GS1 Healthcare
Reference Book
2011/2012

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Inspiration, innovation and implementation

Welcome to the third edition of the GS1 Healthcare Reference Book (Edition 2011/2012).

From this edition, we hope that leaders and professionals will gain valuable information and inspiration on how leading Healthcare organisations have leveraged GS1 Standards to enable automatic identification and data capture (AIDC), master data management, electronic data interchange and traceability. Thirteen remarkable case studies provide a wealth of knowledge, creating opportunities for Healthcare supply chain stakeholders around the world. Beyond the boundaries of each country or region, all stakeholders are facing the same challenges today, to ensure the provision of safer patient care and to increase efficiency, and this should be done using global standards.

We hope that these case studies will be an inspiration, triggering innovation and implementation in your organisation, country or region.

Acknowledgements

Transforming the Healthcare supply chain – Yes, we should!

From pharma security to unique device identification

By **Ulrike Kreysa**, GS1 Global Office
and **Jan Denecker**, GS1 Global Office

"I have a dream…"
(Martin Luther King Jr.)

We have a dream that one day… medicines will be bar coded and scanned at every step in the dispensing process, to avoid medication errors.

We have a dream that one day… medicines will be 'traceable' and verified at the point of dispensing, to fight counterfeit medicines.

We have a dream that one day… medical devices can automatically and uniquely be identified, to enable effective and efficient product recalls and adverse event reporting.

We have a dream that one day… Healthcare will automate all its supply chain process, to increase efficiency and save costs.

We have a dream that one day… all Healthcare stakeholders will recognise that Healthcare supply chains cross borders and that a global framework is needed.

And **we** have more dreams… to turn into reality.

'**We**' are GS1 Healthcare – a global community of Healthcare supply chain stakeholders advancing global standards to transform the Healthcare supply chain, improving patient safety and increasing efficiency. Representing the global Healthcare supply chain, from Pfizer and Johnson & Johnson to the Mayo Clinic and the Hong Kong Hospital Authority.

"Never put off to tomorrow what you can do today."

(Thomas Jefferson)

Over the last 6 years, many volunteers from around the world have invested their time and expertise in the development and enhancement of GS1 Global Standards to identify and automatically capture information regarding products, assets, services and locations in the Healthcare sector, and to share supply chain information between supply chain partners.

Progress has been made in the adoption and implementation of those standards, but GS1 Healthcare urges all Healthcare supply chain stakeholders worldwide to start using the standards in all related supply chain processes, from production to distribution to the point-of-care – there is great benefit for everybody.

"Change before you have to."

(Jack Welch)

Governments worldwide are taking action to address patient safety concerns and the associated rapidly escalating Healthcare costs. Important policy changes are on the way and some of them will have a direct impact on the Healthcare supply chain.

"The best way to predict the future is to create it."

(Peter Drucker)

GS1 Global Standards ensure compatibility and interoperability of supply chain solutions, not only within your organisation, but also in your country and across borders. Without them, how unique is the identification of a product or location? How can purchase orders, dispatch advices and invoices be seamlessly exchanged? How can accurate product information be more effectively shared? Where do traceability systems get reliable physical event data?

Over 100 GS1 Member Organisations worldwide are ready to support you in the implementation of GS1 Global Standards, today.

"The world hates change, yet it is the only thing that has brought progress."

(Charles Kettering)

Roche Argentina: Fighting counterfeit medicines using a traceability system based on GS1 Standards

ABSTRACT

In order to fight the proliferation of counterfeit medicines, Roche Argentina implemented a traceability system in March 2010. The system, based on GS1 Standards, allows the identification of the destination of each unit, and does likewise for the whole distribution chain. Moreover, the patient can validate the legitimacy of the medicine before consuming it (i.e. that the medicine has been released to the market by the corresponding manufacturer and does not have any reported adverse event).

By **Pablo Grimald,**
Roche Argentina

The problem: Counterfeit medicines

Counterfeit medicines are those deliberately and fraudulently processed so that they do not reflect their real content or real source (WHO). Counterfeit medicines comprehend:

*   Absence of Active Ingredient
*   Different Active Ingredient from the declared one
*   Different quantity of Active Ingredient declared
*   Counterfeiting of packaging
*   Adulteration of packaging
*   Inappropriate storage conditions for the product (e.g. in the case of stolen or smuggled medicines)

Figure 1 reflects the consequences caused by counterfeit medicines.

Currently, there is a local trend for counterfeiters to focus on high cost medicines due to:

*   Management of reduced volumes which imply high profits
*   Low investment is required
*   Easiness to hide

The consequences from consumption of counterfeit medicines vary from a lack of therapeutic action to more considerable damage, which may include the risk of death. Most of these medicines are for Oncology treatment, and in many cases provide the only chance of life expectancy to these patients with this serious pathology.

Figure 1: **Counterfeit Medicines**

| Theft | Smuggling | Counterfeiting | Adulteration |

| Storage conditions and irregular transportation | High risk of harm to patient |

| Lack of medical treatment and high risk of harm to patient |

| Manufacturer: economic loss and image damage |

Project objectives

This situation led to the design of a process, which allows the verification of the source of the product before its consumption, avoiding the proliferation of counterfeit medicines, and in case a counterfeit one is found, it contributes to its clear identification.

For such reason, the traceability system has been implemented. It means that each product unit is uniquely identified, in order to track it in the value chain.

Application environment

At the beginning of the project, the first step was to investigate the local and global records on medicine traceability, and these were the findings:

Previous experiences

The existing traceability cases showed:

- In Argentina: important wholesalers who commercialise products for special treatments (Oncology, Aids, Arthritis, etc.) have implemented traceability, but with proprietary coding and identification, not compatible with each other.
- Latin America: implementation of proprietary coding and identification systems at manufacturers was noticed in some countries.
- Experiences in the world: only pilot experiences existed with different identification technologies (RFID and GS1 DataMatrix).

Market standard

- In Argentina: absence of national legislation and existence of traceability systems implemented by wholesalers without a coding, identification or communications standard.
- In the World: in some countries, regulations are very ambiguous, and did not detail neither coding nor technology for code carrier.

Distribution chain

Figure 2 shows a basic diagram of commercialisation of these types of product in Argentina. There are transactions among wholesalers (Step 2).

The absence of legislation that demands the distribution chain to trace units is the obstacle to implementation of steps 2 and 3.

Figure 2: **Distribution Chain**

Manufacturer → Wholesalers → Pharmacies and Healthcare institutions → Patient

Step 1   Step 2   Step 3   Step 4 Consumption
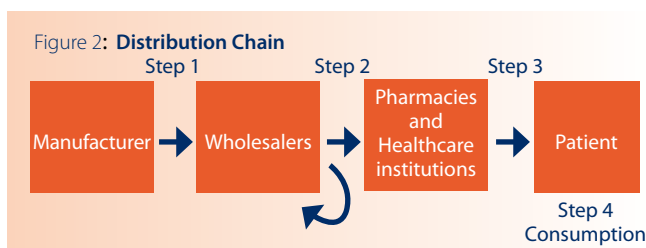
ABOUT ROCHE

Headquartered in Basel, Switzerland, Roche is a leader in research-focused Healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS.

Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised Healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in patients health and quality of life. Roche has over 80,000 employees worldwide and holds several R&D cooperation agreements and alliances.

Logistics

Many of the medicines, which have suffered illicit events, are imported as finished products. Roche's production plants for these types of product are few, specialised and are high volume and highly automated lines. The implementation of identification and traceability at source only for Argentina (GS1 DataMatrix or RFID printing devices) is complex.

Roche, as well as more than 70% of the local pharmaceutical industry, have an internal logistics diagram, which includes three actors, as shown in Figure 3, where the main actors are:

- **Manufacturer:** product owner and responsible to authorities.
- **Distributor:** responsible for manufacturer inventory safekeeping. Manages orders, invoices on behalf of the manufacturer, and in some cases, collects payments. Most distributors delegate the warehouse management, picking, packing and transport to a logistics operator.
- **Logistics Operator:** manages warehouses, picking, packing and transport.

Developed solution

The solution was developed and implemented with the following characteristics:

Market scope

Due to the absence of national legislation, and taking into account the impossibility to have an influence on the whole distribution chain, the implementation was done in steps.

Roche Argentina: Fighting counterfeit medicines using a traceability system based on GS1 Standards

- **Step 1:** Recording sales transactions from the manufacturer to the first connecting link of the distribution chain (Step 1, in Figure 2). Additionally the patient can verify if the product contains a valid serial number from the manufacturer, or identify any events that could harm its quality (Step 4, Figure 2).
- **Step 2:** a data processing solution is implemented for the distribution chain that allows them to obtain traceability, with integration to the system of the laboratories.

Coding and data carriers

Considering the pilot tests already taking place in the world, the use of GS1 Standards was defined for coding and data carriers. This will probably facilitate the adoption of this solution or similar ones using standards, both for the market and for national regulators.

The data carrier is the means that will contain the traceability data. Considering the available technologies (GS1 DataBar, GS1-128, GS1 DataMatrix and RFID) we adopted GS1-128 for the following reasons:

- It is a technology used by all Wholesalers and Pharmacies, which means fewer barriers for the implementation of traceability in the Distribution Chain.
- Traceability solutions currently implemented by local Wholesalers are based on this technology.
- As most products, vulnerable to counterfeiting in the Argentine market, are imported as finished products, and considering that the production plants do not have the infrastructure to handle GS1 DataMatrix and/or RFID, this technology allows us to add a high security tag on finished products, with very low complexity.

Taking into account that this is the oldest technology, from the ones mentioned, and it is believed not to be the most efficient in operative terms for large volumes, a second step will be the migration of the carrier to one of the other technologies available.

Figure 6 shows the tag, which contains the following information:

- GTIN
- Serial number (8)
- Hidden code for validation (scratch-off). This is an additional safety measure to the GS1 Standard, and it is not found in the GS1-128 code, only in Arabic numerals.

The tag contains the following safety measures:

- Logical Measures of Safety
  – Random 8 digit serial number (100 million combinations for each GTIN)
  – Random 6 digit alphanumeric 'scratch-off' code (more than 2 billion combinations for each GTIN)

Figure 3: **Logistics**
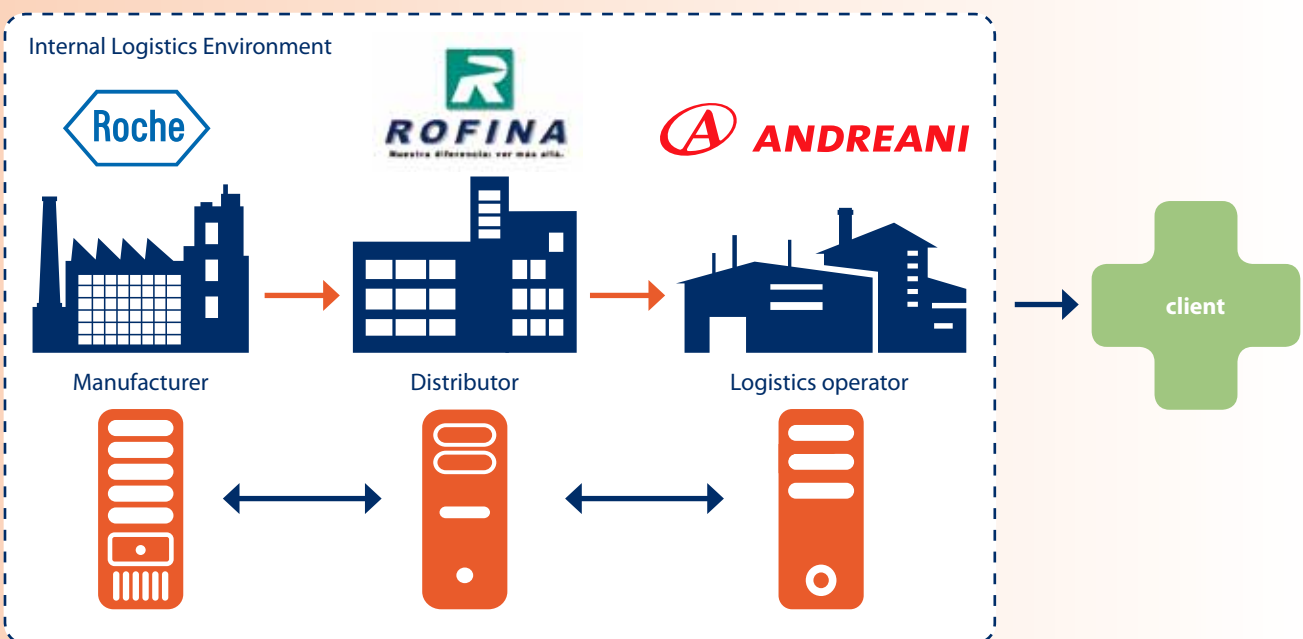
The three actors have independent data processing platforms, which are linked by interfaces that synchronise the information (Inventories, Sales, Accounts Receivable, etc.). Nobody was, at the time of implementation, prepared to handle traceability by unit.

- Physical Measures of Safety in the tag:
  – Destroyable tag when taken off, leaving proof on the container
  – Visible safety measures for the user (micro texts, special inks containing cholesterine, scratch-off, etc.)
  – Safety measures to be verified only by the Manufacturer (UV inks, hidden codes, etc.)

Characteristics of the system

Functions of the system:

Its functions are (Figure 5):

- **Identification:** allows the identification of each unit with a unique serial number. The system generates random unrepeated serial numbers. The products are identified and a relation between serial number and batch is made. It also allows the addition of serial numbers (group of serial numbers in one tag, for example for managing pallets).
- **Traceability:** this module is responsible of managing the serial numbers in the inventory, permitting:
  – Entry of serial numbers, transfers among actors (manufacturer, distributor and logistics operator)
  – Control and adjustments of serial numbers in warehouse
  – Registration of sales transactions (sales and returns)
- **Validation:** informs both the distribution chain and the patient of the status to commercialise or consume a serial numbered item. Consults and validations may be done on the web or by telephone to a toll free number. In the future, the validation will be able to be done by text messaging through mobile phones.

It also generates different types of alert, for example if more than one patient validates a serial number.

Serial number: Status diagram

The serial numbers may have various functions in the system. Each status limits the type of transaction that may be done with it.

Figure 6 shows the status generated by each transaction in a normal sales flow. At the lower part, it also shows the permitted transaction for each status.

Figure 5: **Traceability systems, Main fonctions**

IDENTIFICATION Serialisation	TRACEABILITY Status registration	VALIDATION Verification of authenticity
Assign serial number Identification of units Capturing serial numbers	Receipt Stock management Shipping	Distribution chain Patient validation Alarm
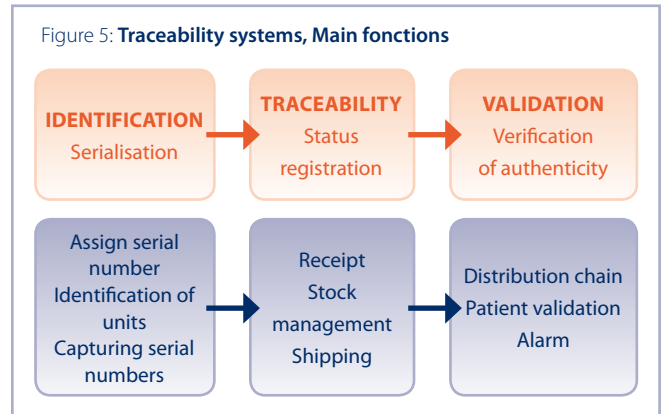
How information is shared

Due to the fact that none of the actors of the internal logistics environment (manufacturer, distributor and logistics operator) have a traceability system implemented, the implementation of a unique and external system was defined, which everyone can access and operate (Figure 7). The advantages are:

- Less interfaces between the systems of the actors, decreasing complexity.
- On-line updating of the serial number status due to the fact that there are no interfaces between systems.

Figure 6: **Serial Number Conditions**

Usual transaction in a sale flow

	SERIAL NUMBER GENERATION	TAG PRINTING	PRODUCT TAGGING	PRODUCT SALE TO CLIENT	VALIDATION BY PATIENT
Generated status	Generated	Entered	Assigned	Sold	Validated
Permitted transaction per status					
Sell from manufacturer	✗	✗	✔	✗	✗
Commercialize in the market	✗	✗	✗	✔	✗
Patient usage	✗	✗	✗	✔	✗

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Figure 7: **Internal logistics and distribution channels**
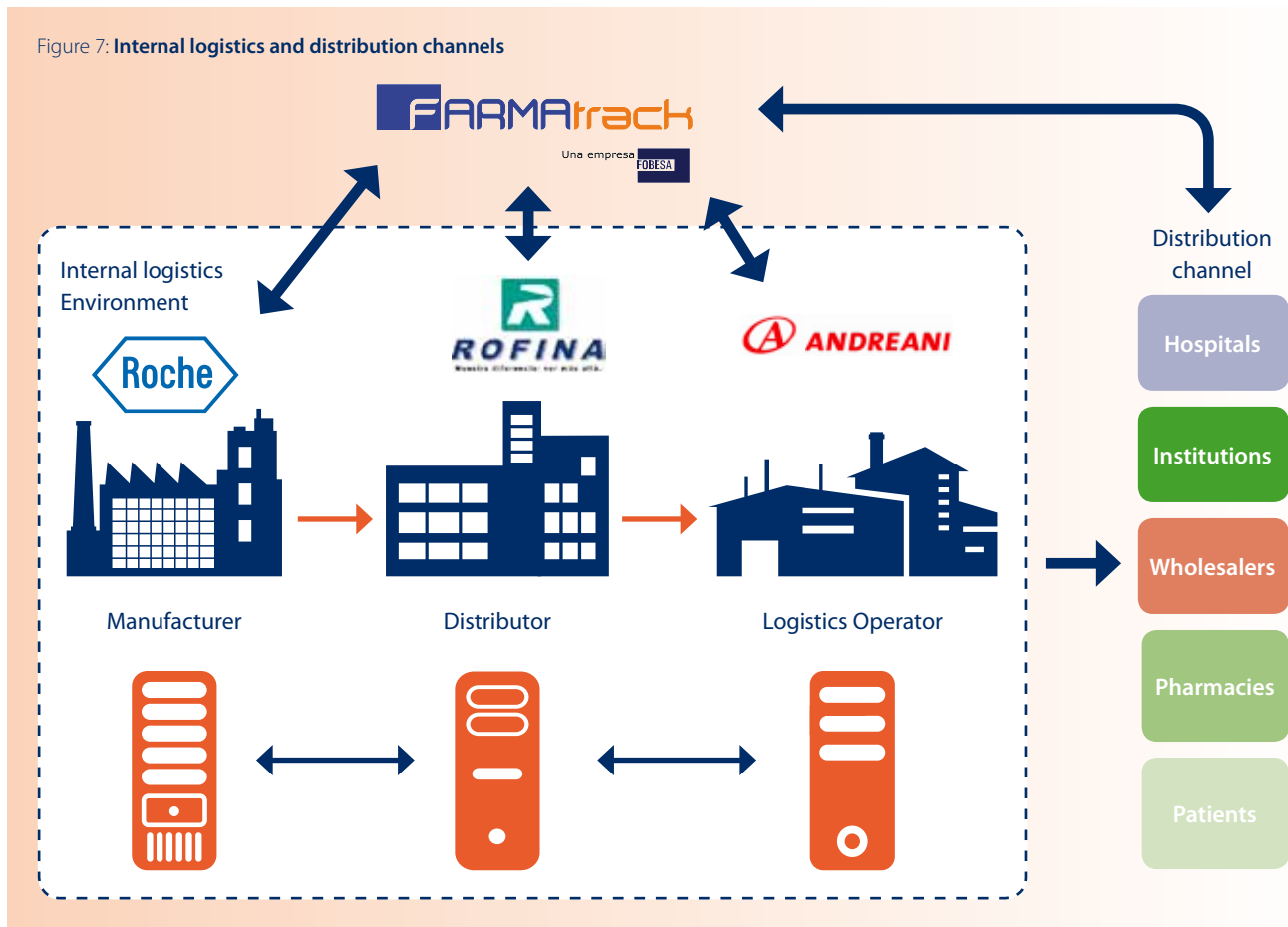
- Unique and centralised information: everyone accesses the same information at the same time.
- Increased safety: considering that the serial numbers are random, and the fact that the serial numbers are found in a unique data repository, decreases the possibility of information extraction.
- In step 2, when the distribution channel is included, the communication will be permitted instantly.

The system is on the web and may be accessed through any Internet connection.

System development and operation diagram

It was decided that the system should be developed by a technology provider with experience in traceability, Farmatrack, from the Fobesa Group was chosen.

In order to have continuous improvements and updates, it was decided to choose the developer for the operation and maintenance of the system; who will provide the traceability service.

Therefore, the Farmatrack System has the following characteristics:

- Investment on development, hardware and communication is done by the provider

- Responsibility for the systems hosting
- Service based on a fee for each serial number used by manufacturer
- The service can be provided to other manufacturers, distributors, logistics operators, wholesalers and pharmacies.

The adoption of this tool, by other manufacturers and other actors of the distribution chain, is a key factor for the long-term sustainability of the project, due to the fact that the bases are established to:

- Contribute to establish a standard for the local market.
- Increase dissemination and knowledge about the tool.
- Incentive for use, so Healthcare professionals and patients become used to validating the products before providing or consuming them.

Implementation

Impact on the operation
Identification
The impact on the identification of the product is summarised in the following:

- Cost of tags
- Operation of tags

Warehouses

It must be guaranteed that all products leave the warehouse are scanned [read], without crossing units (serial numbers) among orders.

During the dispatch process, the serial number reading takes place at the moment of packing, which guarantees that the serial numbers packed are exactly the ones read. The system controls the consistency of batches and quantities of each order, making possible the dispatch of the order only if it is complete and coincides with what is required.

Traceability has an impact on the logistics operation when time is added for picking and inventory management, which is translated into costs.

Validation

The validation on the web has no cost; while through the contact centre there are communication (free call) and operation costs for the contact centre.

Product selection, sequencing and batch considerations

The products traced were chosen in relation to the risk of being counterfeited. Products that have been counterfeited the most were chosen as the highest risk, considering their sales volume and billing amounts.

Based on these variables, SKUs were taken as a priority and were included in an implementation chronogram, incorporating a new SKU every 15 days.

The criteria is tracing only complete batches (not partial ones). Once the SKU begins to be traced, all future batches will be traced.

We have already traced all the products that had suffered adulteration, plus some that were likely of suffering it, with a total of 12 SKUs, which represent more than 80% of the local pharmaceutical sales.

Communication plan

Dissemination is a key factor for success. We have designed a communication plan with the objective of communicating about the new system and motivating patients and health professionals to use it.

The plan, developed in 2010, had various actions targeted inside and outside the company.

