The Global Language of Business

GS1 Healthcare Reference Book

2015-2016

Successful implementations of GS1 standards

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Healthcare success stories

Welcome and acknowledgments

Welcome to the seventh edition of the GS1 Healthcare Reference Book which is a compilation of case studies where industry players share their experiences on how GS1 standards truly make a difference in healthcare, all over the world. Companies and organisations describe their successful implementations of GS1 standards.

GS1 Healthcare would like to share its gratitude to the following organisations and experts who contributed to this year's edition of the GS1 Healthcare Reference Book:

- Bernhoven Hospital - Justin Bitter and Erik van Ark, The Netherlands
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- Hangzhou Huadong Pharmaceutical Group - Wang Xuehua, Shi Jin and Feng Qianqian, China
- HealthShare New South Wales - Valentino Bulaon, Australia
- Hospital Pharmacy Capital Region - Viggo Nielsen, Denmark
- Sanatorio Güemes - Dra. Estela Izquierdo, Argentina
- St James's Hospital - Vincent Callan and Pat Bailey, Ireland
- The Ministry of Health of Turkey - Prof. Özkan Ünal, Turkey
- University Hospital CHU Dijon - Betrand Marechal and Veronique Jost, France

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The power of GS1 standards in healthcare

Improving quality of care

As the world's population ages and medical treatments become more advanced, demand for healthcare services has never been greater. With this increased demand comes a dilemma for healthcare providers: how can they continue to provide high quality care for an ever-growing volume of patients receiving increasingly complex treatments, while simultaneously cutting the cost of delivering that care?

GS1 Healthcare believes that creating and using global standards in the delivery of healthcare leads to significant benefits, including cost-efficiencies through more integrated, streamlined systems and reductions in the burden of administrative duties for professionals, providing more time to spend on quality patient care.

Healthcare professionals worldwide are united in one goal: to give patients the best possible care at all times. As patient safety is a vital objective of our work, progress has been made over the last 10 years to develop GS1 standards to better support the healthcare sector and we are now placing a particular emphasis on expanding the implementation of these global standards with healthcare providers.

Read the variety of case studies that showcase the multiple benefits of adopting GS1 global standards in processes spanning patient care, traceability, eProcurement, automation, regulatory compliance and many more. The different initiatives show best practices, "what works" and how to start when integrating standards into existing or new processes.

For more information about these implementation cases, contact Ulrike Kreysa at ulrike.kreysa@gs1.org or Anouk Chavel at anouk.chavel@gs1.org.

For your nearest GS1 Member Organisation, go to www.gs1.org/contact.

Improving patient care

Argentina

Sanatorio Güemes improves patient safety through traceability initiative

Sanatorio Güemes is a 522-bed private hospital in Buenos Aires, Argentina, that has established best practices regarding patient safety and quality of care. The leading hospital supports the implementation of the country's National Traceability System as a means to improve safety and security in the pharmaceutical supply chain and the care provided to patients. The hospital has implemented processes and policies to enable electronic medical records and improve inventory management, and are meeting many requirements of the National Traceability System as a result. These new processes improve four key areas that the hospital identified as crucial for capturing traceability data for pharmaceuticals: receiving, repackaging, distribution and administration. Successful implementation requires a multi-disciplinary approach, and is dependent upon internal support of and belief in standardisation, not only from hospital management, but also from each staff member responsible for the facilitation of data in the supply chain.

by Dra. Estela Izquierdo

Sanatorio Güemes

Background

Sanatorio Güemes, an ISO-accredited institution, has a mission to provide safe, reliable and quality care to the population of Buenos Aires and surrounding areas. Because the hospital is working based on a quality management system, it is implementing policies and processes to enable pharmaceutical traceability within its hospital in order to improve patient care and the security of the national drug supply chain.

Challenge

The pharmaceutical supply chain in Argentina is not immune to actions that negatively impact the safety of patients, including the introduction of counterfeit drugs, theft and diversion. In order to combat these problems and be consistent with what is being done on a global scale, Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) has established a National Traceability System. The system enables the identification, validation, communication and registration of all drug transactions and movements along the pharmaceutical supply chain.

