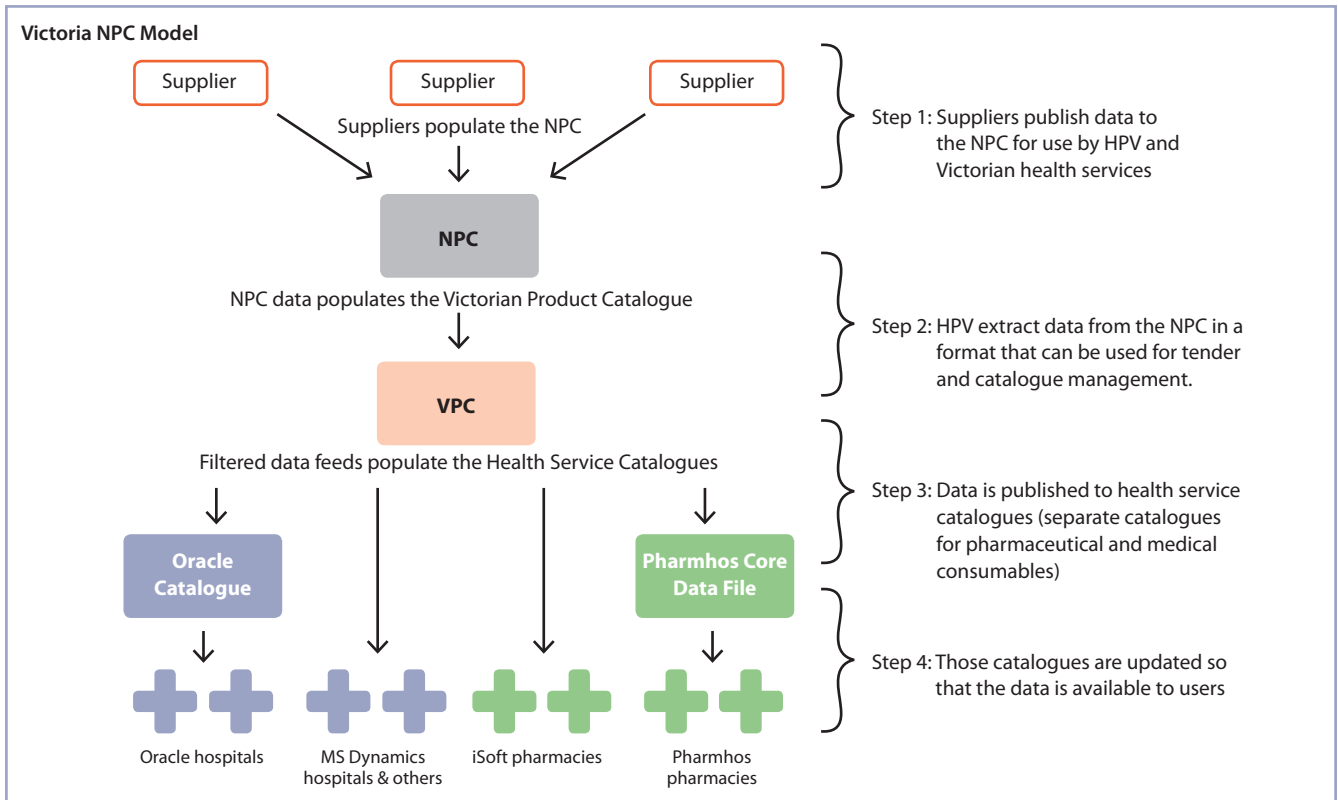
*Figure 4: The potential Victorian NPC solution*

Given these benefits, HPV intends to implement a plan to roll out a similar process for future tenders in other categories of product, e.g., medical devices, consumables.

## Learnings

Given that this tender was the first undertaken using the new process, a number of learnings and process improvements have been identified. These include updates to supplier documentation, specific supplier training sessions in addition to tender briefings and introduction of alternate supplier support mechanisms. Modifications to all of these areas are currently in progress.

Also, due the data quality difference seen as a result of this tender (between NPC Ready / NPC Populated and other companies), HPV are currently assessing their ability to ensure that population of the NPC and completion of the NPC Ready / NPC Population process are mandatory pre-requisites for future tender submission. This will ensure that validated data is presented as part of the tender process.

## NPC implementation in Victoria

Use of the NPC data in contracts and tenders is only one element of the business application of the NPC in Victoria. There is currently a project underway to assess the feasibility to implement a solution to allow the automatic receiving and routing of data from the NPC to the various Victorian health locations. This project is being coordinated by both HPV and the Victorian Department of Health and is integral to the longer term data management and eHealth plan of the state. It should be noted, that apart from the tender process, current data from NPC Ready / NPC Populated companies is being manually accessed by Victorian health locations.

Figure 4 provides an illustration of the potential solution for NPC data synchronisation for Victorian Health.

The opportunity for the use of NPC data in Victoria is significant and the implementation of this system will be a foundation to Victoria's continued development of eHealth infrastructure.

NOTE: The Author would like to acknowledge the contribution the suppliers who participated in the pharmacy tender, GS1 Australia and NEHTA, and his colleagues at HPV, Nigel Allsop, Richard Bowen and Sue McCallum towards assisting with the Pharmaceutical tender and development of this case study.

## ABOUT THE AUTHOR

**Tom Truman** joined HPV in February 2009 from a procurement and contract management role in a public health service. Tom has had over 25 years of experience in the public and private health sector in various management roles in hospital support services, procurement and contract management, including a period as a private consultant. Tom has a degree in Commerce (Deakin) and a Master of Business Systems (Monash) and has a keen interest in supply chain reform. Tom enjoys playing billiards and snooker, and cycling.