Expected benefits

For the patient and the society:

- Product legitimacy validation prior to consumption
- Lower risk of harm from the use of counterfeit medicines
- Access to expected therapy

For the manufacturer:

- Less counterfeit units, which implies:
  - Greater demand for original units, more sales
  - Lower risk of recall
  - Image improvement, if there is more consumption of original units there is provable therapeutic action.
- Recall cost reduction; by identifying only counterfeit units for recall versus the recall of complete batches.

Next steps

Today, two other multinational manufacturers are implementing this solution in Argentina, which will be useful for consolidating the concept in the market. There are two more local companies studying its adoption.

On the other hand, there are several projects, both legislative and from the Argentine Ministry of Health, to regulate and extend the implementation of traceability. The projects are mostly compatible with what we have implemented.

ABOUT THE AUTHOR

Pablo Grimald, Commercial Logistics Manager, Pharma Division in Roche Argentina

Pablo Grimald is responsible for Sales Administration, Distribution and Demand Planning. He has more than 20 years experience in pharmaceutical market and he has leaded several projects, providing his know-how in projects aimed at harmonizing processes and systems among Latin America Region.

Pablo has a degree as Engineer in Information Systems conferred by National Technological University (UTN), and is MBA graduated from CEMA University (UCEMA), Argentina.

Health Corporate Network leverages the GS1 System for eProcurement success

ABSTRACT

Health Corporate Network (HCN), an organisation that delivers shared services, including supply, to the West Australian Department of Health identified an increase in the volume of paper procurement transactions being processed, placing a significant burden on staff. A decision was made to implement eProcurement using the NEHTA eProcurement Solution to automate some of the manual processing. The basis for NEHTA's eProcurement Solution is GS1's eMessaging Standard, GS1 XML combined with the Australian Standard (AS) 5023, which defines message data set and business rules for Healthcare. HCN was conscious that eProcurement processes must be based on accurate and complete product data, and so made the decision to mandate population of the National Product Catalogue (NPC) as a pre-requisite for implementing eProcurement with any supplier. A range of benefits have been realised since eProcurement implementation commenced and these will increase as the number of suppliers involved grows.

By **David Melbourne,**
Health Corporate Network

Background

WA Health is the state of Western Australia's public health system, providing services to around 2.3 million people across an area of almost 2.5 million square kilometres (approximately five times the size of Texas) from the capital city Perth, to rural centres and some of Australia's most remote Outback areas. Facilities run by WA Health include public hospitals, community and mental health services, drug and alcohol prevention and treatment services, dental health services and Aboriginal health services. In 2009, WA Health handled more than 837,000 emergency department visits, completed more than 75,000 elective surgery cases, delivered 22,330 babies and performed more than 91,000 breast cancer screens.

Health Corporate Network (HCN) is a shared-service entity that provides Human Resources, Supply, Finance and Business Systems services to WA Health. HCN's primary role in the WA Health community is to help clinical staff to provide the best service they can to the patient whether through supply chain efficiencies or improved business and administration processes. Its 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 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

Each of the state and territory health jurisdictions have (by their presence on the board of NEHTA) committed to driving and implementation of NEHTA's strategy.

Amongst the foundation work areas identified by NEHTA was supply chain. This work effort was one of the first commenced, given it was seen as a key focus area that would drive efficiency, savings and improved patient safety in Australia's public hospital sector. The supply chain work effort has three areas:

* Creation of a National Product Catalogue (NPC)
* Development and roll out of an eProcurement / eMessaging solution
* Documentation of business intelligence tools and references

eProcurement and the Australian Public Health Sector

Across all Australian states and territories procurement processes have been predominantly manual and lacked standards.

In 2007 NEHTA announced its selection of GS1 XML as the eProcurement format and structure that would form the backbone of its eProcurement solution. The data set to be transacted within the GS1 XML structure has been specified using Australian Standard (AS) 5023. Combined, the use of GS1 XML and AS 5023 provide a strongly standards-based solution, laying the foundation for development of long-term electronic transaction capabilities by all of Australia's states and territories.

Figure 1: **The NEHTA Federated HUB Model**

WA Health

Buyer · Supplier · HUB Provider · Internal HUB
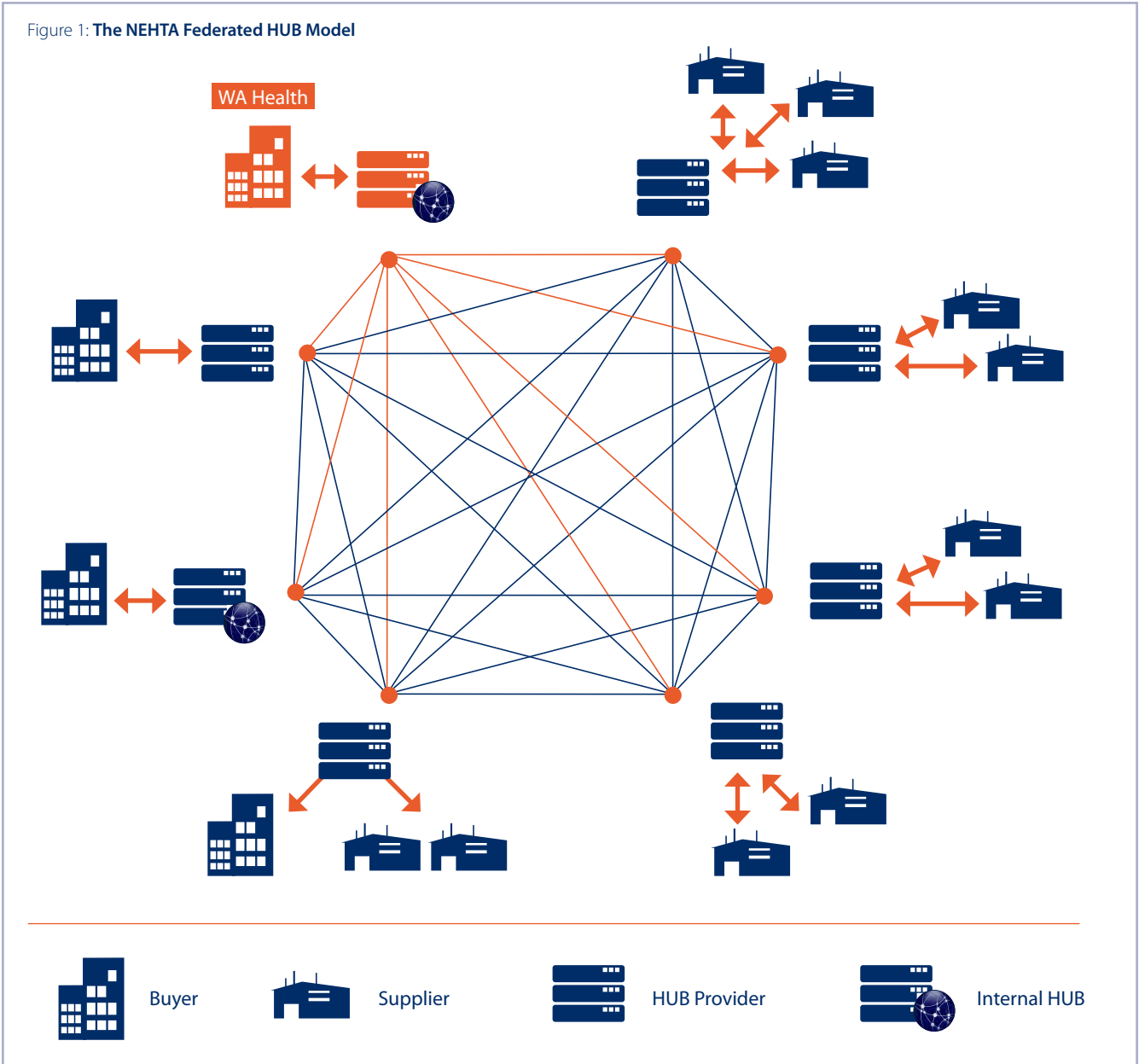
The foundation of the eProcurement solution is four transactional messages, the Purchase Order (incorporating the Purchase Order Change), Purchase Order Response, Despatch Advice (also called Advanced Shipping Notice – ASN), and Invoice.

Also within the NEHTA eProcurement solution is the specification that EDI Service Providers (HUBs) – organisations that provide EDI messaging services to suppliers and buyers – must operate in a federated HUB structure, refer to Figure 1. This means that a supplier and buyer can choose to engage their HUBs based on their own business partner selection criteria and own commercial negotiations. If the supplier and buyer then choose to exchange messages electronically and the messages meet the NEHTA specifications, there is no expectation that the supplier or buyer will pay each other's HUBs any fees, nor will either trading partner's HUB pay for the interconnection fees (connectivity and movement of messages) between the HUBs.

eProcurement in Western Australia

After HCN's formation in 2006, it was identified that there was an increasing trend in the volume of paper transactions being processed by WA Health and this was placing a significant burden on procurement staff. HCN was processing up to 1500 purchase order lines and 3500 invoice lines daily for WA Health. To efficiently and effectively manage all transactions it was identified that HCN would need to change existing processes.

In 2008 a business improvement decision was made to implement eProcurement, in line with NEHTA's eProcurement Solution, to automate as much of the manual processing as possible. A further driver was government budget cuts and subsequent organisational restructuring. Automation was seen as a way to free up employees to focus on value-added tasks. With electronic purchase orders, invoices and other documents, the accounts payable department would have less manual work. HCN was the first health jurisdiction to move down this path.

Health Corporate Network leverages the GS1 System for eProcurement success

Figure 2: **NPC Data Flows**
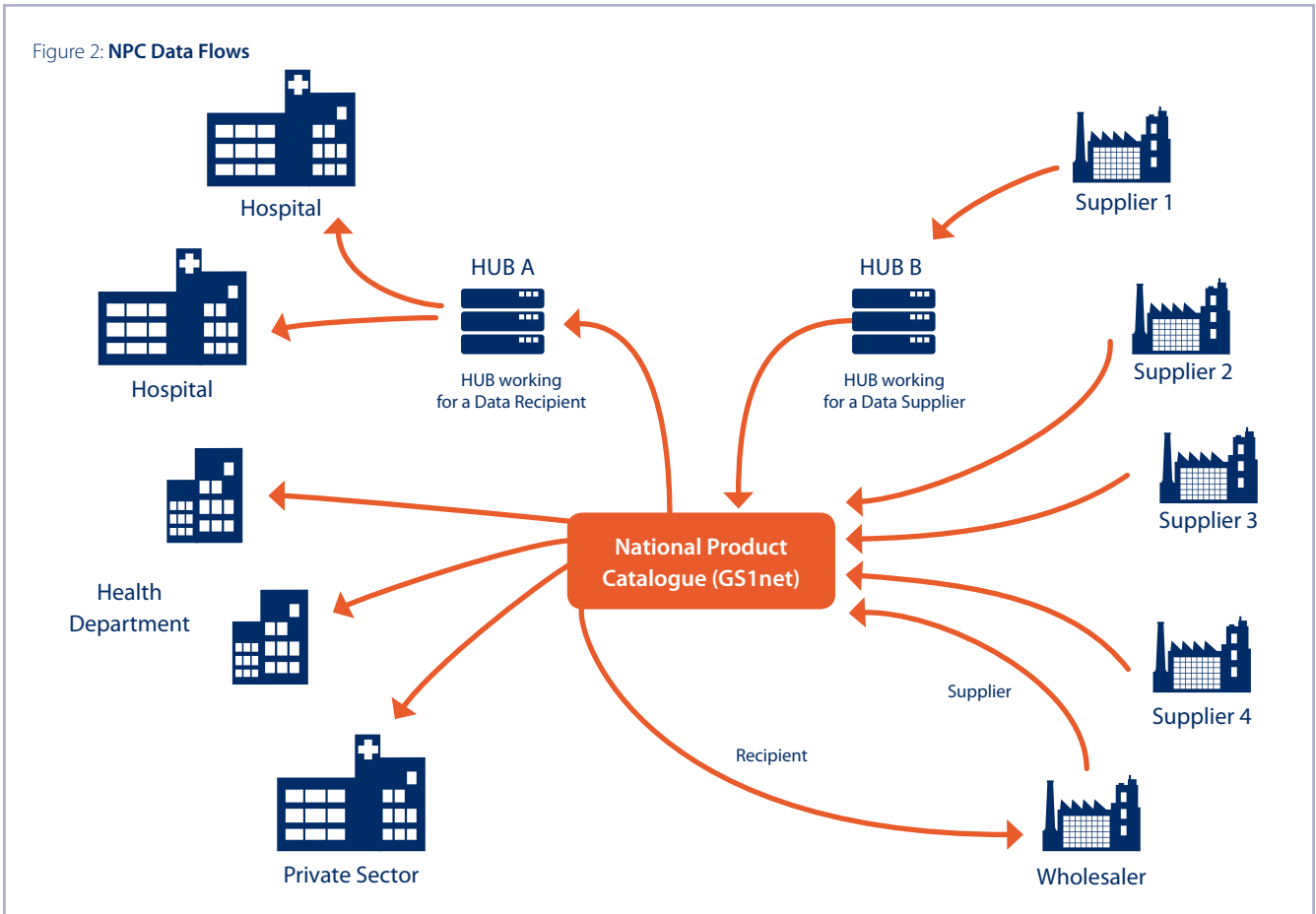
The importance of accurate master data

To implement eProcurement successfully HCN realised that they had to ensure both their own data and their suppliers' data was 100 per cent accurate and kept up to date. It was very clear early in the eProcurement implementation process that using inaccurate data in electronic messages simply added to the work effort of staff. eProcurement without accurate master data causes more work than paper processing.

To achieve synchronised and accurate data HCN turned to the National Product Catalogue (NPC), which has been developed as the 'single source' of item master data for Australian health organisations seeking to purchase medicines, medical devices and other necessary Healthcare items. Figure 2 details the NPC data flow process.

The NPC has been endorsed by all state, territory and federal health departments in Australia as a single repository of product, pricing and Healthcare data and is hosted by GS1 Australia on the GS1net data synchronisation platform. Used by an ever increasing number of suppliers, this solution contains built-in data validation checks that aim to prevent suppliers loading incomplete or inaccurate records.

HCN has mandated that suppliers must have published their data on the NPC as a pre-requisite to implementing eProcurement. HCN tells all suppliers that if they do not have their information on the NPC they cannot provide their trading partners, including

HCN, validated and complete data. Secondly they cannot maintain synchronised data. That means HCN cannot engage in eProcurement with them.

By requiring suppliers to populate the NPC with their data before implementing eMessaging, HCN has put in place a contingency to minimise the risk of incorrect data and therefore increased work effort.

Definition and documentation of business process: The Message Implementation Guideline

For HCN, the next step towards eProcurement implementation with suppliers was to document their business rules, requirements and processes, including data set. The output of this process is called a Message Implementation Guideline (MIG). HCN worked closely with NEHTA throughout this process.

The MIG is an essential part of eProcurement documentation, it provides a set of requirements for all trading partners providing explanations of which GS1 XML messages are used, and how a given jurisdiction's software applications and business processes work. The HCN MIG provides suppliers a guideline for electronic trading using the NEHTA Specifications for the Purchase Order, Purchase Order Response and Invoice messages. HCN intend to move to a full complement of messages, with the Despatch Advice currently being developed.

Figure 3: **The HCN eProcurement Process Overview**
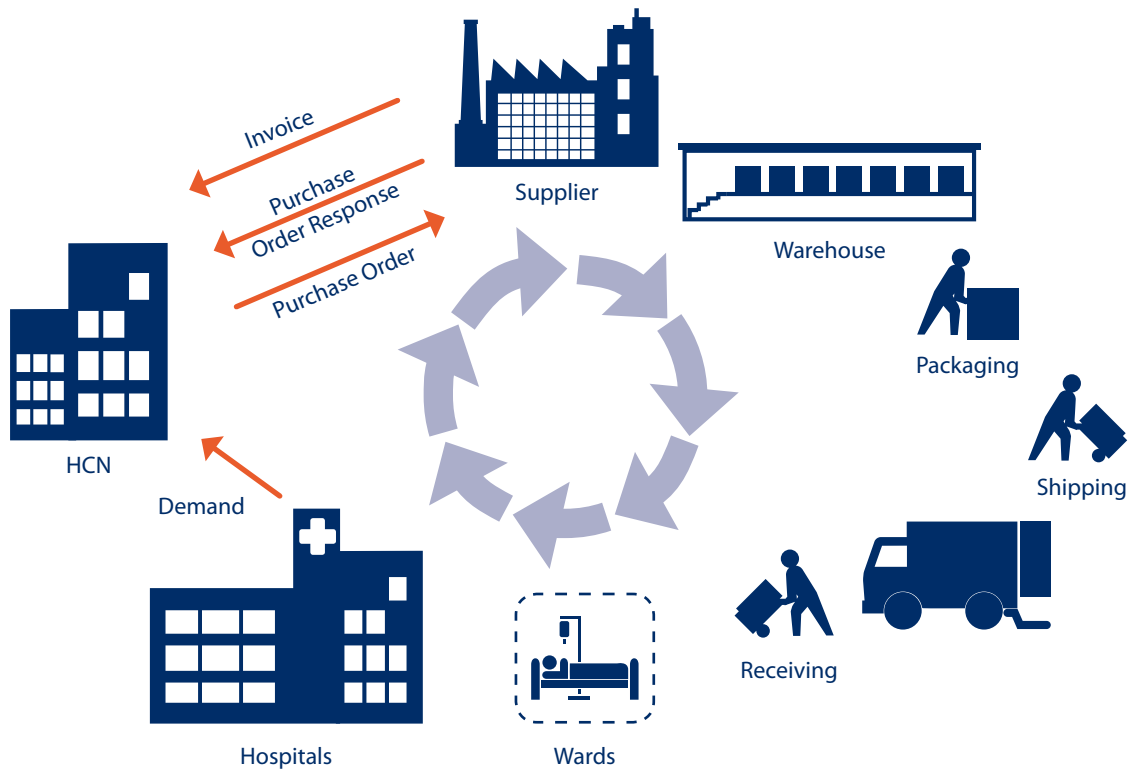
WA is the first Australian jurisdiction to have a MIG and this has ensured that it is simpler for HCN to communicate to their suppliers exactly what is required when implementing eProcurement. This MIG has been subject to self assessment by HCN using the NEHTA Compliance, Conformance and Accreditation (CCA) scheme.

With the development of the MIG, HCN have mapped their business process against best-practice specifications. Leveraging off the successful HCN MIG outcome, South Australia and the Australian Capital Territory (ACT) have also successfully completed the NEHTA compliance process. NEHTA will continue this work effort with all health jurisdictions and the private health sector Australia-wide. All business processes across jurisdictions are to be documented in a single national reference which means suppliers will have a single eProcurement implementation guideline for Australian public Healthcare. Figure 3 details the HCN eProcurement process, highlighting the collaborative and cyclical relationship between the parties involved.

Current HCN status

Since 2008 HCN has commenced eProcurement implementation with a number of companies including Baxter Healthcare, B.Braun Australia, Bunzl Australasia and KCI Medical. Discussions are continuing with a number of other suppliers including Western Biomedical, Becton Dickinson and Medical Sales and Service.

As detailed in Figure 4, HCN have decided to function as their own HUB giving them the flexibility to manage their messaging flows and simply and easily connect with the HUBs selected by their trading partners and move data into their ERP System.

Benefits seen since implementation are:

- More accurate identification of ordered products due to the use of GTINs. There is no confusion as to what pack size, colour, etc is being ordered. When using internal part numbers such confusion is common.
- With prompt receival of a purchase order response, problems can be resolved more quickly. For example, if an item is out of stock, this can subsequently be sourced from an alternative supplier.
- Prompt notification of any price discrepancies means issues can be identified and addressed immediately.
- When electronic invoice and purchase order details are matched, the invoice is validated immediately. This means no intervention is required by Accounts Payable staff, decreasing workload.
- Payments are usually made more quickly. When paper invoices are used, these can often be mislaid or not sent to the Accounts Payable team, which delays payment.

HCN is continually working collaboratively with suppliers to help them become ready to be involved in eProcurement implementation with purchase order, purchase order response

Health Corporate Network leverages the GS1 System for eProcurement success

Figure 4: **HCN Systems and Data Flow**
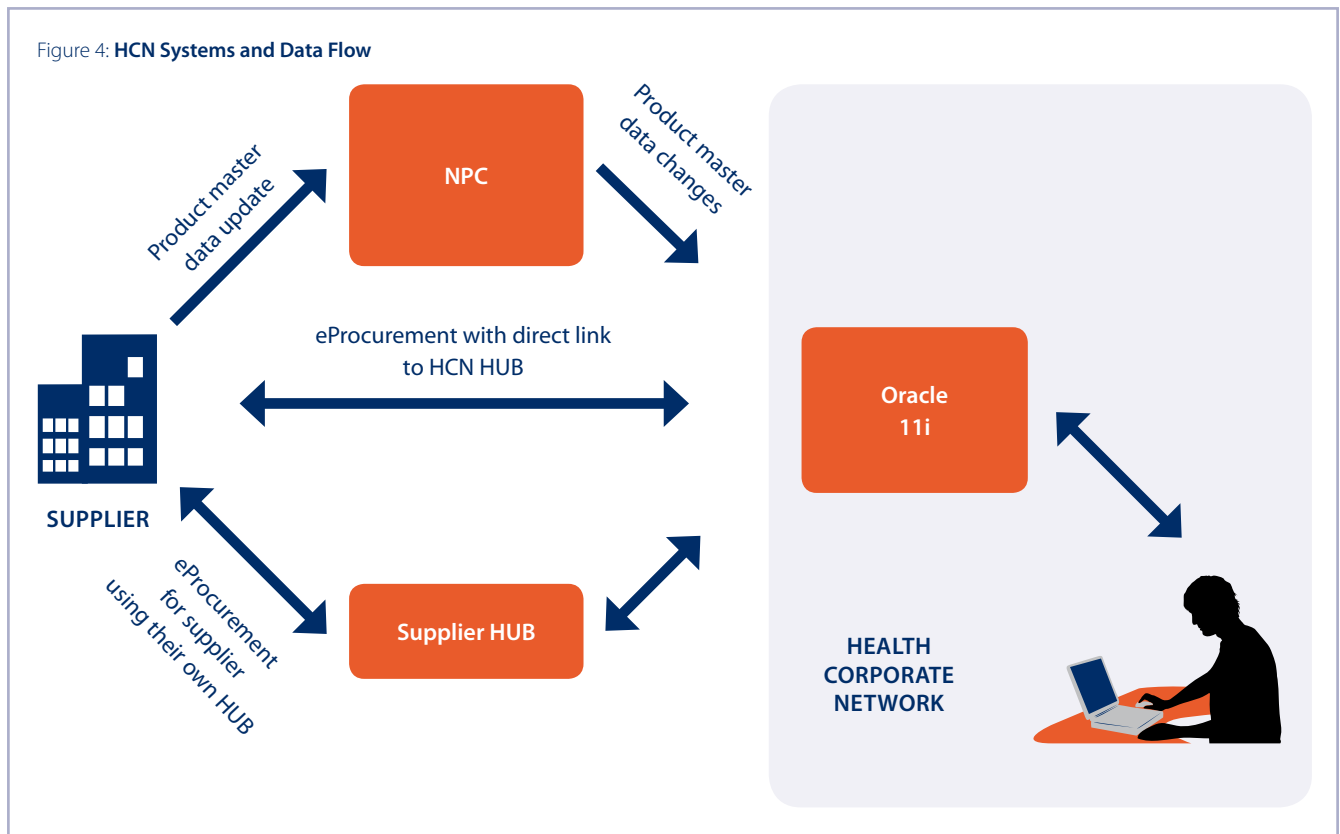
and invoice messages. Suppliers must have published data to the NPC to be considered, but also have the implementation of eProcurement in their own business objectives.