The Argentine pharmaceutical market is complex, and contains numerous supply chain participants, including manufacturers, distributors, provider organisations such as clinics or hospitals, health insurance companies (including pre-paid insurance), social welfare organisations, logistic operators, retail drug stores, and welfare pharmacies. These stakeholders are at various stages in their adoption of electronic processes, and are using disparate information systems that may not be compatible with each other. In addition, in Argentina it is required to identify all drugs with the GS1 Global Trade Item Number (GTIN) and serial number, encoded either in a linear barcode, GS1 DataMatrix or RFID tag.

Solution: the traceability system

In order to improve the quality systems within the hospital while complying with the newly implemented National Traceability System mandated by ANMAT, Sanatorio Güemes decided to develop its own internal traceability system as well. The hospital set out to automate the stock management for all drugs, including those received directly from pharmaceutical manufacturers or distributors, and those that come from different health insurance companies or social welfare organisations. In addition to working on the automation of stock management, the hospital looked to improve its capability to trace drugs internally. Further it developed a tool that could electronically capture all documentation and information related to each drug it received. The system verified the expiration date and origin with the commercial documentation provided. Working on ways to improve and automate stock management helped the hospital prepare for ANMAT's compulsory National Traceability System.

During its automation and process improvements, the hospital identified four areas that are important to capturing traceability information:

- Receiving
- Repackaging
- Distribution
- Administration

The data (GTIN and serial number) associated to the secondary package of each drug is captured at each of the above steps, building the foundation of the traceability system.

To comply with the national (external) traceability regulation, communication to ANMAT then occurs at 2 key moments:

- Receiving
- Administration to patient

Receiving

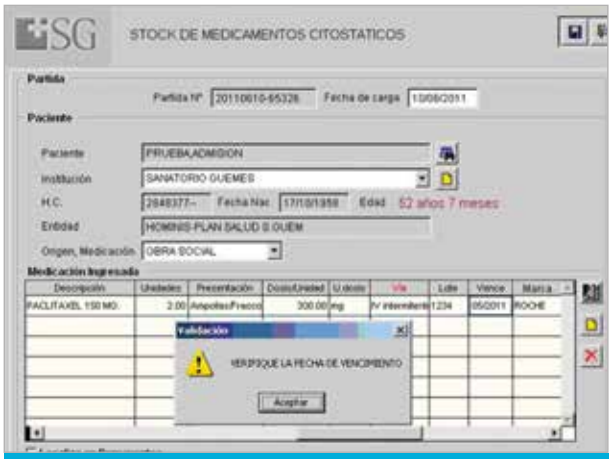
Information linked to the drug (despatch order, invoice, etc.) is encoded in the system and checked against the actual product using GS1 standard identifiers (GTIN and serial number).

In addition, the barcode of the product is scanned and the data (GTIN and serial number) is recorded in both the hospital traceability system (internal) and the central database hosted by ANMAT (external traceability system).

Repackaging

The Argentine legislation requires that each drug is identified on the secondary package, but does not specify the type of data carrier to be used (1D/Linear barcode, 2D/Matrix barcode, RFID, etc.).

As the daily doses are prepared and given directly to the patient, it is necessary to re-pack the pills to dispense them. Therefore, it is important to identify to which commercial product code each drug dose belongs to. Sanatorio Güemes acquired a pill repackaging and fractioning machine, which ensures that the primary package remains intact as they cut each individual blister and repackage it in a pouch. That way, some of the data from the secondary package along with the data delivered with it (expiration date, commercial information, etc.) is transferred to the pouch. When fractioning and repackaging, the product is identified with the following information: original expiration date, lot/batch number, GTIN and serial number of the active ingredient, strength, and pharmaceutical type. The hospital has not yet been able to



Stock management

Drugs reception in the system

capture the manufacturers information required by ANMAT; instead, it is fractioning, repackaging and relabeling the drugs onsite, forcing the creation of a hospital-created product line in the system.

Distribution

As the hospital provides the daily drug doses to different internal units (intensive care unit, emergency room, clinical areas, satellite pharmacy for the surgery room, outpatient hospitals, etc.), it has purchased barcode scanners for each clinical area to automatically capture drug information. Doing so enables internal traceability; the hospital knows at all times the location and quantity of each drug.

Administration

The hospital decided that the administration of the drug to the patient would be reported to ANMAT once the system could demonstrate that it was ensuring the five rights: right patient, right drug, right dose, right route and right time.

Sanatorio Güemes started by implementing a patient safety pilot at their oncologic outpatient hospital that would be extended later to other clinical areas.

In the pilot, Sanatorio Güemes implemented the following policies and processes:

- A multi-disciplinary team was set up to look at business process and interactions with other departments within the hospital to improve patient safety.
- Oncology protocols and all the infusions administered regularly at the oncologic outpatient hospital were standardised. Only the doctor administers the drug dose for infusions, and the action is recorded in the electronic health record.
- The preparation of the oncologic mixtures is done through a stock management system enabling internal traceability. The hospital has also developed a knowledge database for the preparation, handling and manufacturing of these drugs which checks for each preparation expiration date, dose, interactions, stability, etc.
- Once the preparation is made, the internal traceability system assigns it a GS1 DataMatrix. The patient who receives the medication is also identified with a wristband marked with a GS1 DataMatrix (2D barcode), which contains the patient's identification number and medical history, as well as the therapeutic regimen or protocol that the patient will receive. Furthermore, each of the oncologic preparations is identified with an Oncologic Pharmaceutical Preparation (POF) number, automatically generated at the time of its preparation. Each POF is linked to the drug traceability data. Simultaneously, the POFs assigned to the patient are registered in his electronic medical record.

Administration at patient's bedside

Repacking machine

- During the administration process, the patient's wristband is scanned, as is the drug label and the identification label of the nurse/doctor treating the patient. Once the system verifies and matches the POF with the drug and the right patient, the infusion can be administered. At the end of the administration, the procedure is automatically recorded and communicated to ANMAT.

These procedures ensure that the drugs and dosages are correct, and are matched with the right patient at the right time, minimising errors and providing a line of sight to the movement of the pharmaceutical within the hospital.

Benefits

Implementing a traceability system helps ensure the five patient's rights: the right patient receives the right drug, at the right time, at the right dose by the right person via the right route. Sanatorio Güemes is now able to track and trace all the drugs from the moment they are being received up to the moment the patient receives the treatment and beyond. Clearly patient safety is improved, but healthcare professionals are also more protected from errors and mistakes.

Conclusion and next steps

Following the success of the pilot in the oncology department, these processes will be implemented in other departments of the hospital. To ensure consistency and utmost quality, hospital staff must be trained on traceability and improved treatment protocols, especially pharmacy and nursing professionals who come into contact with drugs as part of their daily jobs. These healthcare professionals play an important part in the delivery of safe, quality care to patients, and are on the frontline of the industry's transformation to using electronic data capture to enable valuable drug traceability. The implementation of the traceability system is an opportunity to improve internal processes, for the safety of all patients.

Sanatorio Güemes is now able to track and trace all the drugs from the moment they are being received up to the moment the patient receives the treatment and beyond.

About the author

Dra. Estela Izquierdo, *Chief of Pharmacy, Sanatorio Güemes. Estela Juana Izquierdo is Chief and Technical Director of the Pharmacy Service of Sanatorio Güemes. She is also Director of the residency programme of the hospital, coordinator of the Hospital Pharmacy College of Pharmacists and Vice-president of the Argentine Association of Audit and Healthcare Plan.*

About Sanatorio Güemes

Sanatorio Güemes is the largest private healthcare institution in Latin America with over 40.000m².

China

Chinese pharmaceutical manufacturer uses GS1 standards to help automate the hospital pharmacy process

Manual processes in the hospital setting are prone to errors, many of which could lead to patient safety concerns. With greater focus on automation to reduce errors, improve patient safety and meet regulatory requirements around the world, manufacturers and hospitals alike are looking for ways to evolve their processes to improve product data accuracy and process efficiencies, reduce costs and improve the patient experience. A pharmaceutical manufacturer in China, Hangzhou Huadong Pharmaceutical Group, is adopting GS1 standards to improve the accurate exchange of medicine information within the pharmaceutical supply chain, and is seeing positive results, from the time the medicine is packaged all the way through to its dispensing to the patient. Accuracy of medicine information and process automation through standardisation are leading to reduced costs, greater efficiencies and improved patient safety and satisfaction.

by Wang Xuehua, Shin Jin and Feng Qianqian

Background

Hangzhou Huadong Pharmaceutical Group Co., Ltd. is a large pharmaceutical manufacturer based in Hangzhou, China and is the head office of Huadong Medicine, which is collaborating with the Hangzhou Binjiang Hospital. The company primarily focuses on developing products and services that benefit large and medium-sized hospitals and drugstores across the country.