For suppliers who have published their product data to the NPC but are not ready to move down the eProcurement path, HCN have started providing GTIN and Global Location Number (GLN) information on their paper purchase orders, thus creating familiarity and awareness of their reliance of data from the NPC. Most importantly, these references ensure even suppliers processing orders manually know exactly which items and levels of packaging are being ordered by HCN and the correct locations to which the goods should be shipped. It further enhances the message that if suppliers publish their data to the NPC, HCN will access it and incorporate it into their procurement systems.

HCN's ultimate aim is to send and receive as many procurement transactions electronically as possible. Current targets are to have up to 15 suppliers live with purchase order, purchase order response and invoice messages by the end of 2011. Global Standards and National Healthcare specifications are crucial to this. If everyone is talking the same language, development of solutions for the Australian eHealth Supply Chain sector becomes extremely efficient.

ABOUT THE AUTHOR

David Melbourne, Senior Business Analyst, Health Corporate Network

David Melbourne is currently employed as a Business Analyst by Health Corporate Network and co-ordinates their eCommerce project. He started his working life as a Pharmacist in South Australia before heading to Perth in 1987. In 2006 he was seconded to assist with data mapping for a Pharmacy project which become a career changing move as he is now working closely with NEHTA and GS1 Australia to implement the National Product Catalogue and eProcurement for WA Health.

The traceability system of medicines at Hospital Israelita Albert Einstein in Brazil

ABSTRACT

Focusing on patient safety, Albert Einstein Hospital (HIAE) has evaluated the entire cycle of drugs use and established three specific steps in the process where to implement electronic safety blocks: ordering, dispensing and administration. HIAE initiated the intra-hospital traceability project to monitor the receipt, distribution, dispensing, and administering of drugs. In a first phase, drugs were re-labeled in-house, and in a second phase, a supplier took up the challenge to print a bar code on the label of each unit of electrolyte ampoules in their production line. This allowed to include variable data such as batch number and expiry date. More suppliers were then invited to adopt the GS1 DataMatrix bar code. As a result, HIAE could reduce adverse drug events on dispensation and save costs by replacing in-house re-labeled drugs by industry two-dimensional codes ready identified labels.

By **Nilson Gonçalves Malta**, Hospital Israelita Albert Einstein

Introduction

According to studies by the American Hospital Association and another led by David Philips, both demonstrated by the IOM in its report To Err Is Human, 1999, each year 44,000 to 98,000 people die from medical errors and about 7,000 only by medication errors, inside or outside of hospitals. Additionally, it has been cited, that 2% of hospital admissions were subject to preventable adverse drug events, increasing the length of stay of 4.6 days with an additional cost of $ 4,700 per admission[1]. In statistics from the Centers for Disease Control and Prevention (CDC), this same report concluded that more people die from medical errors than from automobile accidents. Although more than 10 years have passed, these figures are alarming and makes us consider the quality of service nationwide. The costs of errors in estimation followed between 17 and 29 billion U.S. dollars annually. Medication errors in the most recent report of the IOM relied, in 2006, with an annual estimate of 400,000 adverse drug events, with consequent cost of 3.5 billion dollars annually[2].

In a study regarding the possible sources of medication errors, the ASHP, the American Association of Health System Pharmacists reported that 39% of errors occur at the time of prescription, 12% in transcription of medical orders, 11% in dispensing and 38% in medication administration[3]. While

these data are not specifically the national reality, are of vital importance as parameters for the improvements.

The data presented above are relatively recent, but the problem goes back much further. Already in the 1950s and 1960s, the Unit Dose Drug Delivery System (UDDDS) was developed in the USA as a means to reduce the alarming numbers of medication errors at that time. The UDDDS is a system through which the pharmacy dispenses the medication in the form which is ready for use, according to the dose ordered by the doctor, without the need of further manipulation[4]. Despite being recognized as the safest method of dispensing developed so far, the indicators still show that we have many weak points in the process and they deserve our full attention. But now, if we adopt the UDDDS as the best method of dispensing, what else do we need to accomplish?

1   Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: building a safer health system. Washington, DC. National Academy Press; 1999.
2   Aspden P et al. Preventing Medication Errors: Quality Chasm Series. Washington, DC. National Academy Press; 2007.
3   ASHP Report. 2003 ASHP Leadership Conference on Pharmacy Practice Management. Executive Summary: Looking to the future: Leading and managing change. Am J Health-Syst Pharm 2004; 61(10): 1052-58.
4   American Society of Health-System Pharmacists [ASHP]. Best Practices for Health-System Pharmacy. Positions and Practice Standards of ASHP 1998-99. Bethesda, md: ASHP; 1998: p.134-5,139.

The traceability system of medicines at Hospital Israelita Albert Einstein in Brazil

Patient safety at Hospital Israelita Albert Einstein (HIAE)

Focused on patient safety, we have evaluated the entire cycle of drugs use and decided to focus our actions on ordering, dispensing and administration. With the direct involvement of Pharmacy, we implemented an electronic ordering system and a safer logistics process from receipt of the products to their disposal.

These actions were aligned with the culture of quality and safety in HIAE which, even in the late 1990s, was seeking unprecedented certification from the Joint Commission Accreditation on Healthcare Organizations (JCAHO) outside the United States. The project allowed us to fulfill the Joint Commission's standard regarding the traceability of medicines.

> Joint Commission Accreditation on Healthcare Organizations Standard MM.05.01.17 (MMU.3.3 of Joint Commission International)
>
> The [organization] follows a process to retrieve recalled or discontinued medications.

The concept of quality of a Unit Dose System is unquestionable, but we see weak spots. With so many technological advances in our society, it is vital to take all reasonable and available means to safeguard the lives we serve daily. Our actions have been confirmed and reinforced with the publication of the IOM, which recommends the computerization and automation as means to prevent errors and adverse effects[5], in summary, a mechanism widely available and an efficient source of security.

The traceability project

The first step

To improve patient safety, HIAE initiated the intra-hospital traceability project, which had the purpose of monitoring the reception, distribution, dispensing, and administration of medication, and maintaining control over batch and expiry date of medicines in these processes.

Fig. 1 – EAN 13 code

Until then it was not possible to perform traceability because the drugs supplied by the manufacturers did not possess the minimum requirements for such control. Not all suppliers provided properly identified packages. Even if there was a bar code, it reported only what product it was (EAN13 code – Fig. 1), and usually in their secondary packaging. When it comes to dispensing hospital, it is imperative that full identification is carried out on primary packaging.

Fig. 2 – Re-labeled ampoules

To circumvent the problem and meet this demand, the alternative adopted was in re-labeling (re-identification) of medicines in all types of presentation and dosage forms, printing a bar code containing the product data, batch number and possibly expiry date, as well as that information in human readable format. For ampoules and vials it was a cumbersome solution (Fig. 2), but the situation became even more critical when dealing specifically with drugs in solid dosage forms (e.g. tablets, capsules, etc.)[6]. To have this information on each unit of consumption, we had to cut original blister packs and individually overwrap each unit. To facilitate this process, HIAE invested in a table top machine for unit dose repackaging (Fig. 3). In the Brazilian market, the sale of drugs in bulk is practically nonexistent, which makes this activity more costly and creates too much waste, like cartridges, blister packs and package inserts. For this practice, later, with the publication of RDC 67/2007 ANVISA (Resolution of Directive College)[7], in the repackaging process through table top machines, the validity of the drug should be reduced to 25% of its original remaining time. This situation remains until today.

In 2005, for the attendance of 460 beds, emergency care and two outpatient units (Paraisópolis Alphaville), HIAE repackaged approximately 80,000 oral solids and relabeled about 250,000 ampoules or vials per month.

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5   Institute of Medicine. Crossing the Quality Chasm. A New Health System for the 21st Century. Washington, DC. National Academy Press; 2001.

6   Cina J, et al. Implementing a bar code repackaging center: a case study of the process from the department of pharmacy services Brigham & Women's Hospital in Boston. Pharm Purchasing Products 2004; 1:10–11.

7   BRASIL. Agência Nacional de Vigilância Sanitária. RDC nº67, de 1º de outubro de 2007. Regulamento Técnico sobre Boas Práticas de Manipulação de Preparações Magistrais e Oficinais para Uso Humano em farmácias. Diário Oficial da República Federativa do Brasil, Poder Executivo, Brasilia, DF, 8 de outubro de 2007, Seção 1. Available at <http://www.anvisa.gov.br/legis/resol/2007/rdc/67_rdc_anexo.pdf> accessed on February 3, 2011.

Risks

The activity of re-labeling is a critical step as it adds cost - namely the high cost of manpower - and risk - the risk of having of incomplete or inaccurate information. To prevent these errors, a policy and post-labeling quality control need to be developed[8].

We can also see errors when receiving medications. Right now, with lot control in the internal distribution of products, the lot information and expiry date should be typed into the system. With this, we run up against the risk of copy error, compromising the ability of traceability of data over the period of medication use.

Furthermore, we have to pay attention to the printing quality of labels, because faded codes can not be read and the whole chain is compromised. Therefore, it is essential to have an effective program of preventive maintenance on printers, labels and acquisition of appropriate print film, so that it will not fade out during handling or with liquids used in aseptic processes.

The ideal solution

Through our participation in the GS1 Healthcare Brasil user group, we identified a supplier that accepted the challenge of applying the two-dimensional GS1 RSS-14 code (currently called DataBar – Fig. 4) on the label of each unit of electrolyte ampoules in their production line. In this format of higher capacity, you can enter variable data such as batch and expiry date on their information content. Later in 2008, new partners have joined the programme and followed the international guidelines that required the use of GS1 DataMatrix code (Figs. 5 and 6). With this new two-dimensional code with variable content, the re-labeling of all products was no longer needed, and a safer receiving process was established. Upon reading the code, the system automatically imports the data from batch and expiry date, thus eliminating the possibility of error in the inventory system data record. In a survey on the current status of hospital pharmacies by the American Society of Health-System Pharmacists (ASHP)[9], Zellmer[10] indicated the need for manufacturers to supply pre-packed drugs in already bar coded individualized doses to increase security and save costs. This is in line with the group's studies of GS1 Brasil.

Fig. 4 - GS1 DataBar Stacked Omnidirectional

Fig. 5 – GS1 DataMatrix

Fig. 6 – Ampoules with GS1 DataMatrix

A considerable challenge for the national pharmaceutical industry still remains as to the application of bar code on blister packs of oral solids (Fig. 7). It is intended that, once cut (through perforated blister packs), all units have the identification required for full traceability, without re-packing need at hospitals that perform the Unit Dose dispensing process.

By December 2010, other suppliers joined the programme and HIAE expanded its services to about 600 beds, emergency care and four other outpatient units (Paraisópolis, Alphaville, Perdizes-Higienópolis and Ibirapuera). About 180,000 oral solids had to be re-packaged per month and some 250,000 ampoules or vials re-labeled per month. Another 120,000 units of ampoules and vials do not have to be re-labeled anymore as they already carry the GS1 DataMatrix code.

Fig. 7 – Bar code on blister packs

8   Cina J, et al. Medication errors in pharmacy-based bar-code-repackaging center. Am J Health –Syst Pharm 2006; 63(2): 165–168.
9   Pedersen CA, Gumpper KF. ASHP national survey on informatics: Assessment of the adoption and use of pharmacy informatics in U.S. hospitals – 2007. Am J Health-Syst Pharm 2008; 65(23): 2244-2264.
10 Zellmer W. The current state of hospital pharmacy. Am J Health-Syst Pharm 2009; 66(10): 895.

| Receipt | Distribution | Dispensation | Administration |
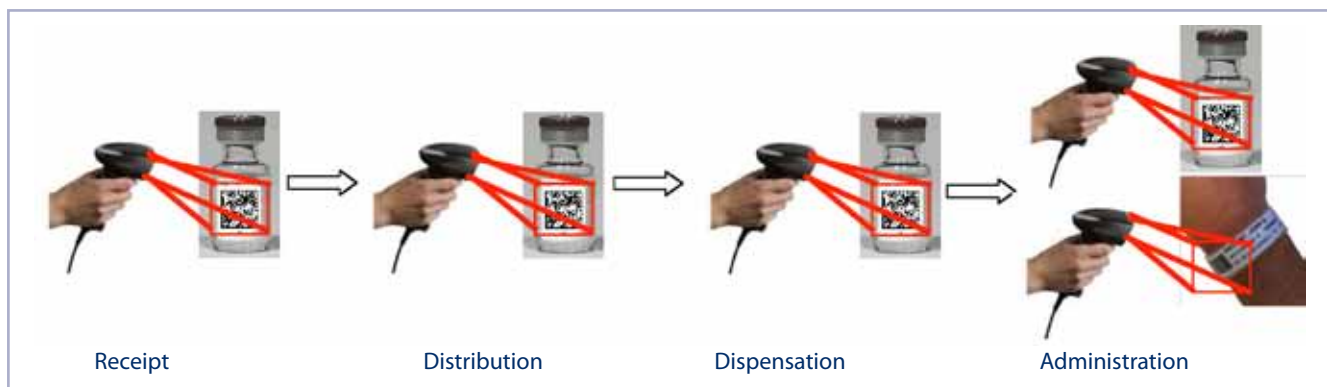
Software assessment

To adopt the standards, all systems used in the hospital logistics had to be customised in order to allow the code information recovery.

In the process of reading the code, the system should recognize the character FNC1, relevant Application Identifiers (AI) and save it. In the most basic example, the system must understand that specific product GTIN14 (AI 01) corresponds to a unique product in its internal inventory. It must therefore record the batch information and expiry date, and make a full identification of the medicine in the internal supply chain.

Though seemingly complex, it is not. GS1 offered thorough support so that the necessary adjustments were easily understood.

Bedside check medication administration

The solution will also directly impact medication administration, one of the most critical and sensitive stages for error as shown in the ASHP statistics. In 2011, HIAE will adopt an electronic checking system of medication administration at bedside. In this process, the nursing staff reads the patient id code and the bar code of the medicine dispensed by the pharmacy, confirming the drug. In the absence of a bar code on the primary packaging of the product, this process becomes impractical.

Much has been discussed and published about the automation of this process and the main objective is to achieve the five well-known rights: right patient, right drug, right route, right time and right dose. This particular issue has been further studied and the number 5 now comes to 9[11], where we perceive that the automated process allows most of them to be covered with the deployment of technology: electronic checking allows right patient, right drug, right dose, right time, right registration (documentation), right of refusal and right justification. Patient education and right route still remain inherent to the professional involved.

Additional security checks

According to James Reason[12], the errors are not confined to a few individuals. Even the most qualified professionals are subject to failure. Often circumstances lead to errors. The mere proposal of the use of bar code makes use of medications safer leveraging technology.

Wherever possible, additional security checks during the process should be considered, The Swiss cheese model of Reason makes it very clear when failures momentarily align and potential errors become real (Fig. 8).

Legislation

Traceability of medicines has also entered the merit of norms of the National Agency for Sanitary Surveillance (ANVISA), the national body responsible for regulating the health sector in Brazil[13,14,15,16,17,18].

11 Elliott, M. and Liu, Y. The nine rights of medication administration: an overview. British Journal of Nursing 2010. 19(5), p.300-305.

12 Reason J. Human Error: Models and Management, BMJ 2000, 320: p 768–770.

13 BRASIL. Agência Nacional de Vigilância Sanitária. Consulta Pública nº 8, de 4 de março de 2008. Diário Oficial [da República Federativa do Brasil], Brasília, DF, 5 de março de 2008, Seção 1. Available at <http://www4.anvisa.gov.br/base/visadoc/CP/CP%5B21581-1-0%5D.PDF> accessed on February 3, 2011.

14 BRASIL. Lei nº 11.903, de 14 de janeiro de 2009. Dispõe sobre o rastreamento e do consumo de medicamentos por meio de tecnologia de captura, armazenamento e transmissão eletrônica de dados. Diário Oficial [da República Federativa do Brasil], Brasília, DF, n. 10, 15 de janeiro de 2009, Seção 1, p1.

15 BRASIL. Agência Nacional de Vigilância Sanitária. RDC Nº 59, de 24 de novembro de 2009. Dispõe sobre a implantação do Sistema Nacional de Controle de Medicamentos e definição dos mecanismos para rastreamento de medicamentos, por meio de tecnologia de captura, armazenamento e transmissão eletrônica de dados e dá outras providências. Diário Oficial [da República Federativa do Brasil], Brasília, DF, 25 de novembro de 2009, Seção 1, p 58.

16 BRASIL. Agência Nacional de Vigilância Sanitária. Instrução Normativa n°1, de 13 de janeiro de 2010.Regulamenta a Resolução RDC n° 59, de 24 de novembro de 2009, que dispõe sobre a implantação do Sistema Nacional de Controle de Medicamentos, com vistas ao regramento da produção e o controle da distribuição das etiquetas de segurança para o Sistema de Rastreamento de Medicamentos e dá outras providências. Diário Oficial [da República Federativa do Brasil], Brasília, DF, 14 de janeiro de 2010, Seção 1, p 60.

17 BRASIL. Agência Nacional de Vigilância Sanitária. Instrução Normativa n°8, de 15 de junho de 2010. Dá nova redação ao caput e revoga os §§1º, 2º, 3º e 4º do art. 9º da Instrução Normativa nº 1, de 13 de janeiro de 2010 [da República Federativa do Brasil], Brasília, DF, 17 de junho de 2010, Seção 1, p 39.

18 BRASIL. Agência Nacional de Vigilância Sanitária. Instrução Normativa n°11, de 29 de outubro de 2010. Dispõe sobre a tecnologia, a produção, o fornecimento e o controle da distribuição das etiquetas auto-adesivas de segurança para o Sistema de Rastreamento de Medicamentos e dá outras providências. [da República Federativa do Brasil], Brasília, DF, 3 de novembro de 2010, Seção 1, p 17.
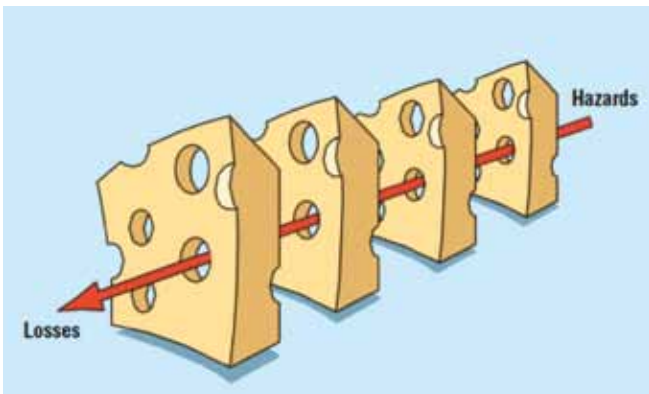
Fig. 8 – The Swiss cheese model of reason

Concerned about the continued practice of drug counterfeiting and theft of cargo, ANVISA published specific legislation to put a control in this matter. On January 14, 2009 the law 11,903 was published, determining the creation of the national traceability system of drugs from production to consumption through electronic means.

Subsequently, it was published on November 25, 2009, the RDC 59 (Resolution of Directive College), providing the establishment of the National System of Control of Drugs and the mechanisms for tracking medicines electronically. The resolution clarifies that the drugs should be identified with the DataMatrix code in its secondary packaging. Without this, the identification must be on the primary packaging. The law does not meet the security needs of traceability inside the hospital, however, demonstrates an important breakthrough for the security of the population that uses drugs in retail pharmacies.

Many normative statements were published (#1 on January 14, 2010, #8 on June 17, 2010 and #11 on November 3, 2010), detailing the specific mechanism for tracking and control of medicines. The normative determine the use of GS1 DataMatrix as a tool, which shall have minimum amount of information, among which the GTIN, lot, expiry date and IUM (unique identifier of medicine - following serialization standard of GS1), which is directly linked to product registration in the ANVISA and CNPJ (Juridical Person National Register/Tax Number) of the receiving company.

Results achieved through the implementation of traceability using two-dimensional bar codes at HIAE.

The process is safer based on the GS1 DataMatrix previously printed on the label on the primary packaging of pharmaceutical product (smallest unit of consumption).

- Agility in the dispensing process, with online inventory decrement
- Conference of the item dispensed as ordered

- History of the batch of the drug from the receipt to the time it is used by patients (TRACEABILITY inside the hospital)
- Item History, from manufacturing to its consumption (complete TRACEABILITY outside and inside the hospital)
- Guarantee the dispensing drugs in condition of use, with lots being blocked from dispensing which may have been recalled or are expired
- History of the batch sent to each sector
- Agility in localizing products banned for recall
- Electronic bedside check of medication administration, according to the order and ensuring control over 7 of 9 rights proposed
- Important tool for obtaining quality certifications
- Reduced about 330 hours of manpower costs at the relabeling activity

Final thoughts

On several occasions those responsible for hospital pharmacies face many obstacles that hinder the development of traceability projects and it is not unusual that financial reasons or lack of management support take place. It is noteworthy that, compared to the costs generated by the error and the time of manpower spent on tasks that do not add any value, but offer more risk, are factors that easily demonstrate the rapid return on investment.

Additionally, attention to the legislation is the focal point of the moment. With the progress of the national project and the encouragement of other institutions at the national level, we hope to elevate Healthcare to a higher level in quality. Currently attention is focused on legislation to guarantee genuine products and of legal origin; however, it is expect that in the future we will have regulation for the primary packaging based on the GS1 DataMatrix identification.

ABOUT THE AUTHOR

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About Hospital Israelita Albert Einstein

In 1955, a group of idealists from the Jewish community of São Paulo founded Sociedade Beneficente Israelita Brasileira Albert Einstein (SBIBAE), based upon four traditional Jewish principles:

- Good Deeds (Mitzvá)
- Health, Healing (Refuá)
- Education (Chinuch)
- Solidarity, Justice (Tsedaká)

Over half a century later, SBIBAE has become a great and modern institution, governed by high quality standards and in tune with the most advanced technologies available. SBIBAE is aligned to modernization and focused on health above all things. Daring innovation and persistence in the pursuit for quality are the Society's distinguished attributes.

Hospital Israelita Albert Einstein (HIAE), founded in 1971, is a patient-oriented institution and therefore prepared to offer, with attention and respect, unique and innovative services: from preventive medicine to complete rehabilitation.

Several initiatives are in place to prevent, eliminate or minimize risks and flaws in our service. Our procedures are guided by the American Institute of Medicine (AIOM), Joint Commission International (JCI), Institute of Health Care Improvement (IHI), the World Health Organization, and the Einstein Quality System.

HIAE is one of the most reputable organizations in Latin America. In 1999, it was the first hospital outside the USA to be accredited by the Joint Commission International – the international arm of The Joint Commission.

Enabling vaccine traceability in Canada using GS1 Standards

The Public Health Agency of Canada's Automated Identification of Vaccine Project

ABSTRACT

The Public Health Agency of Canada's (PHAC) Automated Identification of Vaccine Projects (AIVP) initiative was established in 2002 to improve the safe use of vaccines, as well as immunisation record keeping, by incorporating standardised bar codes onto vaccine product labeling. To examine this issue, PHAC established the AIVP Advisory Task Group, a collaborative effort between all stakeholder groups in the area of immunisation, co-chaired by PHAC and the vaccine industry, including key representation from GS1 Canada. In 2010, the AIVP Advisory Task Group reached consensus on the use of GS1 Standards for the identification of vaccine products approved for use in Canada.

By **Dr. Monika Naus,** British Columbia Centre for Disease Control

And **Dr. Robert Van Exan,** Sanofi Pasteur Limited.

Introduction

Over 20 million doses of vaccines are administered in Canada every year, with each patient's health record manually updated by Healthcare providers to track the details of the vaccination. However, such transcription of the details of the vaccine given may not be accurate or complete. Studies examining immunisation records in the provinces of British Columbia and Manitoba estimated that between 5 and 15 percent of patient immunisation records are missing core data elements. Up to 24 percent of records lack data or contain errors that can cause barriers to detailed follow-up of adverse events following an immunisation.

In order to reduce costs associated with correcting errors, support the use of electronic information systems, minimise manual data entry, and enhance patient safety through improved vaccine traceability – from the point delivery of a vaccine to its administration – the Public Health Agency of Canada (PHAC), GS1 Canada, and the Vaccine Industry Committee of BIOTECanada (VIC), are working to determine the Canadian requirements for product identification in the global standards-setting process.

At the Point-of-Care

The idea of bar coding vaccines in Canada is not a recent development. The potential benefits of vaccine bar coding for both inventory management and efficient population of immunisation registries have been evident for over a decade, stimulated by the increasing number of vaccines in use in Canada.[1] The collaboration with GS1 Canada supports PHAC's immunisation traceability initiative, the Automated Identification of Vaccine Projects (AIVP). Established in 2002, the initiative's goal is to improve the safe use of vaccines as well as immunisation record-keeping by incorporating bar codes onto vaccine product labeling.

The AIVP initiative was developed in response to a resolution passed in 1999 by the National Advisory Committee on Immunization (NACI), a longstanding group of experts that develop evidence-based recommendations for vaccine use in Canada. NACI recommended that bar codes be placed on all vaccine products to facilitate much needed cost savings in Healthcare, improve patient health record-keeping, and ultimately the safe use of vaccines. In support of this

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1   Naus, Monika. Bar Coding Vaccines – More than a "check-out" issue. Invited editorial. Canadian Journal of Infectious Diseases, July/August 2000; 11(3): 173-4.

recommendation, NACI recommends the following variables related to the identity of the vaccine be recorded on the patient record: trade name of the product, disease(s) against which it protects, dose, manufacturer and lot number.[2]

Bar code enabled identification of a vaccine, when used in conjunction with an electronic system that has built-in product recognition functionality, has the potential to optimise the safe administration of vaccines. For instance, an optimally configured system could identify that a patient has already received the vaccine, or that the vaccine has expired, prior to its administration. As well, bar code enabled product identification facilitates complete recording of the product, format and lot number should an adverse event requiring lot-specific follow-up occur in the future.

While vaccines have an admirable safety record, lot specific investigations in recent years have occurred with the measles, mumps and rubella vaccine[3] and the adjuvanted 2009 H1N1 pandemic vaccine,[4] complete electronic data would obviate the need for paper-based record searches and limitations in investigations hampered by missing data.

Ensuring public confidence in the Healthcare system to handle vaccine products and their administration in as safe a manner as possible is yet another benefit that can be realised through the AIVP initiative.

First steps

In the initial phase of the project, PHAC, in collaboration with VIC, established the AIVP Advisory Task Group to support the use of product identification based on global standards. A collaborative effort between all stakeholder groups in the area of immunisation and co-chaired by PHAC and VIC, the Task Group included representation from vaccine manufacturers, provincial/territorial jurisdictions, health authorities, health professional associations, regulators, international standard setting agencies, electronic health record (EHR) and clinical management software developers, as well as key representation from GS1 Canada.

The AIVP Advisory Task Group developed a five year strategic plan, spanning from 2008 to 2013. One of the first missions was the undertaking of an independent cost-benefit analysis for the adoption and implementation of bar coding of vaccine products. This cost-benefit analysis is the first of its kind, determining the return on investment (ROI) of implementing GS1 Standards in the Canadian vaccine industry. Previously, studies on Healthcare information technology were chiefly concerned with electronic health records and patient administrative processing, with research on bar coding in Healthcare primarily focused on medicines and patient bedside tracking.[5] For example, previous studies included reviews of the errors resulting from early or late administration of medications to determine their potential to harm patients[6], or how bar coding patient identification tags, caregiver badges, and immediate-container medications can increase patient safety during medication administration.[7]

2   Canadian Immunization Guide, 7th Edition, 2006. Part I, General Guidelines, Immunization Records. Public Health Agency of Canada. Text Prepared by the National Advisory Committee on Immunization. www.phac-aspc.gc.ca/naci-ccni/index-eng.php
3   MMR Vaccine Recall Issued by Merck in Canada After 5 Injuries. www.newsinferno.com/legal-news/mmr-vaccine-recall-issued-by-merck-in-canada-after-5-injuries/, December 14, 2007.
4   Health Canada, Drugs and Health Products. www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/qual-vaccin-eng.php. March 19, 2010.

5   Cost-Benefit Analysis for Adoption and Implementation of the Automated Identification (Bar Coding) of Vaccine Products, Final Report. February 6, 2009. HDR|Decision Economics
6   Poon, Eric G et al. Effect of Bar-Code Technology on the Safety of Medication Administration, The New England Journal of Medicine. May 6, 2010.
7   Neuenschwander, M et al. Practical guide to bar coding for patient medication safety, American Journal of Health-System Pharmacy. Vol 60, April 15, 2011.

Figure 1: **Quantifiable results of CBA
Costs, Benefits, and Net Present Value**
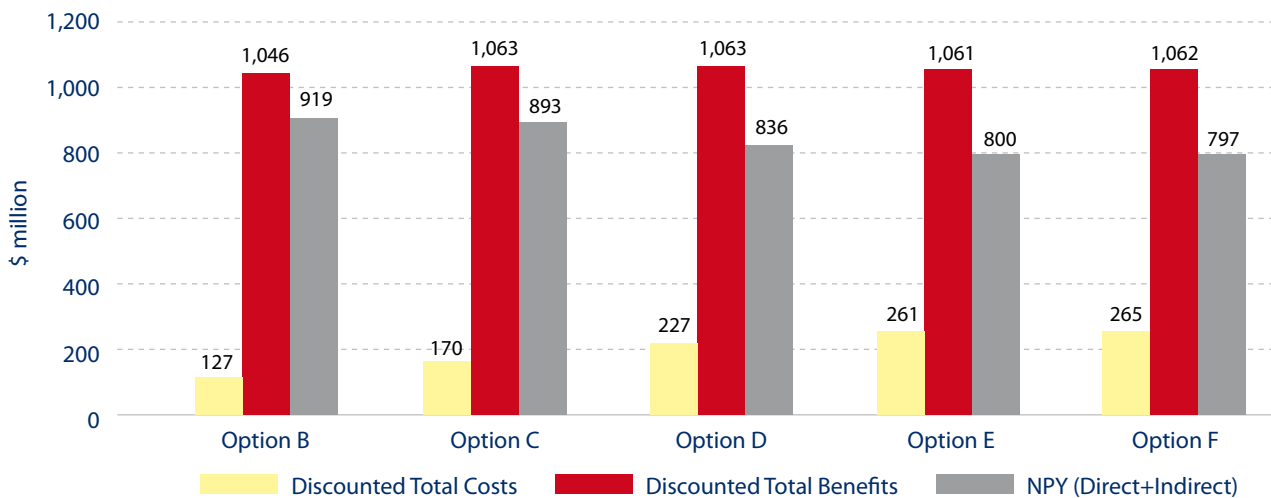
Cost-benefit analysis

The cost-benefit analysis was completed in February 2009 by HDR | Decision Economics (HDR) and focused on achieving three main objectives: reviewing previous documentation concerning potential costs and benefits associated with implementing the GS1 bar code on vaccine products; providing a description and enumeration, where possible, of the relevant costs and benefits based on implementation options; and ultimately recommending the preferred bar coding options with supporting rationale.

Six different bar code implementation options were selected by the AIVP Advisory Task Group and the Implementation Options Task Group, a temporary sub-group set up to carry out this specific task. These six options varied in technical detail and the relative cost and benefits anticipated. The options, labeled A through F, considered bar coding primary (vial or ampoule containing the vaccine) and secondary packaging (the carton which is the unit of issue and contains one or multiple doses of the vaccine product), one dimensional (1D) versus two dimensional (2D) bar codes, as well as bar codes carrying variable data (lot number and expiration date) versus non-variable data. [5]

This cost-benefit analysis examined the savings the Healthcare system could realise compared to what was labeled Option A, which was considered the status quo at the time. The costs and benefits of each option were assessed based on an assumption that 2012 would be the year of implementation for all the options. In order to better understand the long-term versus short-term costs, the cost-benefit analysis evaluated costs over a 20-year evaluation period for each option. The analysis concluded that Options B through F were expected to have a "significantly positive net present value, ranging from CA$797 million to CA$919 million (mean estimates, 2008 dollars)."[5]

The cost-benefit analysis was the first such analysis conducted on this issue, and concluded that significant ROI could be achieved by implementing the GS1 bar code on vaccines. It indicated that, as technology in the Healthcare sector improves and as new vaccines are launched, the cost savings and efficiencies achieved would continue to increase.

Consensus: The GS1 Bar Code System

One of the primary objectives of the AIVP Advisory Task Group was to develop a proposed standard for bar codes on vaccine products in Canada by working with GS1 Canada and taking into consideration the results of the cost-benefit analysis. In February 2009, at their annual meeting, the Task Group reached a consensus on the Canadian bar code proposed standards for vaccine products.

The AIVP Advisory Task Group agreed on the following recommendations to bar code vaccines in Canada, documented in the Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products released in late 2009:

- 2D bar codes on the primary package, which include the Global Trade Item Number (GTIN) and the lot number
- 2D or linear (also known as 1D) bar codes on the secondary package, which include the GTIN and the lot number [8]

By identifying primary and secondary packaging, electronic health records can be maintained efficiently and completely, the number of immunisation errors are reduced due to complete and accurate record-keeping and any follow-up resulting from immunisation is sped up. In addition, inventory management and vaccine supply chain forecasting are improved, which results in fewer interruptions in supply and less wastage due to expiry.[8]

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8   Lamarche, Louis et al. Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products. 2009.

Figure 2: **Quantifiable Benefits and Analysis[5]**

QUANTIFIABLE COSTS	QUANTIFIABLE BENEFITS

• Pre-development work
• Development and implementation of agreed upon standards
• Bar code design development
• Database development: The Vaccine Identification Database System (VIDS) and ongoing data collection and maintenance
• Database configuration – immunisation registry
• Scanner purchase and replacement
• Redesign of procedures and layout at clinics
• Redesign of procedures at manufacturing plants
• Bar code printing
• Training practitioners
	• Time savings (bar code scanning vs. manual entry)
	  – Patient and practitioner
	• Improved immunisation record completeness and accuracy
	  – Decrease in number of vaccine-preventable disease incidents
	  – Quicker follow-up (time savings) to adverse events following immunisation
	• Reduction in supply shortages
	  – Decrease in social costs from insufficient supply
	• Fewer re-immunisations
	  – Cost of immunisation
	  – Time savings (patient and practitioner)
	• Improved supply chain management
	  – Reduced waste
	  – Reduced inventory holding costs

The GS1 bar codes of choice[8]

GS1 DataMatrix

Increasingly the bar code of choice in Healthcare is the 2D bar code, or GS1 DataMatrix. This format is resilient, holding up well on products that are handled frequently. Its benefits include the ability to provide a significant amount of information on a very small surface such as a vaccine vial.

Figure 3: **GS1 DataMatrix**

(01)07612345678900(17)100503
(10)AC3453G3

GS1 DataBar™

Both linear and 2D, the GS1 DataBar™ is also appropriate for vaccines due to its small size.

Figure 4: **GS1 DataBar™**

(01) 0 0012345 67890 5

GTIN 128

Linear in structure and already used on products throughout the world, the GTIN is recommended in place of the Canadian Drug Identification Number (DIN), which is neither unique to the format of the product nor is it used outside Canada, limiting the interoperability of the supply chain across borders.

Figure 5: **GTIN-128**

(01)0001234567890 5

The Vaccine Identification Database System (VIDS)

In addition to the AIVP Advisory Task Group's work to determine the Canadian requirements for product identification in the global standards setting process, the AIVP project is also pursuing the development of the VIDS, set to become the single, web-based repository of comprehensive information on all vaccines licensed for use in Canada.

The VIDS is being established to act as the link between bar coded vaccines, including travel vaccines, which are not publicly funded in Canada, and the electronic health record or immunisation registry. More specifically, when a Healthcare worker scans the bar code on a vaccine, the VIDS will enable vaccine information to be electronically populated into a patient's health record.[8] Available for access by all Healthcare professionals in Canada, the VIDS will help support the tracking and administration of vaccines at point-of-care by leveraging GTINs as an identifier.

In order to support population of the VIDS, GS1 Canada will be working with Canadian vaccine manufacturers to publish vaccine product information to the VIDS currently loaded to ECCnet Registry, a comprehensive and continually-validated product registry in Canada. Managed by GS1 Canada, ECCnet Registry enables Canadian suppliers across various sectors to share their product data with providers and/or retail trading partners. Product attribute fields in ECCnet Registry that will be fed to the VIDS were determined by Canadian industry to meet the demands of Canadian businesses for trading partner transactions such as product listing.

Any information that is not available in ECCnet Registry will be manually entered into the VIDS by PHAC or received electronically from the regulatory agency within Health Canada. This information could include transaction information such as lot number or serial number.

In support of the use of vaccine product identification based on global standards, the AIVP Advisory Task Group has set milestones for every vaccine sold and/or marketed in Canada to have an assigned GTIN at both the primary and secondary packaging levels, using bar codes that include variable date information.

Next steps

Over the next year, the AIVP Advisory Task Group will continue conducting its comprehensive assessment of the state of readiness of public health, private health and hospitals to use bar code technology, which began in 2009. The results of this assessment will guide the Canadian Healthcare sector's next steps as it continues to work towards implementing the standards for bar coding on vaccine products.

GS1 Canada is now leading the Implementation Roadmap Work Group, which is working to identify product identification, technology, and education timelines required to support immunisation traceability in Canada using the GS1 System of standards. As of 2011, this Work Group is currently assessing the capabilities of Canadian manufacturers to bar code their vaccine products with variable data on primary packages and create a work plan to operationalise the VIDS and populate supplier data.

ABOUT THE AUTHORS

Dr. Monika Naus, MD MHSc FRCPC FACPM, Associate Director, Epidemiology Services, British Columbia Centre for Disease Control

Dr. Naus obtained her medical training in Canada at the University of Alberta and her training in community medicine at the University of Toronto. Prior to joining the British Columbia Centre for Disease Control in 2001, she was the Provincial Epidemiologist in Ontario and Senior Medical Consultant in Vaccine Preventable Diseases and TB Control for the Ontario Ministry of Health. In addition, Dr. Naus was member of the National Advisory Committee on Immunization for 12 years, including acting as chair person between 2003-2007.

Her interests include various aspects of planning and evaluation of old and new immunization programs, surveillance of communicable diseases, and outbreak investigation, including participating on the Automated Identification of Vaccine Products (AIVP) Advisory Task Group.

Dr. Robert Van Exan, PhD, Director, Immunization Policy, Sanofi Pasteur Limited

Dr. Van Exan joined Sanofi Pasteur in 1981 as a cell biologist and manager of the Cell Culture Production Department – Viral Vaccine Production Division. Since 2002, he has been the Director of Immunization Policy and is responsible for industry collaboration and input for the development of a national immunization strategy in Canada.

A member of various advisory boards, he is a founding chair of the Vaccine Industry Committee of BIOTECanada. In addition, Dr. Van Exan is a current member of the Automated Identification of Vaccine Products (AIVP) Advisory Task Group and a co-chair of the GS1 Canada Healthcare Pharmacy Sector Board.

Just-in-time supply and automation at Strasbourg University Hospitals

ABSTRACT

The construction of a new logistics centre at les Hôpitaux Universitaires de Strasbourg (HUS) enabled the hospital to ensure Just-In-Time (JIT) supply and facilitate automation of the internal transportation flow. GS1 Standards support the flow of information from the warehouse to the point-of-care.

By **Dr Raphaël Passemard,** Strasbourg University Hospitals

and **Caroline Mons,** Strasbourg University Hospitals

Background

In recent years, French hospitals have conducted a number of projects targeting the traceability of all products delivered to them, with the aim of facilitating their internal tracking. These projects have also been motivated by a new orientation in management methods focused increasingly on the quest for efficiency, cost reduction and the improvement of their financial situation.

In 2009-2010, these projects culminated in, firstly, the launch of logistics platforms designed to manage deliveries of medical systems, medication and hospital room supplies all the way to the treatment departments, and secondly, in Healthcare traceability projects courtesy of the introduction of the unitary identification of surgical instruments. The choice of the GS1 standards was based on the need to ensure interoperability between all of the activities managed by the hospitals, to improve the flow of information useful to the different departments and thus to improve patient safety. These initial achievements are starting points and are set to be rolled out across all of the hospitals' activities.

Indeed, the early ROI indicators demonstrate that these applications, while requiring a certain human and financial investment for launch, become profitable fairly swiftly. For the moment, however, they are still too isolated and need to serve as examples for other establishments.

A major advantage on the French market is the new "Hospital 2012" law, which requires Healthcare establishments to pool their skill centres in order to improve competitiveness and cut operating costs. This law will encourage the grouping together of sterilisation centres and storage facilities, or even the creation of logistics centres serving several establishments within a given region, not to mention plenty of other projects. It will therefore increase the need to be able to exchange information and for products to be circulated between organisations on the basis of shared standards.

About Strasbourg University Hospitals

Strasbourg University Hospitals (SUH) offers a variety of treatment options capable of handling health-related conditions. Where education is concerned, the SUH have forged special links with universities and more specifically with schools of medicine, pharmacy and dentistry. However, the SUH's teaching role is not limited to university studies, as it also applies to the initial or specialist training of nurses, paramedics and other Healthcare providers. In this capacity, the SUH directly operates eight schools and training institutes. Biomedical research is also an integral part of the institution.

Growing steadily over the years, Strasbourg University Hospitals have become a vast group of seven hospital establishments with 2,783 beds, employing over 10,000 staff.

It should also be noted that medication traceability regulations are heading in the same direction as, since 1 January 2011, they have imposed not only the marking of sale units with a GS1 DataMatrix bar code incorporating a 13-character AMM code, a batch number and a use-by date, but also the transmission of information in an electronic shipping note between the different links in the chain.

Some of France's 17 GS1-compliant hospitals are aiming to develop other applications and, with this in mind, GS1 France is supporting hospitals which wish to deploy the standards in all of their activities.

Among the hospital platforms, the Strasbourg University Hospitals (HUS) offer an example of use of the GS1 standards. The HUS logistics centre applies the GS1 recommendations for the hospital environment and has opted for Aldata's solution to manage its platform. The hospital wished to use the GS1 standards to ensure better traceability of medicines and to improve its management of supplies, stocks and orders. They counted on the fact that manufacturers would be marking products and would therefore be in a position to allow them to increase the reliability of their traceability system and to ensure the safety of their patients.

Innovating the hospital supply chain

The construction of the logistics centre fits in with Strasbourg University Hospitals' modernisation plan developed in 1996, which targeted the updating of logistics via a pooling of the principal functions (central store, pharmacy, purchasing sectors, central food production unit, transport, garage) on a single site.

Unveiled in 2009, this logistics centre is designed to supply all of the six HUS sites, based on two logistical principles that are innovative in the hospital field:

- Just-In-Time (JIT) supply
- Automation of the internal transportation flow (use of AGV on one site)

The logistics centre's warehouse consists of two entities:

- The central store, managing office supplies, hospital room supplies, groceries and non-sterile medical equipment.
- The pharmacy, managing medication and sterile and implantable medical equipment.

France's regulations governing hospitals require the separation of information flows about pharmaceuticals, as well as the physical separation of the storage and preparation areas.

This new hub needed to consider the grouping together on the same site of very different products which, before the platform's creation, were managed in separate stores. These products present a high degree of variability in terms of storage constraints (positive and negative temperature control) and different requirements in terms of materials traceability (a use-by date for food products, an expiry date for health products, a batch number and/or serial number depending on their level of risk).

The computerisation of all of these characteristics of hospital logistics required the implementation of significant change management among the teams running this logistics centre.

Managing supply chain data from the warehouse to the point-of-care

The G.O.L.D. Stock and VDW (PDA Vocal) solutions were deployed for the management of the site as a whole. Flows are managed in real time via the use of mobile equipment (PDA, Tablet PC, on-board terminals), a warehouse WiFi network and the integration of RFID technology for the management of shipments.

The majority of the hospitals' receipts take place in two stages:

A first-level receipt concerning all of the warehouse's flows: The WMS – warehouse management system – then ensures the distinction between the pharmaceutical flow and the non-pharmaceutical flow, required for the completion of the subsequent stages.

A second-level receipt for storage and the preparation of internal deliveries: The information system then ensures the reconciliation of the flows at the shipping stage level. Placing in stock is carried out using forklift trucks with retractable forks. The drivers are supervised via on-board terminals.

Order preparation takes place in multimodal mode, including voice (mono-client / multi-clients, full packages / individually prepared packages):

- The central store carries out preparation in post-package mode.
- The pharmacy carries out the preparation in pre-package mode with the use of a mechanised chain.