With current medicine reform and market demand changes in China and around the world, pharmaceutical supply chain management is evolving day by day. Huadong Medicine, with the support of GS1 China, provides management consulting services for the hospital pharmacy management industry to incorporate best practices in the pharmaceutical and hospital supply chains.

Challenge

In the traditional model, the hospital or retail pharmacist would conduct a series of manual operations when dispensing medications. Because these manual operations are complex, the pharmacist cannot complete the process rapidly and effectively. This affects the patient who may not receive his medicine in a timely manner, which affects the quality of care and service levels.

In addition, the pharmacist is responsible for researching and procuring the medication, verifying its authenticity, planning its proper storage and inventory, and ultimately its safe

disposal when it expires. The pharmacist also dispenses the medical information to patients to ensure proper dosing and adherence to prescribing protocols, reducing the occurrence of the drug-related adverse events, and providing related drug consultation and pharmaceutical service. With the pressures on the pharmacist under the current model, the pharmacist cannot always effectively perform his or her role, and also cannot consistently deliver good service to the patients.

How to improve the working efficiency of the pharmacy and the service experience of patients has become one of the transformational goals in current hospital management.

Solution

Using the GS1 Global Trade Item Number (GTIN) and the additional product information (application identifiers or AIs), enables identification of all the drug packs in a standardised way. Furthermore, the item identification information encoded can be automatically collected and exchanged throughout the whole supply chain. Additionally, GS1 barcodes can be marked on multiple levels of the packaging (primary, secondary and even on the shipper/container lever). The two-dimensional GS1 DataMatrix barcode, for example is ideal for encoding large amounts of information in a relatively small space compared to a linear barcode, such as an expiration date or lot/batch number.

Benefits

Currently, about 60 % of the medicines used in the hospital are already marked with a GS1 barcode. This enables the hospital pharmacy to track and trace the drug from the moment it leaves the warehouse up to the point of dispense.

To enable full traceability with GS1 standards, for all of the medicines these are the steps followed:

1. Mark the medicine

The medicine distribution centre marks a GS1-128 on the case level (which includes medicine batch number, expiration date, and quantity of the trade items). The medicine warehouse uses a PDA barcode scanner to scan the specific information of the medicine required by the customers (hospital), to verify that the order matches the shipment.

When receiving the goods, the hospital can use a wireless handheld barcode scanner to scan the barcodes of the outer cartons one by one, to identify the related information, and check the storage information of the medicine.

2. Print two-dimensional barcode according to GS1 standards (GS1 DataMatrix) on secondary package

When there is no medicine batch number, expiration date and other information included in the barcode on the box of the medicine, the hospital decided to create a GS1 DataMatrix which includes the medicine product code, product batch number.

Picture 1
Medicine package and GS1 DataMatrix barcode

Picture 2
Automatic integrated closed medicine cabinet scans the barcode

Picture 3
Internal structure of automatic integrated closed medicine cabinet

The DataMatrix is then printed on an adhesive sticker through the online barcode printer, which then automatically sticks them to the corresponding medicine (box-packed) as shown on Picture 1.

3. Automate warehouse management

The automatic integrated closed medicine cabinet (automatic dispensing cabinet) reads the GS1 DataMatrix on the product package, obtains specific information of the medicine, and scans the size of the package by using a Infrared-3D scanner, shown in Picture 2.

The automatic integrated closed medicine cabinet automatically records the three-dimensional size of the medicine package and checks the medicine, and gets rid of the incorrect medicine through the detection system, so as to ensure the correct medicine is put on the conveyor belt. The cabinet is made of high-dense taper slots (saving space to store medicine), and uses the manipulator to send the single-packed medicine to the position specified by the cabinet for storage, shown in Picture 3. Inside the cabinet, the system is constantly temperature controlled, and a transparent observation window allows to monitor the operation of the internal manipulator inside the cabinet.