Just-in-time supply and automation at Strasbourg University Hospitals

The combination of voice-mode preparation with "ring"-type bar code scanners and the use of linear bar code or 2D (DataMatrix) bar code technologies enables safe preparation by means of cross-referenced entry (product location and code) and the reliable detection of the material's traceability indicators (batch number, expiry date, serial number).

All preparations are grouped together on trolleys for delivery to one or more treatment departments. Also identified by means of the GS1 standards, these trolleys are equipped with two associated technologies permitting full shipment traceability: bar codes and radio frequency identification. The operator will therefore scan each trolley and each package it contains in order to ensure the traceability of these packages and of the prepared batches. An RFID tag will be read when the trolley enters the delivery lorry, with the trolley's destination then defining the destination of the lorry. Installation of RFID on the shipping bay doors enables full traceability of the trolleys (incoming and outgoing).

Upon arrival at sites equipped with security gates, this same RFID tag will be read, thereby providing confirmation of the date and time of actual delivery to the treatment unit. For other sites not yet equipped with such gates, control will take place by manually scanning the bar code on the trolley.

The system thus provides the basis for traceability by managing the products and quantities delivered together with their batch numbers and expiry dates.

The project was implemented in compliance with the new AFSSAPS regulations for the coding of medicines (development of the GS1 identification and marking standards and integration of DESADV-type electronic messages). Sent by the manufacturer at the time of "sealing of the lorry", this message contains the details of the delivery and facilitates the receipt of packages identified by a unique code, the SSCC. Upon receipt, the information system makes the link with the shipping note data, thereby facilitating the validation stages and permitting the tracing of all products redistributed within the treatment units.

Hospitals receive all types of products (health, food, textile, etc.), so they will use the general profile of the GS1 EANCOM® (version D96A or D01B) shipping note while integrating the particularities of the sector. Before long, they will be asking manufacturers to identify and mark their packages with an SSCC and to transmit the corresponding shipping note. By doing so, they aim to meet their constraints in terms of traceability and Healthcare safety and to optimise their internal and external logistics circuit.

G.O.L.D. Stock and VDW allow the optimisation of the warehouse from receipt to shipping with the capture of various traceability indicators right along the chain. This may take place manually (scanning, voice, etc.), or automatically via RFID. The dual-phase receipt offers clear visibility of the path of products within the warehouse (pharmacy, general goods) and the control of the constraints on the different segments of that course. Storage is optimised and all traceability indicators are managed for improved use of stock and positioning.

All operators are supervised using the G.O.L.D. solution, thus maximising the productivity of the different jobs, particularly the forklift truck operators (optimisation of paths and roles) and preparers (maximum productivity and quality, courtesy of voice technology).

ABOUT THE AUTHORS

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Dr Raphaël Passemard is currently leading the supply and delivery of global pharmaceutical products (including drugs, medical devices, …) at the Strasbourg University Hospitals (SUH). He also manages the logistic platform project at the SUH and within this project, is specillay involved in pharmaceutical products and processes traceability issues using GS1 Standards.
Dr Raphaël Passemard holds a Pharmaceutical Diploma along with a Diploma in Quality Management from the Strasbourg University.

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She is is currently leading the supply and delivery of food, hotel supplies, office equipment, linen…
Caroline Mons is a graduate of Ecole des Hautes Etudes en Santé Publique (EHESP).

When the nursing staff become bar code fans

ABSTRACT

Heidelberg University Hospital records its materials by scanning them: a fitness programme for DRG billing, the ordering system and budget management.

By **Tobias Schneider,**
Heidelberg University Hospital

About Heidelberg University Hospital

Heidelberg University Hospital with its more than 40 specialised clinical departments is one of the leading medical centers in Europe.

7,300 employees, including 1,200 professors and doctors, treat hundreds of thousands of patients every year from all over Germany and many other countries, coming here to make use of our modern treatment facilities.

*Scanning at Heidelberg University Hospital
(Source: Heidelberg University Hospital)*

The impact of Diagnosis Related Groups (DRGs) billing

"How much material do we consume for each individual patient or, in technical terms, for each individual case?" An important question for the controlling department of Heidelberg University Hospital and the other German hospitals. Since the introduction of the Diagnosis Related Groups (DRGs), health insurance companies are billed on a patient-related basis, so it is important to carefully track the individual materials consumed at the hospital. Transparency is also important in the hospital for planning and controlling internal processes. The overview of which ward consumes what volume of materials facilitates the processes for procurement and inventory control, as well as those for budget management and planning.
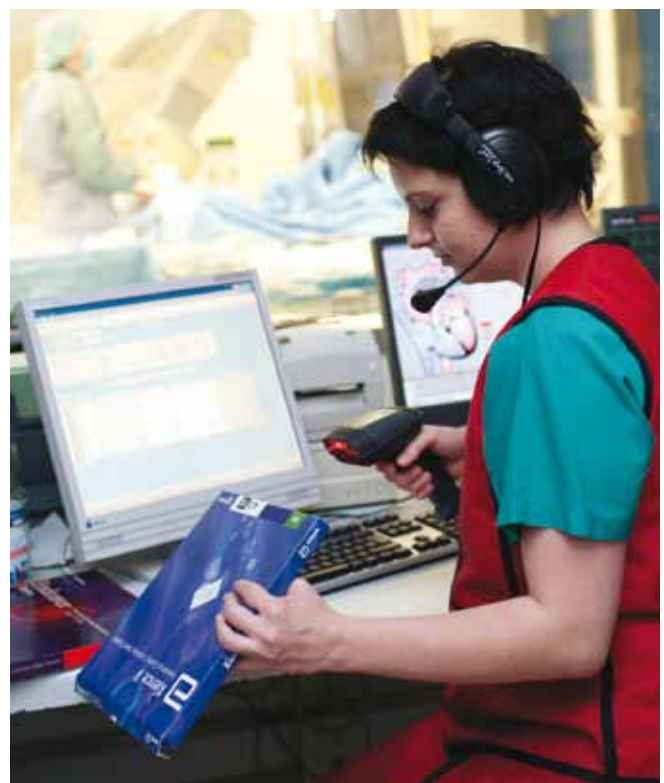
When the nursing staff become bar code fans

Introducing bar coding to ensure transparency

Before scanning was introduced, implants were recorded accurately, but the nursing staff only kept rough records of screws, nails, catheters, covers, and other material, on paper. Precise billing for a patient was consequently only possible with a great deal of effort, and was in some cases impossible. The hospital therefore, had no transparency for some costs. For repeat orders patient labels were attached to internal order forms. The forms were forwarded to purchasing, which initiated the order and posted it to the case number, to the patient. This system is not only complex, but quickly reaches its limits, for example whenever a package contains a larger number of products than, say, in the case of syringes and catheters. As a rule these products are not labelled individually. The employee then affixes the label from the box onto the order form, but has not used up all the contents of the box for the patient. Furthermore, often several materials are used per patient and measure. This can sometimes involve over 50 different products, for instance during an operation.

The controlling department of Heidelberg University Hospital found the remedy by scanning the delivery bar codes on the packaging for the various materials.

This enables the material required for the patient to be recorded as soon as it is used. At the start of the project the University Hospital entered the material master data, including the unique GTIN (Global Trade Item Number), in the database of the merchandise management system. The hospital works with SAP software here. Both the merchandise management system and the hospital information system are SAP modules. The staff records all the activities for each patient in worklists. The medical products used for each measure can also be recorded. To do this, the employee goes from the measure concerned in the worklist to a material list. When they scan the bar code, the product is automatically included in the material list, the system taking the data which is linked to the GTIN encrypted in the bar code from a database. The material has now been entered in the list and the next material can be scanned. Scanning, recording, scanning the next product, and so on. This automatic recording of the products fulfils one major condition: the nursing staff has a user-friendly system at its disposal.

Label with GS1-128 bar code (Source: GS1)

The system learns from mistakes

The Heidelberg University Hospital goes one step further when scanning. It checks the success of each individual material recording operation. Has all the material data been entered correctly? Are there problems with the supplier information? Is the GTIN, which is unique worldwide, contained in the material master data? Is the bar code clearly legible? What are the staff on site doing while scanning? Thanks to a sophisticated error management system the controlling staff can answer all these questions. The system automatically stores every scan operation centrally. Using this database the Controlling staff can evaluate the success of the scan project, with the result that the number of faulty scan operations is reduced.

In addition, nothing in the documentation is lost because if no product information from the database is available when a bar code is scanned, the team can research this information and enter it retroactively.

Currently 600 scan operations take place each day in the hospital in various wards, for example Vascular Surgery, Endoscopy and Urology. In the medium term the number is scheduled to rise to approx 5,000 per day.

Need for (standardised) bar codes

Another important requirement for Heidelberg University Hospital for a solution for precise patient-related billing concerns the product labelling. Around 90 per cent of the materials used in the hospital have a bar code, and 75 per cent of these are unique. At least three out of four products can thus be recorded unambiguously using the bar code. Most products have a GS1 bar code. The others either have none or only an internal bar code which permits no unique assignment. With these products an employee must assign the correct information to each product. Despite a high level of automation, this often requires painstaking care.

But from the experience of the users, Heidelberg University Hospital knows that scanning is fast and efficient only when the bar code is located in the correct place, the packaging contains no more than one bar code, and ideally the product is labelled or even has a bar code directly on its individual packaging. In this it is of the same opinion as other hospitals. Here they must rely on the suppliers. It is in their hands to decide which bar codes are affixed to the packaging and how.

For this reason, a number of hospitals have already expressed their wishes for product labelling to their suppliers, for example at joint road show meetings in 2010. Here the EK-UNICO and the hospital purchasing syndicates which are organised in the German Association of Purchasing Institutions in the Healthcare Sector (BVBG) spoke in favour of medical products being identified unambiguously by means of GTIN at various packaging levels.
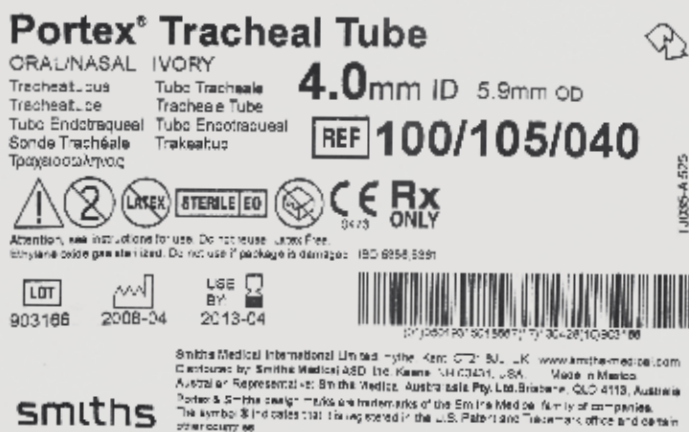
Drugs package with GS1 DataMatrix (Source: Bluhm Systeme)

In addition, the packages should, as far as possible, only have one clearly legible GS1 bar code, and the master data for the products should be transferred electronically using GS1 standards.

In addition to the classical GS1 code, GS1 offers two further bar codes which are tailored to the special features of the Healthcare sector: the GS1-128 bar code and the 2D code GS1 DataMatrix.

Users can encrypt master and movement data in the GS1-128 bar code. The GS1-128 symbols offer a high level of security and delimit the data contents presented there from non-standardized bar code applications.

The GS1 DataMatrix can encrypt a large amount of information in a very small space. The GTIN (Global Trade Item Number), for example, can be accommodated on print areas of less than 25 square millimeters and consequently label very small products. Because of its technical configuration the GS1 DataMatrix is suitable for direct labelling of components or, for instance, surgical instruments. The authentication of the products at the various levels of the supply chain permits unambiguous traceability. Product counterfeiting can thus be reduced and callbacks can be organised more efficiently and more effectively.

The standards are developed by practitioners from pharmaceutical and medical devices companies and hospitals in regular exchanges of ideas at an international level.

Beyond DRG

There are a wide range of applications for the GS1 Standards in hospitals. In addition to the recording of material usage for more efficient DRG calculation chosen by Heidelberg University Hospital, they can be employed, for example, to record patients more easily and to manage their care more effectively. Further information supplied in the bar code, such as the batch number or serial number and the expiry date, can be used to guarantee automatic control of the expiry dates. Storage of the batch number or serial number is helpful for patient documentation, for permitting the batch to be tracked and for possible callbacks. The data identifier system of the GS1-128 bar code and of the GS1 DataMatrix permits information such as the batch number and expiry date to be read out unambiguously.

What is useful for the hospitals should not be detrimental to the suppliers. They, too, profit from the labelling of their products with standardised bar codes.

Little effort, great benefit

In the case of Heidelberg University Hospital the effort and costs for setting up automatic material recording were kept within limits. In addition to the existing IT solutions, the hospital invested in new camera scanners and one or two computers. The scanners are USB-capable and are compatible with every computer. The data processing is designed in such a way that the processes can be freely selected by the users. This means that users can decide whether they scan the material immediately at the time it is used or later. Every area – be it, for example, the care sector or the OP area – can decide according to its needs.

Sceptical at the beginning, the staff on the wards are now thrilled by the speed and the potential of scanning. Even though it initially entails more effort because all the material used for a patient is recorded in this way, they are now fascinated by the additional options. The new transparency makes transactions such as orders and budget management easier for the nursing staff. The hospital management profits from the precise overview of the materials consumed not only in the billing of the health insurance companies, in budget control and procurement management: it also has more leeway in negotiations with the health insurance companies.

Other hospitals, too, have already looked into bar code scanning and tested it in practice. GS1 bar codes applied by the supplier achieved time savings of up to 86 per cent for patient-related consumption recording at the Heart Centre Bad Krozingen. In a project in the logistics and document centre at the St.-Marien-Hospital in Bonn, for instance, scanning the materials enabled a total saving of 472 working hours when extrapolated over the year.

Although the Heidelberg University Hospital cannot yet put any figure on the money and time it has saved by scanning, it feels the benefits every day in the procedures. And that despite a quarter of the materials not yet being adequately labelled. One further important aim is therefore to work with the suppliers to achieve optimum product labelling.

ABOUT THE AUTHOR

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Bar coding on pharmaceutical packaging cuts costs and improves patient safety

ABSTRACT

The bar code has been in use in the retail industry for decades, in fact the first bar code was scanned in 1974 from a packet of Wrigleys chewing gum. It is now hard to find any retail outlet that does not scan products at the point of sale. The benefits of bar code scanning extend across the supply chain, from manufacture right through to the customer (stock tracking, inventory management, billing, consumer consumption trends).

The push for bar coding on medication rose substantially with the publication of the Institute of Medicine's landmark report, To Err is Human: Building a Safer Health System. The IOM's findings delivered shocking estimates regarding the occurrence and effect of medical errors. What is required to ensure end to end traceability is standardised marking (bar coding) on all medication, so that all parties in the supply chain can capture, understand and share the data. The global standards organisation, GS1, provide a platform for the development and implementation of such standards.

Unlike any other time in history we now have mobile technology that can be leveraged to provide the tools required to implement initiatives that can improve patient safety and support a rapid real time recall.

The advent of the smartphone incorporating an auto focus camera has provided the unlikely platform for an innovative solution that tracks medication, gathers clinical information, increases recording compliance as well as alerting the patient to potential hazards with respect to their medication.

By **Feargal Mc Groarty FIBMS,** St. James's Hospital, Dublin, Ireland

Bar codes in industry and Healthcare

Bar coding technology has had a significant impact on the retail supply chain. The ability to automatically capture, store and analyse product identification from the bar code, and to organise logistics functions and streamline the flow of information has had a significant positive benefit.

The Healthcare industry has to date been slow to fully embrace bar coding for a number of reasons. Firstly, from a hospital point of view, bar coding was viewed as a purely logistics tool for better supply chain management and cost containment. Secondly, hospitals have been traditionally slow to commit funding to implement technology infrastructure unless there is a guaranteed ROI. Finally, the lack of standards, particularly in medication marking, has hindered widespread adoption.

In the retail industry standards for bar coding have been in existence for decades. The slowness of the pharmaceutical industry to develop standards for medication marking at unit level is baffling. Standardised medication bar coding would enhance the pharmaceutical industry internal and external supply chain with associated benefits for stock management and anti counterfeiting. But looking beyond the supply chain in particular, we find benefits that extend to the care giving functions – the core business of Healthcare.

Bar code Case Study – Hospital and home use from Ireland

Interestingly, when the entire Healthcare system works with patients to deliver and track the supply chain of services for wellness, Healthcare savings and improved patient outcomes can be achieved. More than a just a vision of the future, this is being achieved with suppliers, hospital and patients in Ireland.

The National Centre for Hereditary Coagulation Disorders (NCHCD) located at St James's Hospital, Dublin, manages patients with inherited and acquired bleeding disorders. In Ireland, there are approximately 2000 patients with such a condition, of which there

are approximately 200 patients with severe haemophilia that require intensive care/treatment. Essential to this care involves taking a medication on a regular basis, which replaces the missing factor that causes excessive bleeding. Over 75% patients with the severe form of the condition are required to self medicate at home.

This expensive medication requires specific cold chain handling that extends from suppliers all the way to the patients home and medication use.

Although the patient safety issue that has been brought to prominence is the high frequency of medical errors and the impact on patient safety of administering wrong medication, just as important is the issue of safety of the blood and blood products themselves being used to treat patients. This latter issue was brought sharply into focus in the 1980s when patients suffering from the blood disease Haemophilia became infected with HIV/Hepatitis due to blood product contamination. The situation was compounded by the fact that infected medication (plasma product) remained in the supply chain even after a recall was initiated, leading to further infections. In Ireland this lead to a national Tribunal of enquiry (The Lindsey Tribunal), which acted as a catalyst for this unique initiative.

The plan was to apply the retail supply chain model, incorporating a serialised GTIN, to all haemophilia medication packaging. This would allow electronic track and trace of the product as it moved from manufacturer to the patient (particularly important as the majority of severely affected patients self medicate in the home).

However, the absence of standardised bar codes on medication packaging coming from the main haemophilia medication manufacturers (in fact some of the medication had no bar code) meant that a unique standardised bar code could only be applied once the products reached the Cold Chain supply company (TCP Ltd.) who were contacted by the hospital to deliver the medication to the patient home.

Unique Identifiers

The key objectives of the NCHCD initiative were to implement real time identification of CFCs to ensure immediate product recall, optimize stock management and save on wastage. The unique GS1 code allocated to each patient, drug product and location facilitates the automatic linking and capture of data during the supply process, validating each step of the cold chain storage and delivery process in real-time, ensuring that the correct drug is prescribed to the right patient as well as automatically updating the stock management system so that patient consumption trends can be analyzed.

How the Haemophilia medication Tracking system works

The key to the success of this project involves harnessing the power of bar codes. Each patient is allocated a unique identifier,

as is each unit of medication and each location in the supply chain.

The process starts at the Cold Chain Company where the medication from the suppliers is received. Information on each vial box (Product name in the form of a GTIN, expiry date, batch number) is entered into their stock management system. A GS1 standard bar coded Vial Box Serial Number (VBSN) label is generated and applied to each unit of medication. The medication is then stored in validated cold chain conditions. Once a prescription is received for a patient or hospital delivery, all picking packing and shipping is performed using bar code scanning to track and trace the product as it moves through the supply chain, to either the patient home or the hospital. Within the hospital another software system then takes over the tracking and tracing of the medication as it moves around the hospital, again based on bar code scanning.

Measurable success

The result has been an overwhelming success on a number of fronts. St. James's Hospital now has total visibility of each unit of Haemophilia medication in the supply chain. In the event of a recall the location of 100% of any selected batch of product can be identified within 10 minutes (a key recommendation of the Tribunal). Patients are extremely happy with a Cold Chain delivery service they can rely on. Product wastage due to failure of cold chain conditions or documentation issues has been eliminated. Interestingly, possibly because patients have confidence in the delivery method, €5 million worth of medication has been removed from the supply chain. This is due, most likely, to the fact that patients no longer "over order" and the fact that patient consumption trends are now visible in real time.

Datamatrix bar codes

Bar code advancements

The prospects for the use of bar codes in Healthcare have advanced considerably with the introduction of 2 Dimensional (2-D) bar codes. 2-D bar codes are much smaller than linear bar codes while at the same time capable of carrying significantly more information. It is the ideal format where the size of the package or vial is small,

Datamatrix bar codes

and the space is not available for printing linear bar codes. This is particularly relevant for medication that is administered as a single dose unit within the hospital or the home. For example, the Data Matrix bar code, shown here, requires the least amount of label space than any other available bar code standard. Datamatrix bar codes also apply error correction algorithms. In simple terms this means that up to 60% of the label can be damaged without affecting the integrity of the scan.

Patient handheld devices and point of care

Extending the concept of traceability to drug administration at the bedside and within the patient home is providing the final piece of the jigsaw. The bar code on the packaging (and the vial) serves as an index key in clinical databases. At the point where medication is administered, bar codes can be used to identify the drug, patient and/or the person administering the drug. This will assure a match between the patient and their prescribed medication, and also identify who is administering it. The system can be linked to software that references information in the patient Electronic Patient Record (EPR) to comply with the "Five Rights" of patient medication administration ensuring the right drug is administered at the right time to the right patient in the right dose by the correct route. However, the technology used needs to be portable and easy to use.

4.74 inches (120.5mm)

0.43 inch (11mm)   2.64 inches (67mm)

Smartphone with Medication Scanning App

As part of the Irish initiative mobile devices (smartphones) such as the HTC above, are currently being rolled out. As well as having standard mobile phone features, the devices are equipped with a software application (App) to allow the patient records their medication usage by simply scanning the B/C on the Vial Box. A realtime check is then performed against the EPR to ensure that the medication is not subject to a recall. In addition, the application offers the patient the opportunity to record key clinical information relating to why they needed to take the medication. The information (medication taken and reason for treatment) can then be transmitted back to the EPR and form part of the treatment history. Other significant benefits have also emerged as a result of this application. For example, because information is gathered in "real time", care givers can now identify the time of day that treatment is being administered. Due to the fact that it has a specific half life, it is recommended that it should be taken before the patient is most active. But information gathered to date showed that some patients were self infusing last thing at night. Changing this practice would give improved protection against "breakout bleeds" that can lead to a decrease in quality of life, as well as reducing the necessity for additional, non prophylaxis, treatment.

Initial feedback from the patients has been overwhelmingly positive. Compliance with medication recording has improved significantly, which in turn helps the caregivers manage the patient's condition more effectively. A patient focus group has been established to feed back ideas on software and service improvements.

The Irish initiative should help encourage the pharmaceutical and Healthcare industries to reach an agreement on a bar code standard for medication. Once they have achieved a standard,and medication packaging contains the bar code, vendors of medication administration applications and EPR systems will begin supporting it. This in turn will lead to wider adoption within the Healthcare industry, and hospitals in particular, leading to improved patient safety whilst simultaneously driving down the cost of Healthcare delivery.

ABOUT THE AUTHOR

Feargal Mc Groarty, Project Manager, IMS Department, St James's Hospital, Ireland

Feargal Mc Groarty is Project Manager, IMS Department, St James's Hospital, Ireland. A Medical Laboratory Scientist (MLS) by profession Feargal has over 20 years experience in Laboratory Haematology, Coagulation and Blood Transfusion. He headed up a large routine diagnostic Haematology laboratory, and has a particular interest in Laboratory Information Systems (LIS) and laboratory automation.

In his present role he is responsible for managing the multi faceted initiative that combines a number of strands including the use of bar code technology, an Electronic Patient Record (EPR) along with a cold chain delivery service to provide integrated patient management processes which is the first of its kind.

Mr. Mc Groarty holds a Fellowship in Haematology from the Institute of Biomedical Science along with a Diploma in Management and Employee Relations from the National College of Ireland (NCI).

Logistics management of pharmaceutical products with bar codes and RFID tags
TBC Tokyo, Toho Pharmaceutical Co., Ltd.

ABSTRACT

Toho Pharmaceutical Co., Ltd. (Toho Pharmaceutical) is a wholesaler of pharmaceutical products, which was established in 1948. Toho Pharmaceutical has nine subsidiaries and three affiliated companies. These companies all belong to the Kyoso Mirai Group and work in cooperation to provide services in areas across Japan.

The Kyoso Mirai Group, which is currently a holding company, has total group sales exceeding 1 trillion (¥) Yen and serves about 100,000 clients including; hospitals, clinics and dispensing pharmacies.

The group's nationwide logistics network is supported by logistics centres located in six areas in Japan. In this article, we report on TBC Tokyo, the largest of these centres.

By **Ryuta Suzuki,**
TOHO Pharmaceutical
Co., Ltd

Background

Before explaining TBC Tokyo, we would like to briefly discuss its historical background along with the Japanese pharmaceutical product supply chain. In Japan, wholesalers provide all the services that connect pharmaceutical manufacturers and medical institutions including; securing product stocks, providing information on pharmaceutical products, determining prices and delivering goods. Since trusted wholesalers deliver products produced by trusted manufacturers to medical institutions, problems with fake medicines do not exist in present-day Japan.

Toho Pharmaceutical created its first large logistics centre in 1988. At that time there were already standardised pharmaceutical product codes compliant to EAN specifications and attempts were being made to print JAN codes (EAN-13 in Japan) on sales packages. JAN codes (present-day GS1 codes) were put to full use for automatic product checking together with the original company bar codes attached to transportation equipment (such as folding containers) for automatic transportation within the storehouse. We at Toho Pharmaceutical not only improve economic performance and efficiency through a concentration of products, but we also strictly control the amount of supply for each product item and provide a steady supply of products.

In 2002, the Ministry of Health, Labour and Welfare issued the Revised Pharmaceutical Affairs Law, which was aimed at ensuring the post-marketing safety of pharmaceutical products of biological origin (products made from materials of human or animal origin, such as blood). This revision of the law, which obligated companies to keep records of the LOT numbers of such pharmaceutical products sold or dispensed, served to raise awareness of the importance of LOT management in the pharmaceutical industry. There was also an increasing interest among medical institutions in obtaining information on the LOTs and expiration dates of delivered products, which created the need to manage products by LOT rather than by item.

We subsequently created a series of centres to implement stock management by LOT, and in November 2006, TBC Tokyo started operations as a replacement for our first logistics centre.

Operations at TBC Tokyo

Overview and specifications
TBC Tokyo was created to realise a high level of accuracy, efficiency and automation in the distribution of pharmaceutical products based on the knowledge and experience accumulated over many years. Although bar code checking at each process had been conducted, even in the previous logistics centre, TBC Tokyo introduced a 100% paperless environment, which pursues the integration of human and machine processes to attain higher automation and accuracy of the operation. Flashing RFID tags are also adopted to prevent errors in picking areas.

**Logistics management of pharmaceutical products
with bar codes and RFID tags**

Outline of TBC Tokyo

Established: November 2006
(Shinagawa-ku, Tokyo)
Site area: Approx. 10,000 m²
Total floor area: Approx. 20,000 m²
(4 floors)
Stock items: 22,000 items (98% of
which are prescription drugs)
Amount of Supply: 25 billion (¥)
Yen per month
Suppliers: 300 companies
Sales offices: 75 (These sales offices
provide products to a total of
35,000 medical institutions.)

4F: Sales package digital picking area
Combination of digital picking and handy terminals;
simple transportation lines; flashing RFID tags

**3F: Area for refrigerated products and
psychotropic drugs; area for products of
irregular shapes**
Fingerprint identification lock
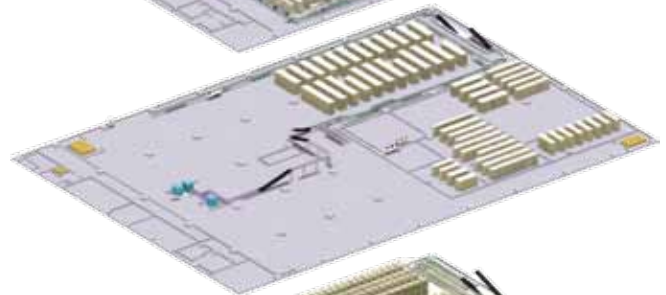
2F: Automatic packing and storage area
100% automated area with a location-free system
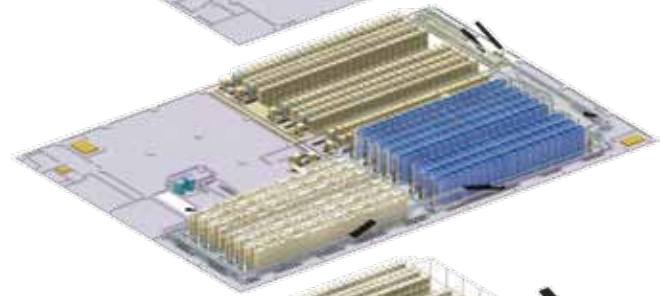
**1F: Receiving and shipping area; storage with
automatic pallets**
Receipt and shipment of products and buffer lines

Receipt of products (manufacturers' original packs and sales packages)

TBC Tokyo receives 10,000 cases of manufacturers' original packs and 10,000 boxes of sales packages per day on average. Although we are working to check all these products using bar codes, about 30% of original packs do not have bar codes. (At present manufacturers are required to print bar codes (GS1 GTIN) on sales packages, but have no obligation to mark bar codes on original packs except for biological products).

Since stocks are managed by LOT at TBC Tokyo, information on the LOT and expiration dates of products need to be entered into the computer system when they are delivered to the centre. To this end, we obtain, in advance, the data on products scheduled for delivery from manufacturers and check delivered products by comparing them against the obtained information. At present, bar coding of information on LOT and expiration dates has not been fully implemented, except for biological products, but we do hope this could be achieved in the near future.

Automatic transportation

Conveyor lines with a total length of 3,000 meters are installed in the logistics centre, where storage control labels are attached to original packs and handling containers, as they are transported by conveyors. These originally designed control labels have bar codes to be read by bar code readers at the side of the conveyors. The bar code readers determine transportation routes and automatically transport products to their assigned destination. The control labels are automatically attached by pneumatic machines and transportation is performed entirely without manual operation.

Automatic labelling

Handling containers transported by conveyors

Automated storage

Upon receipt, original packs are automatically transported to automated storage devices.

There are a total of 14 automated storage devices with either rotary racks or shelves, and 22,300 stacks of products are managed using a free location system. Products are controlled with the storage control labels linked with storage locations and are stored in stacks on a 100% first-in-first-out basis.

Products to be delivered to sales offices, in original packs, are automatically transported out of the automated storage area to the shipping area, entirely without manual operation. The supply of sales packs for picking is also done automatically from the storage area to the shipping floor.

Automated storage for original packs (with rotary racks)

Automated storage for original packs (with shelves)

Automatic folding machines for the handling containers

Sales package picking

On the sales package shipping floor, products are stocked on dedicated shelves, from which packages are picked by using instructions given from lights built into the shelves (DPS: Digital Picking System) or by using 'handy' terminals. Products are managed using a free location system on this floor as well, with stock on each stack linked with a particular LOT and expiration date. Operators pick packages from designated stacks without having to paying attention to LOT numbers or expiration dates.

In order to double-check shipping errors, GS1 codes are read with scanners to inspect all items that have been picked from shelves.

Picking

Flashing tags

The shipping floor, where sales packages are processed, is divided into a total of 16 areas. TBC Tokyo's shipping system is known as the relay system, in which handling containers, which are automatically assembled further up the line, are delivered to individual areas as needed. Picking starts in individual areas without waiting for containers (advance picking system). This system eliminates operators' waiting time but creates the need to match baskets containing products that have been picked to appropriate handling containers.

With a view to overcoming an identification difficulty, we developed a flashing tag (jointly developed with the Ubiquitous Networking Laboratory; a patent application has been filed). This flashing tag is attached to a basket before products are picked and flashes when the matching container arrives at this area, and the bar code on its control label is read. This flashing tag, designed to enable operators to accurately perform their jobs without stress, was developed in order to avoid errors in these operations, which can result in a large number of erroneous shipments.

Flushing Tag Specifications
Conform with : ARIB STD-T67
Communication
frequency: 429 MHz band
Modulation rate: 14.4 kbps
Battery: Lithium ion

Shipment

Handling containers, filled with products in the sales package shipping floor and original packages transferred out of the automated storage area, are transported to the shipping area and are stacked in the buffer area to be sorted according to destination before final shipment. Operators check how packages are being processed, using their terminals, and give instructions to send correctly identified sets of products to relevant shipping lines.

Containers and original packs with the same destination are subsequently sent to the designated line in batches. The package at the head of each batch is examined with a 'handy' terminal to check its control label against the cargo destination bar code.

Summary

Thanks to the above operations, TBC Tokyo has achieved a shipping accuracy of 99.9999%. In fact, only several times a year where shipping errors have occurred it is mostly with products without bar codes, such as hygiene products. These results prove the importance of carefully checking products using the GS1 code as a means of preventing shipping errors.

At Toho Pharmaceutical's logistics centres, we are working to create a system designed to achieve seamless integration between manual and machine operations, and we believe that we have achieved a certain level of perfection for our system at TBC Tokyo. Transportation within the logistics centre is automated using bar codes, and all operations, including

labelling, are automated. Our system, which enables even inexperienced operators to perform jobs without errors by following instructions from machines, is designed to ensure accuracy in the final outcome.

There are many operations left unmentioned in this report, which all make use of variations of automation technology using bar codes, some in combination with attempts at developing new technologies.

Although at TBC Tokyo, staff still perform the main roles, with the support of machines but in a fully automated system, of the future, this maybe reversed with machines performing the main roles, with staff providing the support.

We receive as many as 20,000 products from about 300 companies, which vary in packaging and shape. There is also no unified standard about where to place source-marked bar codes, which will create difficulties in further promoting automation. Accordingly, apart from various standardisation efforts, the development of automatic identification technologies, such as RFID and image recognition, that meet our needs is likely to be an important key to the future.

ABOUT THE AUTHOR

Ryuta Suzuki, Deputy Director, Information Systems Planning Office, Development Division TOHO Pharmaceutical Co., Ltd

After joining TOHO Pharmaceutical Co., Ltd.(TOHO Pharma) in 1987, he had been engaged in the development of electronic ordering system between medical institutions and the company as the staff of TOHO System Service Co., Ltd. (a subsidiary of TOHO Pharma) since 1988. Returning to TOHO Pharma in 1995, He has been in charge of various system developments such as in-company network system and barcode system for supply chain.

He has been involved in the establishment of bar code indication rules for drugs in Japan since 2004 when he joined a working group of JPWA (Japan Pharmaceutical Wholesalers Association) and was concurrently appointed as a member of the code system study working group of the Ministry of Health, Labour and Welfare.

The role of Korea Pharmaceutical Information Service (KPIS) in patient safety

ABSTRACT

Many countries are committed to enhance patient safety in the public health domain by applying IT technology to pharmaceuticals and medical devices such as surgical instruments and implants. Korea is also engaged in this, having recently mandated the use of bar codes in pharmaceutical products. Safety, efficacy and adequacy in dispensing of pharmaceutical products must be ensured. Given its large impact on the society and the high level of expertise required, the state needs to develop an institutional mechanism to manage all phases of the product life cycle, including development, manufacturing, distribution, sales and dispensing.

By **Dr. Jeong,**
Korea Pharmaceutical Information Service Center

Introduction

In this paper, the conditions that necessitate pharmaceutical information management will be reviewed. Moreover, the role and functions of the Korea Pharmaceutical Information Service (KPIS) will be explained through its major activities including standardisation for information management, collection of finished pharmaceuticals information and management of pharmaceutical bar code label system, with checking detailed accounts for patient safety.

Benefits of pharmaceutical information management

Knowledge-information is deemed as a determining factor to competitiveness of a modern society. Currently, massive investments to build high value-added contents are made by countries that aspire to assume a leadership position in information society.

Informatisation in the pharmaceutical industry contributes to ensuring people's safe use of drugs, promoting the industry development and is likely to create more value than in other industries. The cost of pharmaceuticals takes up 30% of all health insurance benefits in Korea, a country with universal Healthcare coverage. Pharmaceutical information management is also emerging as an important issue because it contributes to fiscally sound operations in medical insurance.

If a country's logistics system is to be modernised, its information turned into knowledge and its efficiency secured in the pharmaceuticals sector at production, distribution and consumption levels, there needs to be a standardised information management system that successfully engages manufacturers, sellers and buyers. Moreover, efficient operation of such system will only be ensured when distribution information is managed through standardisation of pharmaceutical codes, by promoting drug use safety through pharmaceutical record management and by removing uncertainties in government policy implementations through the establishment of knowledge.

A sound information management system will bring many benefits to the Korean pharmaceutical industry. Not only will it help the industry resolve high cost problem coming from its complex distribution channels, but it will also counter illegal and counterfeit drugs and ensure swift recall of hazardous drugs that affect safety, efficacy and quality. Moreover, the system will promote public health by responding effectively to essential drug shortages, which can escalate into a serious national threat if left unaddressed.
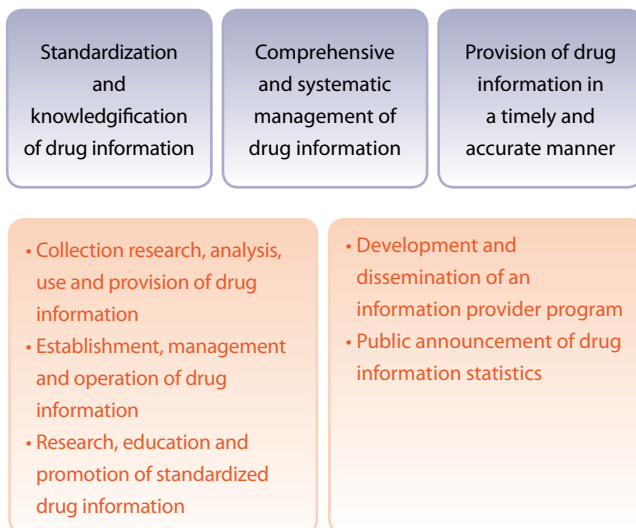
The role of the KPIS

To promote the pharmaceutical industry, the Korean government has taken continuous measures to upgrade the drug distribution system and strengthen industry competitiveness. On October 8, 2007, the government established the Korea Pharmaceutical Information Service (KPIS) as a specialised institution tasked to standardisation of pharmaceutical information and development of knowledge-based information, under the Health Insurance Review & Assessment Service (HIRA) - a public entity established to review and assess medical care expenses under the National Health Insurance Act.

The core function of the KPIS is to collect, study, process, utilise and provide pharmaceutical distribution information with regards to manufacturing, import, supply and consumption activities. Other works of the KPIS include management of Korea Drug codes (including bar codes), informatisation support activities such as development and promotion of programs for collecting distribution information, and research, education for standardisation as well as distribution innovation.

Drug Distribution Information Hub
Promoting National Strastistical Infrastructure and Pharmaceutical Industry

Standardization and knowledgification of drug information	Comprehensive and systematic management of drug information	Provision of drug information in a timely and accurate manner

- Collection research, analysis, use and provision of drug information
- Establishment, management and operation of drug information
- Research, education and promotion of standardized drug information

- Development and dissemination of an information provider program
- Public announcement of drug information statistics

Management of pharmaceutical standard codes and bar codes

Used for drug identification purpose, the pharmaceutical standard code is a GS1 Global Trade Item Number (GTIN) made up of country code, manufacturer's code, item reference and check digit. The standard code is assigned to every pharmaceutical product at item/packaging unit level.

Pharmaceutical Standard Code Structure

Digit	3	4	5		1
Content	Country Code	Company Code	Item Reference		Check Digit
Example	880	6400-6999	Item (including content info)	Packaging Unit	0-9
			0001-9999	0: Representative Code 1: Packaging Unit	

Bar codes are assigned to drugs by packaging unit and used as in filing code for medical insurance (Effective as of January 1, 2010)

Small quantity batch transaction and duplicate shipping error bring complexities to domestic distribution and are thus deemed to incur excessive logistics cost and weaken competitiveness of the pharmaceutical industry. Against this backdrop, the Korean government introduced and effectuated a bar code label regulation on imported and local-manufactured pharmaceuticals from July 1st, 2000. Imposed to the industry as a mandatory requirement, the label system is designed to bring down logistics cost, ensure transparency in business transaction and facilitate advances in the drug distribution system.

Moreover, in order to expand the scope of application, facilitate bar code usage and seek further improvements, the Ministry of Health and Welfare revised its announcement on the "Guidelines for Use and Managing of the Pharmaceutical Bar code." As a result, the GTIN in the standard KDC (Korea Drug Code) was changed to symbol formats such as EAN-13, GS1-128 and GS1 DataMatrix. Standardisation of drug codes improved information credibility, while informatisation in logistics control reduced cost, enhanced safety in distribution and use and contributed to standardisation of the national drug information database.

Moreover, expiration date and lot number information is mandated in bar codes for traceability of specified drugs from 2012 and prescription drugs from 2013, respectively.

A bar code is required for every medicine distributed in Korea. According the relevant laws and decrees, drugs with missing, partial, unreadable or erroneous bar code information are subject to administrative disposition, ultimately leading to a market pull-out order. The KPIS carries out a field study on the use of pharmaceutical bar codes twice a year to identify new errors and provide education, promotion and counseling accordingly.

Use of bar codes is proven to be beneficial to all participants involved. Pharmaceutical companies can manage distribution information at the source (production, supply and consumption), control dispensing based on a FIFO method and operate a Point-of-Production (POP) system. Wholesalers can manage inventory movement and control stocks more easily. Hospitals, clinics and pharmacies can avoid medication error, as the bar codes provide adequate verification against drugs in stock and appropriate medication control against patients. Lastly, the government can manage drug distribution records by using this system.

KPIS and GS1 Korea

In February 2009, the KPIS entered into a "Memorandum of Understanding on Promoting Exchange and Cooperation of Pharmaceutical Information" with the GS1 Korea. The MoU allows the KPIS to exchange its drug information with bar code verification information of GS1 Korea. Through information exchange between the two organisations, manufacturers/importers are able to utilise a free and simplified system of pharmaceutical bar code verification. Also, the system reduces bar code error rate by encouraging the manufacturers/importers to attach correct bar code label to their products.

Pharmaceuticals and RFID

The KPIS also oversees pharmaceuticals applying RFID, which is now in a pilot stage available to a few companies. As an effort to advance and improve transparency in drug distribution, the Korean government plans to push RFID usage to 50% levels in the pharmaceutical industry by 2015.

Based on a pharmaceutical RFID pilot project from 2006 to 2007, the KPIS is also drafting a revised announcement and operating guidelines to promote usage of pharmaceuticals with RFID tags. The KPIS will also launch a consumer pilot project to test provision of drug information and develop an internal system to check distribution flow of drugs with RFID tags.

If RFID becomes more popular in the logistics process and dispensing status gets reported to the KPIS on a real-time basis, then they will surely contribute to improving pharmaceutical use traceability, which in turn will counter use of counterfeit drugs and recall hazardous drugs, thereby improving quality of national health.
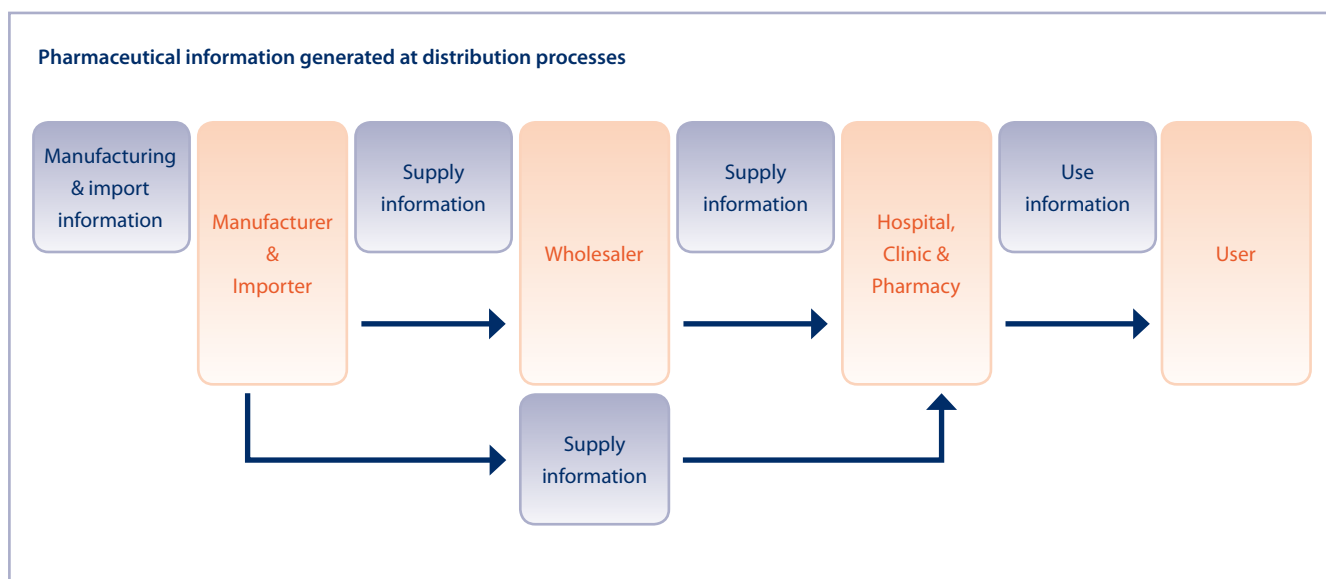
Information collection and management

The legal grounds for collection of pharmaceutical distribution information comes from the Pharmaceutical Affairs Act and the National Health Insurance Act, which require collection and management of information related to production, import, supply and consumption of drugs in Korea. Supplier information is created at manufacturer, importer and wholesaler levels, while user information is generated at hospital, clinic and pharmacy levels.