4. Apply of the barcode technology at the hospital outpatient pharmacy

When the physician issues a prescription, the pharmacy staff scans the code related to the specific patient. The Hospital Information System automatically analyses the barcode and sends the prescription information to the dispensing system control platform. Then, the rapid dispensing system of the automatic medicine cabinet binds the code and the prescription together for the specific patient, and fetches the right medicine with the manipulator inside the medicine cabinet. This medicine is automatically transported to the corresponding medicine-dispensing window,

Picture 4
Internal structure of automatic integrated closed medicine cabinet

shown in Picture 4. The pharmacist uses a bar code scanner to read the GS1 DataMatrix on the outer package of the medicine. After confirming that the medicine information is in line with the prescription information of the patient, the pharmacist then provides the right medicine to right patient, and adds information such as the dosage, usage and side-effects of the medicine.

Conclusion

With the professional advice and technical support from GS1 China, Huadong Medicine developed a barcode solution based on GS1 standards. And thanks to the application of Automatic Identification and Data Capture barcode technology, hospital pharmacies can successfully automate their information management and medicine distribution processes using accurate product data that is recognised across multiple information systems.

Through using “only” barcode identification on the single medicine package, the hospital can accurately and clearly record the medicine information (medicine, patient, prescription, etc.), and establish an effective traceability system to simplify and streamline operational processes. Automation improves working efficiencies, shortening by approximately 40 % the time that it takes to verify, accept and store the medicine, ensuring the accuracy of the medicine information. By allowing full visibility on the medicine’s stock, automation reduces the error rate related to medicine distribution by over 95%.

Other benefits include a reduction in hospital management costs, and improvements in the patient experience, with enhanced safety and better quality of care. Accuracy of medicine information and process automation through standardisation are leading to reduced costs, greater efficiencies and improved patient safety and satisfaction.

About the authors

Wang Xuehua *is Manager of Hangzhou Huadong Pharmaceutical Group Co., Ltd. has experience in GS1 standards application and the hospital information construction for more than ten years.*

Shi Jin *and* **Feng Qianqian** *are conducting research on the application of automatic identification technology in information systems in hospitals, logistics and other industries.*

About the organisations

Hangzhou Huadong Pharmaceutical Group Co., Ltd., is mainly engaged in antibiotics, medicine, chemical synthetic drugs, genetically engineered drug production and wholesale and retail distribution business. The largest integrated pharmaceutical commercial enterprises in Zhejiang Province also heading Huadong Medicine.

Hangzhou Binjiang Hospital of Zhejiang University School of Medicine is a nonprofit medical institution. They have 410,000 outpatient visits and about 16,000 emergency people since 2013.

Denmark

The right medicine for the right patient: GS1 barcodes improve logistic efficiency and patient safety

Denmark's Capital Region Pharmacy moves approximately 20,000 medicine units securely through a central warehouse on a daily basis, and delivers them to 10 hospitals in the Capital Region of Denmark. In order to perform these logistics efficiently and successfully, there must be an extremely efficient system in place. The Capital Region Pharmacy has implemented requirements of zero-error picking and swift delivery, and has made GS1 barcodes an integral part of the needed processes. The next link in the medicine value chain, dispensing medicine to patients, also requires unwavering certainty, which is why the same barcodes are used in hospital medicine rooms where a verification of "the right medicine for the right patient" takes place by scanning the package barcode. If the industry did not agree on the use of a common standard, such as GS1 for the pharmaceutical industry, the work would be considerably harder, and patient safety would be negatively impacted.

By Viggo Nielsen

REGION The Hospital Pharmacy

Background

Denmark is divided into five regions each with its own political management. The regions' largest sphere of responsibility is public healthcare, including the running of hospitals. The Capital Region of Denmark is the largest of the five with a population of around 1.7 million people. The Capital Region employs some 36,000 people and its annual net operating budget is DKK 36 billion.