Performance records show the current status of drug manufacturing/import. As for drug supplier/user category, the purpose is to show market status, promote distribution record keeping, upgrade logistics capability and ensure transparency. The objective is to advance drug distribution and support reimbursement approval activities. Information in the user information category can be used to support review and payment of insurance benefit claims.

Manufacturing / import performance is recorded by requiring manufacturers/importers to submit quarterly performance report to the relevant associations, which then relays the report to the KPIS. As for drug supply details, suppliers are required to submit their monthly transaction records with medical institutions, pharmacies and pharmaceutical wholesalers to the KPIS.

Once collected, information is cross-analysed to identify the accurate distribution flow at the logistics level. Also, field investigations are conducted to push for accurate reporting from suppliers. Enhanced transparency in drug distribution promotes fair trade of pharmaceutical products. Moreover, as pharmaceutical distribution information grows in volume, it is able to provide official data on the Korean market situation. Those outside the pharmaceutical industry can now utilise statistical information on drugs provided on a regular basis.

Pharmaceutical information generated at distribution processes

Analysis and utilisation

When the KPIS can collect drug distribution information in a timely and accurate manner, accumulate multi-year information base from which various relevant statistics are produced and manage pharmaceutical bar codes in an error-free manner, those outside the pharmaceutical industry can also benefit from access to such information.

- Advances in drug statistics management will be realised through establishment of a national statistics infrastructure that contains information on pharmaceutical industry, drug distribution industry and current status of drug use by the general public.
- The KPIS can contribute to transparency in pharmaceutical distribution and soundness in insurance finances.
- Drug history can be traced back, which means illegal, counterfeit and hazardous drugs can be managed thoroughly and recalled whenever necessary. The KPIS can contribute to enhanced public safety with regards to the people's drug use.
- The KPIC can fulfill the needs of pharmaceutical companies on market information and contribute to their business efficiency in terms of new product development, manufacturing and inventory control.
- Facilitated use in pharmaceutical standard code (bar code) can improve distribution efficiency such as order placements, delivery and inventory control and link the acquired information for further knowledgification of information.

Conclusion

Recently, developed countries are found to show more interest in the management of public health safety, which refers to a series of systematic efforts to reduce or eliminate risk factors that are/could be found in medical institutions. Since most patients get prescription treatment in outpatient clinics, accuracy in drug dispensing becomes the highest priority issue in patient safety management.

In this regard, the use of a pharmaceutical bar code to eliminate medication errors is an important aspect of public safety management. In line with the drug standardisation policy since January 2008, the standard code is assigned to every pharmaceutical product in Korea and bar code labeling preparation is required at manufacturer/importer level.

In future, it is expected that traceability will enhance patient safety and enable efficient medical support through the established on-line network. Information collection, advanced studies on future market, and product recalls will be carried out accordingly. In future, Korea will follow other countries to introduce bar code and RFID usage in medical devices and other public health products. Patient safety and economic efficiency need to be further improved through systematic approaches including pharmaceutical use traceability.

If Korea is to maximise benefits of information technology in public health sphere, data structure, carrier and exchange need to be based on a global standard.

In future, the KPIS will play the central role in creating value out of and sharing drug information among manufacturers, importers, wholesalers and medical institutions in Korea. Through these efforts, the KPIS will contribute to development of pharmaceutical and distribution industries and promote safe use of drugs by the general public.

ABOUT THE AUTHOR

Jeong, Jeong-ji, Head of the Korea Pharmaceutical Information Service Center

Jeong, Jeong-ji is the head of the Korea Pharmaceutical Information Service Center, an organisation affiliated with Health Insurance Review & Assessment Service. Head Jeong earned a master´s degree in Public Health Administration from Sungkyunkwan University in 2000 and a Ph.D. in Business Administration from Konyang University in 2008, respectively. She joined the HIRA (formerly known as the National Federation of Medical Insurance until 1999) in September 1979 and has worked for the national health insurance.

Dr. Jeong developed the model to assess pharmaceutical expenditure's appropriateness in 2000. She pushed ahead with the business to standardise the medical device code for medical product traceability management system and developed a voluntary model to improve optimal integration in 2008. She also developed the total profile system for Healthcare provider in 2009 and built a management system to trace fees for medical services and developed fees for medical services to implement u-Health in 2010, respectively.

Improvement of drug inventory management through GTIN and mobile system at the Seoul National University Hospital

ABSTRACT

In Korea, the Ministry of Health and Welfare (MOHW) has mandated the use of the Global Trade Item Number (GTIN) in pharmaceutical products starting January 1st, 2010. In response to the new policy, the Seoul National University Hospital (SNUH) began to develop a real-time inventory management system that uses Personal Digital Assistants (PDAs) to read the GTINs printed on drug packaging. The system is designed to control inventory movement, by reading information assigned to the bar code of inbound/outbound sheet with a PDA, which will show a drug list on its screen and compare it against the GTIN affixed to the pharmaceutical packaging. Development of a GTIN-compliant system led to improved job satisfaction of employees at the SNUH as it helped them prevent medication error and reduce the time in drug inventory management.

By **You, Ock-Su**, Seoul National University Hospital

and **Kim, Kwi-Suk,** Seoul National University Hospital

About SNUH

The 125-year history of the SNUH (Seoul National University Hospital), a total care general hospital with 1,625 beds, can be traced back to 1885 when it was established as the first national western-style hospital in Korea, Gwanghyewon. In January 2008, the SNUH established the Division of Pharmacy Inventory Control under its Logistics Management Department to promote efficiency in inventory & purchasing functions and build expertise in drug management.

Background

The Division of Pharmacy Inventory Control provides pharmaceutical products to the Main Hospital, the Children's Hospital, the Healthcare System Gangnam Center and the Clinical Research Institute. Its Medical Information System established an on-line connection among the Division of Pharmacy Inventory Control, EZMEDICOM (contracting agent) and vendors. The SNUH has also in place an international standardised classification system, the UNSPSC (United Nations Standard Products and Services Code), as well as an international standardised attribute system, the GDAS (Global Data Attribute System).

The hospital controls drug inventory by using item codes in its integrated logistics system and manages prescription and dispensing by using drug codes in the OCS (Order Communication System). When the Logistics Management Department was established in early 2008, the SNUH adopted item codes by assigning a 13-digit serial number with prefix 2005 to every pharmaceutical product in use. GTINs were allocated to products that were newly introduced or changed of contract terms since 2008.

As of the end of 2010, the SNUH keeps an inventory of 2,005 items and runs on a purchasing budget of KRW 123 billion. With the exception of narcotics, inventory management is on a consignment-basis, which means that the hospital will use drugs that are deposited to the inventory by the wholesalers and make deferred payment twice each month.

In Korea, national university hospitals can purchase pharmaceuticals only through an annual bidding process. Subsequently, the SNUH commits to yearly contracts based on unit price. If a contract brings change in the pharmaceutical manufacturer, drug code of the product will stay the same regardless of the brand name or package unit. In contrast, item code needs to be reallocated whenever there is a replacement of the manufacturer, and thus requires continuous updating of bar code information.

Moreover, there were other issues to the use of item codes, as open bidding results in frequent change of the brand name, being prone to medication errors coming from similar appearance & packaging, and tracking & tracing issues for problematic pharmaceuticals in use. Thus, the SNUH came to seek an efficient improvement measure.

Also to be noted is the announcement by the Ministry of Health & Welfare on "Pharmaceuticals Standard Code: Guidelines for Use and Management of Drug Bar codes," which was released on January 15, 2008. The ministry mandated use of pharmaceuticals bar code labels from January 1, 2010, pursuant to Article 75, Provision 1, Paragraph 9 of the Pharmaceutical Affairs Act Enforcement Rule. This announcement led to the establishment of a GTIN inventory management system at the SNUH.

System overview

In order to develop a GTIN-based program, the hospital needed to create a bar code information database. On GTIN labeled drugs, bar code information was collected at every packaging unit level of a single item code and matched against its conversion volume. The SNUH's PDA devices can read bar code information at the primary (GTIN-13, GTIN-14) and secondary levels and non-GTIN bar codes in bulk package such as those used in the manufacturing country of a pharmaceutical product. When a product carries a non-GTIN label, the bar code information was registered before use in the SNUH database. Also, the hospital made it a requirement for all vendors to attach GTIN to their products after the annual contract system was introduced in 2009. Raw materials for hospital formulary and compounding drugs have been newly applied with the bar code label requirement. Since May 2009, the SNUH has exerted efforts to collect and verify bar code information on new product releases and added the information to complete its database establishment. The IT team then developed a GTIN inventory management program and conducted an operational review before its completion in September. Program implementation began with narcotics and was expanded to other drugs in November.

Figure 1: **Inbound Control Workflow**

Improvement of drug inventory management through GTIN and mobile system at the Seoul National University Hospital

1. Inbound Control Program

- The PDA screen will show an incoming list after reading the bar code information in the inbound sheet.
- The PDA will then read the GTIN of the inbound drugs. If the bar code matches the information in the database, the PDA screen will display product information and volume. The user will confirm with the click of a button when the information is correct. Afterwards, the PDA will display the confirmed drug in a shady color and show a list of unconfirmed items underneath.
- After the pharmaceuticals are all confirmed, the user can press the "submit" button to complete the inbound control activity. The program was designed in a way that makes it easy for the user to keep control of the volume, by displaying a drug by its conversion unit and box volume when the PDA reads its GTIN.

2. Outbound Control Program

- The PDA screen will show an outgoing list of drugs after reading bar code information in the outbound sheet.
- The PDA will then read bar code information printed on the packaging of the outbound drug. If input data is identical to the actual bar code information, the PDA screen will display product information, volume and stock. The user can click the "confirm" button if the stock volume is correct. Afterwards, the drug will be displayed in shady color with the number of unconfirmed products shown beneath it.
- The user will press the submit button to complete outbound activity when inspection is done. The outbound control program allows for a real-time inventory check-up, by showing the volumes of outbound products against outstanding inventory on the same PDA screen.

Figure 2: **Outbound Control Workflow**
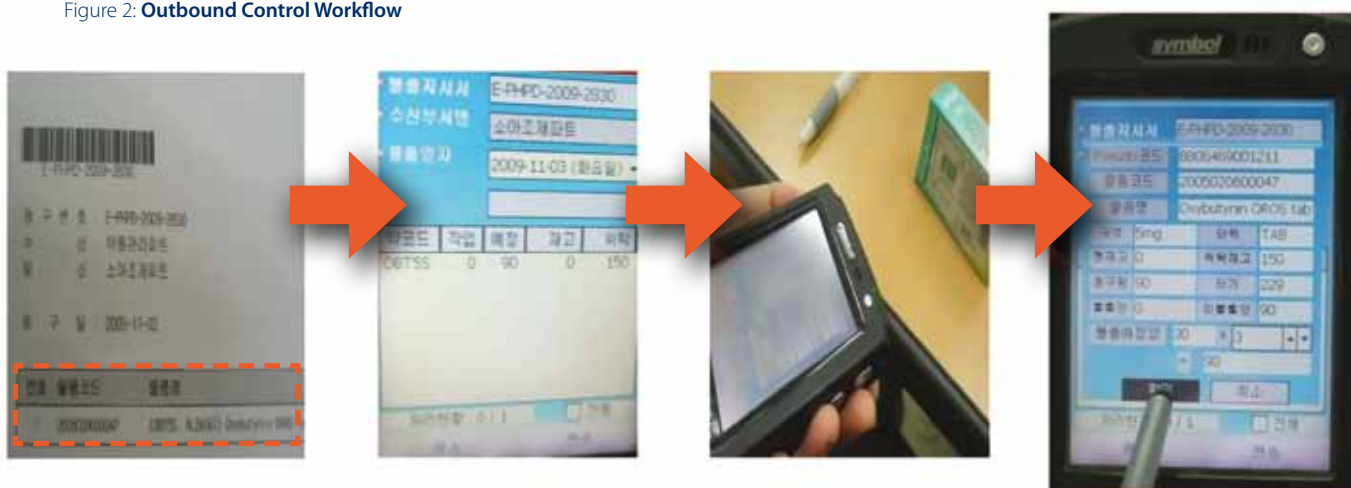
Benefits

The GTIN inventory management program allows the hospital to control drugs at the entry point, in an effort to enhance patient safety. Moreover, reduced time in inventory movement and drug management, such as inventory check-up and shelf-life control, can lead to higher efficiency in drug management work and enhanced job satisfaction at the employee level. The program relieves much of the administrative burden associated with labor-intensive manual tasks, thus contributing to prevention of musculo-skeletal disorders in employees. Furthermore, the GTIN program promotes timely and efficient management of pharmaceuticals logistics, thereby enhancing satisfaction also at the patient level.

Next steps

Some of the drugs have GTIN information on the unit of use packaging but not on the shipper case. It creates inconvenience as the shipper case packaging needs to be removed every time to access the GTIN. Tracking & tracing of drugs in use will become much easier when encoding the expiration date and lot number in GS1 DataMatrix becomes mandatory in 2013, as the SNUH will

be able to control shelf-life and manage inventory at the lot level. Moreover, the SNUH will continue to pursue for a more efficient program, developing further from the current PDA-based technology to include other reading formats as well.

ABOUT THE AUTHORS

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Kim, Kwi-Suk, Chief of Division of Pharmacy Inventory Control, Logistics Management Department, Seoul National University Hospital

Ms. Kim, Kwi-suk joined the SNU Hospital's Pharmacy Division 27 years and 6 months ago. Since August 2008, she has been responsible for management of drug movement, inventory, narcotics and dangerous materials. She is a pharmacist specialising in nutrition support pharmacotherapy and the Chairperson of the Editorial Committee for the Korean Society of Health-System Pharmacists.

St. Antonius Hospital:
The traceability of implants

ABSTRACT

The St. Antonius Hospital (STZ) in Nieuwegein, the Netherlands, implemented a standards-based solution to improve the efficiency of the electronic tracking and ordering of Implantable Medical Devices (IMD). STZ and other hospitals around the world are looking for ways to track IMDs at every step along the entire supply chain simply, accurately, reliably, and efficiently.

By **Menno Manschot,**
St. Antonius Hospital

Introduction

Group Purchasing Organisations (GPOs) in the United States are ahead in this field. This is due partly to the U.S. Food and Drug Administration's public support for standardisation of the Healthcare supply chain and its close involvement with making logistical improvements to that chain. The Netherlands is lagging slightly behind, but there are certain developments, such as bundled purchasing, that are clearly on the rise.

At present IMDs are largely tracked by hand in a variety of systems used for different purposes: Electronic Health Records (EHR), Diagnosis Related Groups (DRGs), purchasing, R&D, etc. The supply chain for IMDs is inefficient, there is limited traceability of IMDs along the chain, and different systems and standards are in use.

Bar code scanning enables traceability

With this project, St. Antonius applied bar code scanning to automatically register IMDs and link them to patient records. This reduces the number of transactions, both manual and automatic. The improved knowledge about 'which items are in use with which patient' can benefit patient safety. In addition, the registration of devices is intended to enable item re-ordering the moment that it is used, thus reducing inventories. A pre-condition for this project is that the IMD is scanned at each point of transfer within the supply chain.

The hospital's Board of Directors approved the project plan. The project sponsor is the hospital's medical staff.

About St. Antonius Hospital

The St. Antonius Hospital is the largest non-academic teaching hospital and provides clinical care in the Netherlands. St. Antonius is a modern 880-bed hospital, where almost all specialties are represented. Nationally, the hospital is known for treating patients with cardiac, vascular and lung diseases.

St. Antonius has six locations, including Nieuwegein, Utrecht Overvecht, Utrecht Oudenrijn, Utrecht Meern, Vleuten and Houten. A new hospital is being built in Leidsche Rijn with an innovative care concept.

St. Antonius Hospital
The traceability of implants

"To a cardiothoracic surgeon an automated bar code system means the following: Safety, traceability, inventory control and order processing, database support and cost savings by reducing invoicing errors: all crucial to be able to perform your work efficiently and safely."

Drs. Wim Jan van Boven, Cardiothoracic surgeon, St. Antonius Hospital, Nieuwegein, The Netherlands
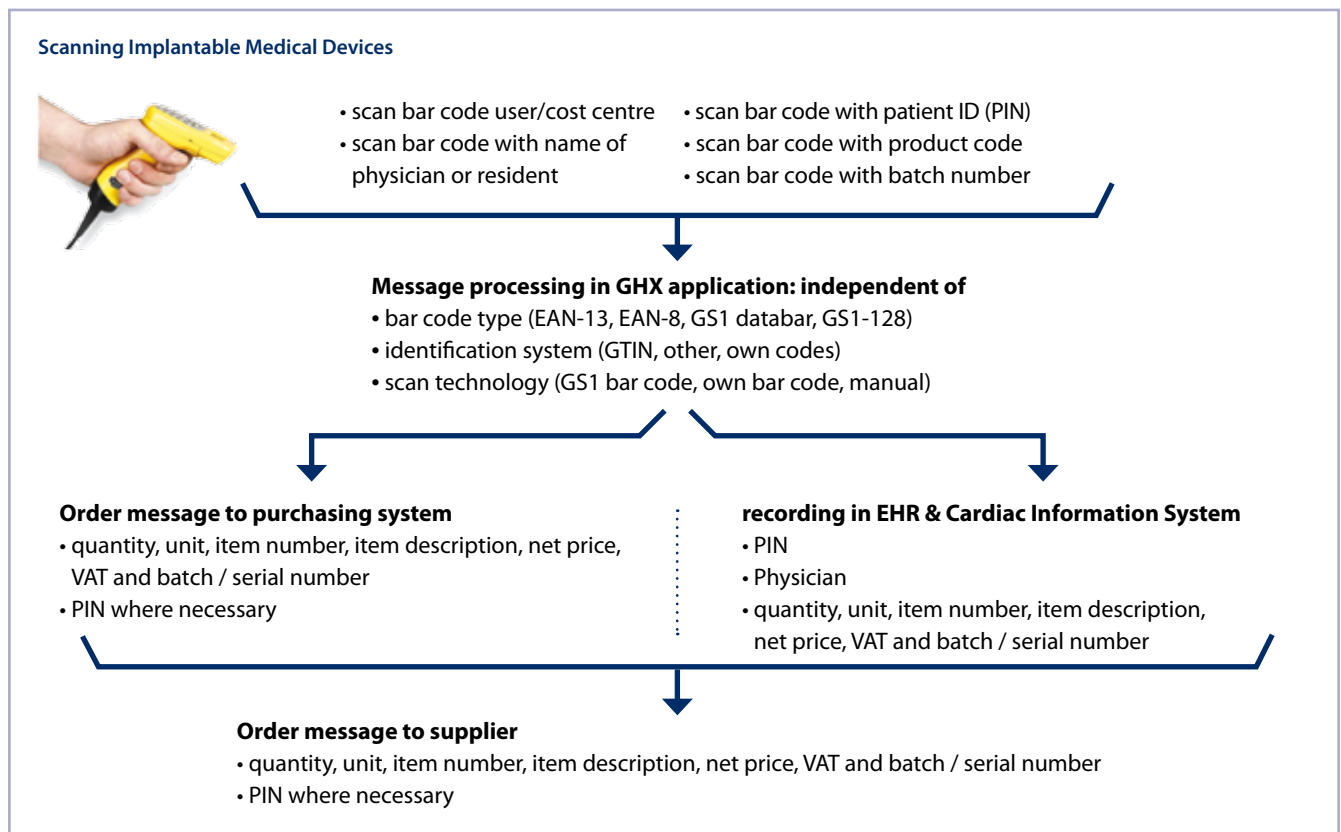
Project participants

A pilot was carried out in 2007 in the hospital's Oral Surgery Department (outpatient). It was relatively simple to implement electronic tracking and replenishment. There was a single supplier and only one product type. This new way of working has since been made fully operational within Oral Surgery.

In 2008 the electronic registration, tracking, and ordering of IMDs was implemented and has since also become operational in the Intervention rooms. Implementation here was much more complex. There is sometimes more than one bar code on a single item, and the bar codes are not all the same type (GS1, other).

In 2011, the activities will be expanded to the following departments:

- Cardiothoracic surgery – 1st Quarter
- Vascular surgery – 2nd Quarter
- Orthopaedics and trauma – 3rd Quarter
- Pain control and perfusion – 4th Quarter
- ENT and ophthalmology – 4th Quarter
- Cardiac Rhythm Management (CRM) – 1st Quarter

The project participants have all received an explanation and instructions in the use of the scanners, item bar codes and the software.

Scanning Implantable Medical Devices

- scan bar code user/cost centre
- scan bar code with name of physician or resident
- scan bar code with patient ID (PIN)
- scan bar code with product code
- scan bar code with batch number

Message processing in GHX application: independent of
- bar code type (EAN-13, EAN-8, GS1 databar, GS1-128)
- identification system (GTIN, other, own codes)
- scan technology (GS1 bar code, own bar code, manual)

Order message to purchasing system
- quantity, unit, item number, item description, net price, VAT and batch / serial number
- PIN where necessary

recording in EHR & Cardiac Information System
- PIN
- Physician
- quantity, unit, item number, item description, net price, VAT and batch / serial number

Order message to supplier
- quantity, unit, item number, item description, net price, VAT and batch / serial number
- PIN where necessary

Automation systems already in place

- Secure Medical Registration by GHX. In collaboration with St. Antonius Hospital, GHX has developed a bar code scan-solution in which the items used are linked to patient records in the different systems.
- Catalogue management
- Electronic messaging. At present only the order module is implemented. In the future, St. Antonius would also like to use other messaging modules: trade item data, order response, despatch advice, and invoice. Internally: such as for item information (item number, batch number) in the EHR.
- iSoft hospital information system. There is a link between iSoft and GHX for ordering.

Data recorded and tracked

In order to meet the project's two goals, St. Antonius Hospital records at least the following data:

- Item number
- Batch number
- Serial number
- Patient number (internal number)
- Employee number: physician or assistant (internal number)
- Cost centre (internal number)
- Quantity
- Item unit
- Price

It is also important to track expiration dates for both logistical and commercial purposes. At present, these are seldom applied as a bar code to the packaging. St. Antonius does however need this information in order to know when items will pass their expiration dates. The hospital will be able to minimise loss and thus realise savings.

Lessons learned

St. Antonius' project implementation was held back by the following points:

- There is no standardised bar code and identification system for IMDs. This leads to delays in scanning. The user must first see whether there is a bar code on the item. The bar codes are not always in the same place on the packaging and look different. Sometimes a single bar code will contain varied information and at other times each information item has its own separate bar code.
- Supplier cooperation. Suppliers' knowledge of GS1 standards is not optimal.
- Different bar code(s) on the packaging. The order in which bar codes are scanned from the packaging is important and can lead to erroneous information in the system. The user must check carefully which bar code should be scanned first (for example, first the item number and then the batch number).
- Management and updating of revised codes and systems. Data quality is not optimal.

- Verification of scanning accuracy. At present this is done after the operation rather than at the moment of use since it would otherwise take too much time. The result is that not all items used during the operation can be identified and tracked. Verification shows, for example, that the batch number from a bar code ended up in the item number field in the system.

Solutions have been found for most of the problematic bar codes. 1% of the bar codes still lead to various problems (the information embedded in the code is incorrect or ends up in the wrong place in the system). This requires manual verification, resulting in more time being needed for data processing.

Improving logistics and patient safety

The project has two goals: improving logistics and patient safety.

1. Logistics

The simple and clear electronic tracking of IMDs so they can be automatically re-ordered. The order process will become faster and more accurate as a result.

Because 1% of the bar codes create problems, the optimum benefit has not yet been obtained. While the re-ordering process is faster, inventories have not yet been reduced. The time savings in the ordering process is as expected, but since data quality is still not at its optimum and 1% of scans still create problems, people lose more time on post-control and data management than expected.

St. Antonius has found savings in its consignment inventories. Costs have been reduced now there is improved stock insight. Item and batch numbers are 99% recorded in the system.

2. Patient safety

The simple and clear electronic tracking of IMDs so that the data on the IMD can be automatically linked to the patient's record. This will guarantee traceability down to the patient and thus improve patient safety.

Traceability down to the patient is now entirely automated and is 98% complete. 1% is corrected manually due to scanning problems, and another 1% needs to have the patient number entered after the fact due to emergency procedures.

This was an entirely manual process in the past. The labels with bar codes and numbers were pasted into the paper patient file and as such this data was not centrally available. Since this data (item, batch, and patient number) have become digitally available, there is now much more control over the data and the process. Mistakes are detected earlier, making it possible to rectify the situation faster. This has certainly benefited patient safety.

Positive side effects

The far greater amount of information available in the system from bar code scanning has yielded a number of positive side effects. St. Antonius Hospital uses this information for:

- Research (which implants have what effect on the patient)
- Financial statistics (cost calculations for Diagnosis Treatment Combination, reimbursements)
- Automated catalogue management (adding new items to the catalogue, updating product information)

Conclusion

Scanning provides faster IMD tracking, but as the bar codes and the information they contain is not standardised the scanning process is not yet optimal. Hospitals should join forces to speak as a single voice with suppliers to apply GS1 bar codes to their packaging. We need guidelines for the standardisation of bar codes. The pertinent data, item number, batch number and expiration date, must be contained in a single bar code to preclude this data ending up in the wrong place in the system. Information on the importance of the scanning sequence in staff training should be included; first check which bar code contains the item number, then which has the batch number, and which bar code has the expiration date. Last, but not least, information on traceability projects should be shared with colleagues from other hospitals so that we can learn from each other; to further improve and facilitate implementation.

ABOUT THE AUTHOR

Menno Manschot, Staff Member Purchase Department, St. Antonius Hospital, the Netherlands

Menno Manschot joined the St. Antonius Hospital in 1996 and is responsible for the management of the procurement and logistics system in the hospital. He leads or participates in several strategic projects, including the implementation of a system for traceability and ordering via bar code scanning. Menno Manschot also actively participates in GS1 and GHX user groups.

Using GS1 Standards to combat counterfeiting and improve patient safety

ABSTRACT

AstraZeneca enhances patient safety, combats counterfeiting and meets global regulatory requirements by advocating GS1 Standards and working together with industry and GS1 to drive the development of harmonised standards and solutions globally.

By **Christoph Krähenbühl,** AstraZeneca

and **Ian Haynes,** AstraZeneca

Background

Our global product security strategy focuses on safeguarding patients and protecting brand integrity by combating the counterfeiting and illegal trade of AstraZeneca products. The strategy focuses on these key areas: enforcement, product security systems and technical solutions, securing the supply chain, and collaboration with stakeholders. We work towards full GS1 compliance and are regularly involved in industry workgroups that promote the use of consistent and harmonised standards. We are also members of the global user group – GS1 Healthcare.

The company currently codes an increasing number of its packs using GS1 GTINs (Global Trade Item Numbers) and employs Axway Track & Trace, a GS1 EPCIS certified track and trace solution developed by Axway as a central component in its systems and technology approach.

About AstraZeneca

AstraZeneca is one of the world's leading pharmaceutical companies, with a major presence in the UK. We are focused on providing innovative, effective medicines that make a real difference in important areas of Healthcare. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US$32.8 billion in 2009.

Complex global market requirements

The global growth of counterfeit medicines entering the legal supply chain and of reimbursement fraud has resulted in patient safety risks that both governments and pharmaceutical manufacturers are keen to address.

With the adoption of the EU Falsified Medicines Directive by the European Parliament on 16th February, which includes the requirements for safety features, tamper-evidence and coding to be applied to individual packs, industry is at a critical point in the development of coding and serialisation systems in Europe. Markets such as Turkey and France have already begun to impose regulations requiring pharmaceutical manufacturers to include GS1 2D DataMatrix codes, based on GS1 Standards identifiers such as GTINs, on all packs, for identification and traceability purposes. The US Food and Drug Administration (FDA) is also currently working on regulations to improve the identification and authentication of medicines in the supply chain, driven by the pending ePedigree solution in the State of California. Regulators, legislators and customers in other markets around the world, amongst them Brazil, China, and India, have mandated or are actively discussing coding requirements with similar declared aims.

The increasing number and rate of change, some not based on global standards, present a significant challenge for globally sourced pharmaceutical manufacturers. Keeping track of and understanding these requirements and implementing solutions to comply with them involves many people in different parts of our global organisation. Once implemented, manufacturing systems are required to switch between coding requirements on an order-by-order basis; this approach is costly, complex and can present a risk to supply.

Moving ahead of regulations and implementing GS1 Standards

In 2006, AstraZeneca decided to implement a product security solution to achieve our global product security strategy and ultimately improve patient safety. We chose Axway, a global Business Interaction Networks company, and Systech Tips, provider of at-line serialisation equipment, as the lead system providers; and as global GS1 Standards evolved, we also engaged with GS1 UK Solution Partner to develop the current solution.

AstraZeneca chose to pursue its product security item-level serialisation and verification project as an internal initiative at a time when there were no market requirements to do so. This forward-thinking strategy has put us in a position to respond quickly to emerging market requirements thanks to the choice of a flexible, scalable and GS1-compatible solution. The benefits of starting ahead of the curve meant that many of the technical challenges could be addressed early on, thus mitigating against the time pressure of complying with diverse requirements as they emerge.

Each product that AstraZeneca serialises at the production line has a unique EPC (Electronic Product Code) assigned to it, which includes a GS1 GTIN (Global Trade Item Number) and a serial number. The company's PSDM solution includes a repository of AstraZeneca's unique product identifiers (EPCs), which is compliant with the GS1 EPCIS (Electronic Product Code Information Services) standard.

AstraZeneca's Product Security Data Management (PSDM) system allows authorised staff to verify suspect packs by tracking any interactions that have been made with the EPC in the EPCIS repository, although until our internal system is linked to wider Product Verification infrastructures, such interactions are limited. At present, staff can check whether the product has been previously blocked, whether the EPC identifies the right product, batch and market variant ,and can trace all events that have been associated with a particular EPC. Packs can also be quickly and efficiently identified and tracked in the event of a product recall.

Where we stand today, AstraZeneca's track and trace solution is flexible and robust enough to meet the current and emerging legal requirements of the markets in which we do business. We also have the capability to create and share lists of GS1 GTINs (product codes) and serial number from our EPCIS track and trace repository; and an increasing number of our packing lines have the capability of coding packs in-line with GS1 DataMatrix 2D bar codes that contain batch variable and even serial numbers in addition to the GTIN.

Currently, AstraZeneca has 10 manufacturing sites and 30 product lines connected to our PSDM system. Axway Track & Trace – the GS1 certified EPCIS repository provided by Axway – holds over 100 million serialised packs and we are currently planning to roll this out further with more sites and brands. Capability extension projects include the exploration of multilevel aggregation and linking third-party Contract Packers to the AZ repository.

Ensuring a global and interoperable solution with GS1 Standards

Many manufacturers and suppliers such as AstraZeneca are already incorporating GS1 Standards into their products and processes due to the global reach of the standard. The European Federation of Pharmaceutical Industries and Associations (EFPIA) supports the approach of applying a combination of tamper-evident packaging and a unique code for each medicine pack, based on one harmonised coding solution across Europe, and recommends the use of GS1 Standards.

In the UK, the pharmaceutical industry has set up a GS1 2D bar code pharma working group facilitated by GS1 UK and driven by the Department of Health to ensure a consistent approach is adopted by the industry including the NHS.

As part of our commitment to the global adoption of GS1 Standards, we continue to work closely with GS1 and have benefited from the support of GS1 UK on a number of projects, such as the move to standardised coding of cases/shippers as part of a larger European ERP consolidation project, and the global process for assigning GTINs throughout the company to ensure full compliance. A cross-functional team is currently working globally to close the gaps in existing processes, better understand these numbers, their use and function, and to assign new GTINs and streamline fragmented legacy ways of working.

AstraZeneca believes that the adoption of global and interoperable GS1 Standards is vital to enable the pharmaceutical sector to cope with new legislation and customer demands.

Conclusion

AstraZeneca has built a strong foundation to combat counterfeiting, respond to different market requirements and improve the visibility of its supply chain. We are currently rolling out the serialisation of our packs at key manufacturing sites around the world. The next phase will be to securely link up our EPCIS repository to external systems as they are established, to allow point-of-dispensing verification and enable our staff to have much greater visibility of our products, thus ensuring greater patient safety and product security.

The adaptability and scalability of our GS1 compliant track and trace solution is vital to AstraZeneca, and will continue to be essential as we ramp up operations moving forward. We will continue to work with GS1 and the industry to ensure that a consistent approach is taken to improve patient safety and combat counterfeiting.

ABOUT THE AUTHORS

Christoph Krähenbühl, Technology Lead, Pack Coding and Product Security at AstraZeneca.

Christoph is one of the experts in AstraZeneca's Pack Coding and Security Features Programme and has been project manager of the Product Security Data Management serialisation system project since 2006. He is currently also involved in improving the global process of handling GTINs in AstraZeneca. Previous roles included leading the work on a global master data management system after the merger between Astra and Zeneca and managing the cross-functional Enterprise Performance Visibility data warehouse. Christoph is a member of the EFPIA Coding and Identification Project team and represents AstraZeneca in GS1 Healthcare. Prior to his move to AstraZeneca in 1998, Christoph worked for Ciba Specialty Chemicals and Ciba-Geigy in Basel, Switzerland in supply chain management and ERP systems projects.

Ian Haynes, Associate Engineering Director, AstraZeneca.

Ian works in the AstraZeneca Global Engineering Technology Group and has a particular interest in packaging and logistics. Ian works closely with the marketing, packaging, purchasing and supply chain functions anticipating and collaborating in the development of AstraZeneca's future requirements for packaging and manufacturing systems. Ian has played a key role in product security being closely involved in the development of the companies approach and technical solutions. Ian joined ICI Pharmaceuticals Division after graduating in 1980 with a first class honours degree in mechanical engineering from Liverpool University. Following a period as design development manager in Zeneca Engineering, he joined the Technology and Development Group of Zeneca Pharmaceuticals which later became AstraZeneca Global Engineering Technology.

BJC HealthCare's Global Data Standardisation Initiative:
Putting supply chain data to work

ABSTRACT

BJC HealthCare, one of the largest nonprofit Healthcare organisations in the U.S., is seeking a way to automate the process of tracking products from the point of manufacture to the point of use in order to help improve patient outcomes and reduce supply chain costs. This case study details how BJC successfully worked with GHX and GS1 Healthcare US to implement the use of Global Location Numbers (GLNs) to identify organisations and locations and Global Trade Item Numbers (GTINs) to identify products in business transactions with suppliers and other Healthcare trading partners. Today, BJC is using GLNs in all of its purchase orders transmitted through the GHX exchange and is prepared to transact with GTINs as its vendors enumerate their products with this standard.

By **Thomas M. Stenger,**
BJC HealthCare

The need for consistent data

Accurate, consistent purchasing data is key to BJC HealthCare being able to reduce costs while improving patient outcomes. The Healthcare system realised that it could improve the quality of its data if all of the parties with which it transacts use the same unique numbers to identify organisations, locations, and products. Toward this end, BJC chose to adopt GS1 Global Location Numbers (GLNs) and Global Trade Item Numbers (GTINs) for organization/location and product identification, respectively.

Defining the project scope

Before BJC could begin using GLNs and GTINs, it had to define the scope of its standards enablement project. Not only did the organisation want to enumerate its bill-to and ship-to locations with GLNs, it also wanted to successfully use both GLNs and GTINs in business transactions. This required BJC to closely collaborate with its trading partners and technology vendors so that it could communicate its needs and all parties could agree on the rules that would govern the transactions.

Members of BJC's materials management team worked with GS1 Healthcare US® and BJC's e-commerce partner GHX to define what it would need in terms of staffing, technologies and financial resources to carry out such a comprehensive project. They then developed a standards enablement plan that outlined the process from start to finish.

Defining the data

The first step was for BJC to define which locations it wanted to enumerate with GLNs. It chose to enumerate those bill-to and ship-to locations that it used in transactions with trading partners. It then narrowed the focus by omitting locations for Just-In-Time (JIT) and desktop deliveries.

BJC's materials management team then had to determine which locations were active. They generated a report that included all of BJC's ship-to and bill-to locations. They shared the list of ship-to locations with the organisation's distribution department and the list of bill-to locations with its accounts payable department to validate which locations were truly active and ensure that no active locations were missing. From there, they deleted inactive locations from BJC's systems and added any new sites identified. Through this process, they determined that BJC had approximately 100 active ship-to locations and three active bill-to locations.

Validating the locations

BJC's group purchasing organisation (GPO), Novation, had enumerated BJC on its behalf in the GS1 US GLN Registry for Healthcare®. It was BJC's responsibility to validate its enumerated locations within the Registry to ensure they were accurate.

BJC's materials management team generated a report containing BJC's active bill-to and ship-to locations and compared this list to the locations that Novation had enumerated in the Registry. They found that there were active locations missing from the Registry, as well as locations that were enumerated in the Registry but missing from BJC's internal list. When they found an enumerated bill-to or ship-to location in the Registry that was not on BJC's list of active locations, they called the location to determine if it was owned by BJC and then confirmed the validity of the location with the organisation's finance department. If it was a valid location, they would add it to BJC's internal list.

Once the team had reconciled BJC's locations within the Registry, they built a cross-reference table to establish a one-to-one relationship between BJC's GLNs and its ship-to and bill-to locations. This table would serve as a crosswalk to bridge the ship-to and bill-to locations to the GLNs during BJC's electronic transactions with trading partners.

Location Name	Street Address	GLN
ALTON MEMORIAL HOSPITAL	ONE MEMORIAL DRIVE, ALTON, IL.	1100003663918

Reconciling GLNs with trading partners

The next step was to reconcile BJC's GLNs to its trading partners' data values, including its GPO membership identification numbers (IDs), supplier account numbers and its e-commerce partner's facility IDs. BJC improved the accuracy of its supply chain data by correcting errors, deleting duplicate or inactive locations, adding missing locations, and consolidating multiple account numbers.

Reconciling GLNs with a GPO

The team reconciled BJC's GLNs with Novation's membership roster by establishing a one-to-one relationship within its cross-reference table between BJC's ship-to and bill-to locations, GLNs and GPO membership IDs and submitting the table to Novation, which was then able to ensure that it was using the correct GLNs for BJC's locations in its roster.

Location Name	Street Address	GLN	GPO ID
ALTON MEMORIAL HOSPITAL	ONE MEMORIAL DRIVE, ALTON, IL.	1100003663918	123

They found instances where Novation's membership roster contained locations that BJC had not accounted for during its GLN reconciliation. In some cases, these were ship-to locations for affiliates that BJC does not own but for which it receives rebates. They added these locations and their corresponding GLNs to BJC's cross-reference table to ensure that the organisation did not lose its rebates. In other cases, where they identified affiliate locations for which BJC did not receive rebates, Novation took control of the GLNs for these locations and BJC removed the locations from its cross-reference table.

Reconciling GLNs with suppliers

BJC then reconciled its GLNs with its suppliers. For each supplier, the team added its supplier-assigned account numbers to the corresponding locations, GLNs, and GPO IDs in its cross-reference table and then sent this table to the supplier to verify that its systems contained the same account number/location matching.

Location Name	Street Address	GLN	GPO ID	Supplier Account Number
ALTON MEMORIAL HOSPITAL	ONE MEMORIAL DRIVE, ALTON, IL.	1100003663918	123	12345

The team found that, in some cases, BJC had between four and six supplier-assigned account numbers for the same ship-to locations. With 100 ship-to locations and 4,600 suppliers, they faced the possibility of managing over 1 million account numbers. This caused a variety of issues, including products shipped to the wrong locations, increasing costs for both BJC and its suppliers.

Instead of replacing all of its supplier-assigned account numbers with GLNs, BJC engaged its suppliers in a reconciliation process whereby it eliminated any account numbers that did not serve a legitimate business purpose. When it was deemed necessary to keep more than one account number for the same location, BJC would assign a new GLN to this account number so that there was always a one-to-one relationship between account numbers and GLNs.

Reconciling GLNs with an e-Commerce partner

The final step was for BJC to reconcile its GLNs with its e-commerce partner. The team worked closely with GHX to ensure that BJC's cross-reference table met the necessary requirements for e-commerce.

Transacting with suppliers using GLNs

BJC participated in a GLN enablement programme with GHX to use GLNs in transactions sent through the exchange. One of the challenges was that most of BJC's suppliers are not yet ready to accept and process GLNs in electronic transactions.

To address this issue, BJC can send both its GLNs and its supplier's account numbers on 850 purchase orders (POs) to suppliers. When BJC submits an electronic data exchange (EDI) transaction through the exchange, its enterprise resource planning (ERP) system selects and transmits both the GLN and account number for the specified location. If a supplier cannot accept the GLN, GHX suppresses it so that the supplier receives only the account number.

While BJC initially reconciled GLNs with its suppliers, GHX now performs this process for the organisation. For those suppliers that can accept GLNs in electronic transactions, GHX also works with both the supplier and BJC to ensure that transactions are successfully processed. BJC's EDI coordinator works with GHX and the supplier to complete the re-boarding process through which BJC and the supplier reconcile BJC's GLNs with the supplier's active account numbers. Each time BJC begins transacting with a supplier using GLNs through the exchange, GHX tests the initial transactions sent by the trading partner pair to ensure that each party has the data it needs to successfully transact.

For suppliers that do not conduct business electronically, BJC works directly with them to transition from account numbers to GLNs. When a supplier is ready to accept GLNs, BJC inserts a GLN in the address field of the transaction so that it prints on the paper PO, which is manually delivered to the supplier.

Preparing for GTINs

For the past 10 years, BJC transacted with three of its vendors using a different industry standard for product identification. As a result, BJC was set up to hold product identifiers and had no trouble preparing its systems to store and process the GTINs. BJC's current ERP system features an item number field that can store the 14-character GTIN and output it on 850 PO transactions. As a result, BJC is prepared to conduct business transactions with trading partners using the GTINs as soon as suppliers begin using this standard in place of proprietary item numbers.

BJC is upgrading to a new ERP system, which has the ability to tie multiple GTINs under one BJC item number. This will enable BJC to use GTINs to manage its inventory by specific packaging levels. Once a supplier enumerates products with GTINs at each specific packaging level, BJC can record that it has received a case of a specific product, and using a bar code scanner, account for the fact that it has decremented its inventory by a box or by an individual item. BJC will also tie its ERP system into other internal systems to automate additional supply chain functions. For example, when a product is scanned and used, a PO could be automatically generated and sent through GHX to reorder that specific item.

GLN/GTIN status today

Today, BJC is transmitting GLNs on all transactions sent to suppliers through the exchange. It has completed the GLN reconciliation process with 15 of its suppliers, 10 of which have the capability to accept GLNs in EDI transactions. GHX is currently suppressing GLNs and sending only account numbers for those suppliers who are not yet capable of processing transactions containing GLNs. This keeps electronic transactions flowing through the exchange while preparing BJC to transact with GLNs. Although none of its suppliers have indicated that they are prepared to transact with GTINs at this time, BJC will be ready when they are.

The ultimate solution

As an organisation dedicated to continually improving the delivery of Healthcare, BJC has adopted GS1 Standards to not only address current challenges in operational management and patient care, but also to set the stage for future advancements. The BJC materials management team is working to achieve the "Ultimate Solution," an integrated network of systems through which the Healthcare industry could track product usage and patient outcomes and automate supply chain processes to increase operational efficiency, reduce costs and improve patient care.

In order to achieve BJC's vision, all supply chain partners need to take an active role in product tracking. Manufacturers and distributors would feed sales tracing reports to a central data repository. These reports would include GLNs for the providers who purchased the products and GTINs for the products sold. Providers would integrate their bedside, operating room, supply chain, billing and medical records systems so when a clinician

scans a product at the point of use, the information contained within the GTIN would be automatically transmitted to each of these systems to facilitate a broad range of processes – from decrementing the provider's inventory to recording product usage in the patient's electronic medical record.

Scanning every product used on a patient and automatically documenting product details would improve efficiencies by reducing the manual labor currently required for these tasks, increase patient safety by better managing product recalls and help providers enhance the quality of patient care.

Conclusion

For over 30 years, retailers have been using the Universal Product Code (U.P.C.) to uniquely identify consumer products, which has enabled the retail industry to achieve greater supply chain accuracy, efficiency and visibility. While the Healthcare industry can look to the retail sector for best practices in standards adoption and product tracking, trading partners must first address the complexities inherent to our industry, including the fact that we have thousands of facilities, thousands of departments, hundreds of software platforms and millions of people utilizing these systems and functions. Collaboration is

key to overcoming this challenge. In order for the Healthcare industry to make progress in this area, providers, suppliers and technology vendors need to come together, communicate their needs and develop a mutually beneficial solution.

ABOUT THE AUTHOR

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Tom Stenger is responsible for the development, integration, training and support of material services technologies for BJC HealthCare. Under his direction, the system successfully converted to a single MMIS from seven different programmes and nine different databases. He also developed an item master database that manages the systems contracts. A long-time proponent of supply chain standards adoption, Stenger participates in numerous industry standards groups and is a pioneer in adapting technology to enable the use of standards in business transactions. He holds a Masters of Science in Finance, with honors, from St. Louis University.