Medicine is a significant element of hospital treatment and roughly half of all medicine is used to treat patients in hospitals. The other half is the medicine sold to individuals at privately-run pharmacies. Medicine use in the Capital Region amounted to DKK 3.1 billion in 2014, corresponding to 4.6 million individual medicine packages.

The Capital Region Pharmacy was established to serve as a central hub for supplying medicine to hospitals and institutions in the Capital Region.

Challenge

The logistics process is vital – round the clock

The logistics process must support 24/7 access to the right medicine for the clinics and thus for patients. This makes **efficiency, quality** and **reliability** important factors.

A product can be visually identified by reading text, item numbers or other types of identifying information. However, this method is far from certain as many products are very similar, and the essential and critical information is often allotted a tiny portion of the total space on packages.

Medications in hospital pharmacy

Branding and design are often higher priorities than reliable identification.

Stakeholders in the medicine value chain

By viewing the medicine's journey as an end-to-end process from manufacturer to patient, it becomes clear that many independent stakeholders are involved: manufacturer and packaging developers, pharmaceutical wholesalers, hospital pharmacies, and doctors and nurses, which is the most important as they deliver care directly to the patient.

During this journey, there is a need to identify the product at least once in every link in order to constantly ensure that it is the correct medicine, which is being moved along the value chain.

Using barcodes as a tool in these many links requires the barcode to make sense to the relevant stakeholders. The manufacturer must be able to configure and print the barcode in order for it to generate value throughout the supply chain.

Solution

The logistics process

GS1 standards provide many solutions to address the challenges. The manufacturer prints an unambiguous barcode on the packaging, either a linear barcode (EAN-13) or a 2D barcode (GS1 DataMatrix) which include a Global Trade Item Number (GTIN). The barcodes are reported together with other product master data when the product is listed. In Denmark, this function is managed by Amgros I/S, which is a joint procurement company for all Danish hospital pharmacies.

The pharmacy's enterprise resource planning (ERP) systems have inbuilt controls which verify the relevant packaging ID by scanning the packaging barcode at critical points.

The first point is during the medicine receiving process, and putting the product in storage, where it is important to place the product at the right location in the storage facility. This process also enables a quality assurance check of the product barcode. A recent survey showed that about 90 % of the 400 most common products can be scanned without problems.

When the products are extracted for delivery to the pharmacy's customers, for instance the hospital medicine rooms, picking accuracy is obviously important for ensuring delivery of the right product. When the goods have been delivered to the right storage location, the deliverer verifies the product by scanning its barcode and quantity.

Benefits

What value does the barcode create for logistics?

Value is generated at two levels:

- The process is significantly **faster** and can be completed by one person, as the prescribed control takes place using the ERP system and data capture. The alternative to this process would be to control it by another employee.
- The process is **safer** as a correctly placed barcode on the packaging combined with the correct master data is 100% reliable.

After delivering the right medicine to the medicine rooms, patients are next in line to receive the medicine.

Medicine room and patient safety

This task involves three stages:

- **Prescription** where (usually) a doctor decides on the medicine and dose to be administered to the patient. The prescription is documented in the medical records.
- **Dispensing** where a nurse takes out the prescribed medicine and ensures that it conforms to the prescription: the right medicine for the right patient in the right quantity.
- **Administration** where medicine is given to and taken by the patient.

In many ways, the dispensing process is similar to the process undertaken at the pharmacy's central warehouse. The packages are the same. The right medicine must be identified and verified by means of a control procedure. In the medicine room, the control also takes place by scanning the packaging barcode, which involves verifying the scanned data against the prescription registered in the medical records. Master data is constantly synchronised and updated between the pharmacy's ERP system and the medical records system.

Conclusion

GS1 standards offer a unique opportunity for practical application of a data standard that make the medicine value chain safer and more efficient. It provides a standard that identifies the entity, a barcode that captures the information – in linear as well as 2D format – and a way to share the data among each stakeholder of the value chain.

The entire pharmaceutical industry supports the use of GS1 standards, which is a considerable breakthrough and is needed for widespread industry adoption and for all stakeholders to receive the benefits related to logistics quality, efficiency and higher patient safety.

Efforts are continuously invested in engaging the manufacturers whose products have not yet been supplied with barcodes, and barcodes will be mandatory on primary as well as secondary packaging in the future.

With the future initiatives such as the EU Falsified Medicines Directive, the barcode will become even more important to ensure the authentication of all drugs sold in Europe as well as open up for data capture of lot numbers and expiration dates.

About the author

Viggo Nielsen *is currently Supply Chain Manager at the Hospital Pharmacy of the Capital Region in Denmark.*

He leads the operations of centralised supply functions (warehousing and distribution) of 4.5 million packages of medicine. Prior to working for the Capital Region of Denmark, Viggo has been working 25 years in supply chain management in the FMCG sector. Viggo is a member of GS1 Denmark's advisory Board, and is involved in 5 working committees for adapting EDI standards in Denmark. He has also been the first to introduce EDI for ordering and invoicing in Denmark. Viggo holds B.Sc. in business economics.

About the Capital Region

Denmark is divided into five regions each with its own political management. The regions' largest sphere of responsibility is public healthcare, including the running of hospitals. The Capital Region of Denmark is the largest of the five with a population of around 1.7 million people. The Capital Region employs some 36,000 people and its annual net operating budget is DKK 36 billion.

France

Enabling traceability at Dijon University Hospital through identification of all rooms and locations

University Hospital CHU Dijon, the largest public hospital in the Bourgogne region of France, has taken steps to ensure greater supply chain security and efficiency by implementing a process that enables the internal traceability of medical products, from the warehouse to individual care units within the hospital. The ability to electronically track and trace a product has the potential to not only save time and costs, but also to improve patient safety and the quality of care. The hospital established a warehouse logistics platform using GS1 standards as the basis of its traceability process, and is seeing significant improvements in efficiency, traceability and, ultimately, patient safety.

By Betrand Marechal and Veronique Jost

Background

The University Hospital CHU Dijon is a 1,700-bed hospital employing more than 6,300 people, collecting 8,000 human samples per day. It is the largest public hospital in the Bourgogne region of France. To improve supply chain security and efficiency, the hospital is implementing procedures to enable the internal traceability of products, from the warehouse to the care units.

Challenge

With soaring healthcare costs, providing quality care while ensuring patient safety has become a real challenge in the current healthcare environment. The ability to electronically track and trace a product within the hospital has the potential to not only save time and costs, but also improve patient safety and the quality of care.

Solution

Dijon hospital decided to invest and set up a logistics platform for its warehouse that includes a traceability system. The system, which is housed in an 5,500 m^2 building, is fully operated and managed by hospital employees. It is used to track and trace the internal deliveries of the products the hospital stocks using GS1 standards, such as the Global Trade Item Number (GTIN), the Serial Shipping Container Code (SSCC), the Global Location Number (GLN) and the Global Returnable Asset Identifier (GRAI).

These standards are used for all products stocked in this warehouse, including all drugs and medical devices as well as “hotel products”, such as tableware, cleaning products and detergents. The movement of these products throughout the hospital are electronically recorded in the warehouse delivery system.

In order to ensure the traceability of these internal deliveries, Dijon CHU first used the GLN to identify all the physical locations in the hospital and logistic platform: rooms, care units,

Global Trade Item Number (GTIN): Product identification

Standardised product identifier that can be used by a company to uniquely identify all of its trade items.

Global Location Number (GLN): Location Identification

Standardised location identifier that can be used by companies to identify their locations.

Serial Shipping Container Code (SSCC): logistics unit identification

Standardised number that can be used by companies to identify a logistic unit, which can be any combination of trade items packaged together for storage and/or transport purposes.

Global Returnable Asset Identifier (GRAI): asset identification

Standardised number for asset identification. This GS1 Key is especially suitable for the management of reusable transport items, transport equipment, and tools and can identify these returnable assets by type and if needed also individually for tracking and sorting purposes.

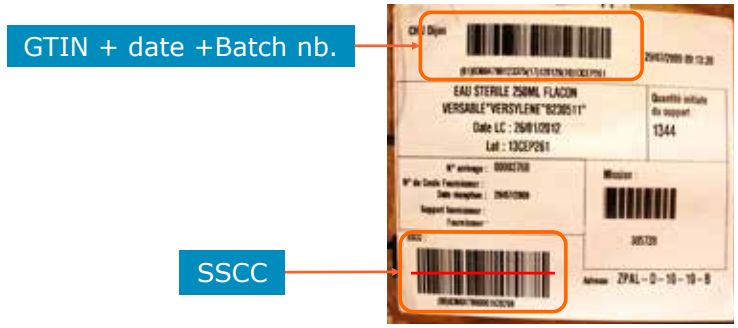


Image of a delivery box

points of departure, arrival and storage areas of the products. For a 1,700-bed hospital, this represents nearly 12,000 GLNs. All delivery boxes are also individually identified and marked with a GRAI.

When a ward or care unit orders products, the order picker preparing the order identifies the shipment with a GS1 Serial Shipping Container Code (SSCC), then links this SSCC with the unique identifier of the delivery box (the GRAI) to the GLN of the destination, and finally links all the latter with his own personal identification number.

Then the products ordered are picked and scanned and their GTIN is linked to this order. In parallel, when the GTIN is scanned, its commercial name, batch/lot number and expiration date are retrieved and all the above information is recorded and linked in the Warehouse Management System (WMS).

Upon delivery to the care unit, the logistician scans the expected destination GLN (as marked on the delivery box), with the actual GLN of the location, and the SSCC to ensure the shipment is effectively delivered at the right place. All the operations are time-stamped and recorded in the WMS.

All this data ensures that deliveries are completely tracked from the logistic platform to the care units, that the restocking frequency is monitored, and that targeted batch recalls can be carried out in the care units as efficiently as possible. Faster and more efficient recalls lead to improvements in patient safety and quality of care.

The platform manages the medicines and solutions, medical devices and sterile medical devices, hotel products for the hospital as well as the stocks of all the official documents, such as prescriptions and reimbursement claim forms given to the patient to be reimbursed by social security.

Benefits

Stocks - Efficiency gains

The creation of the logistic platform managing most of the stocks has allowed the reduction of storage location size in the care units, which have been redistributed to medical care. This has led to a reduction of the construction cost per m^2 for the new hospital.

1. The products are now managed through a central stock and by stock managers, instead of being disseminated throughout the hospital.
2. Productivity has been increased by streamlining storage facilities to reduce the picking circuit while respecting the stocking constraints (temperature, regulatory constraints, flammable substances, medical gases, etc.) helped by:
    - short rotations of stocks
    - better management of storage conditions for each type of product
    - better management of order preparation and picking
3. The set-up of the logistic platform also led to a rationalisation of care unit replenishment, with new quantities calculated on real consumption, new frequencies, and systematic scan:
    - better inventory valuation
    - reduction of waste due to a better management of expired products and overstocking
    - time savings for inventory management
    - better management of products returned from the care units (reduction in order or delivery errors, enhanced security by checking the returned batches, etc.)
4. Improvement in hygiene with a monitoring of the cleaning of the boxes, by registration of the GRAI at the entrance and exit of the cleaning process on the logistic platform.
5. Reduction in waste materials in the care units (products unpacked on the platform); reduction in the time allotted to recovery of the waste materials in the care units
6. Better organisation of the flows between the logistic platform and the wards; planned frequency and better reactivity to urgent requests.
7. Harmonisation of ordering methods between the different care units and the different type of products.

Some benefits already visible in the warehouse:

- 40% increase in productivity in the warehouse in the first few months.
- Supply of all the care units at least 1 time a day and up to 3 times a day for wards situated in the main building.

Traceability

1. All the pharmaceutical products stocked in the warehouse are identified by a GTIN (CIP13), a batch number and expiry date from reception.
2. Knowledge of what has been delivered and in which ward, which in turn ensures that the right product is delivered to the right place at the right time, contributing to patient safety and improved quality of care.
3. All the deliveries record the GTINs, batch number and expiry date (in FEFO mode) – First Expiring First Out
4. Security, efficiency and time saving when managing batch withdrawals.

The identification of products and locations has allowed the hospital to work more efficiently, enable traceability and save time to improve patient care.

About the authors

The logistic platform build to ensure this internal traceability has been conceived and set up by François Bisch - Director of Logistics - from 2009, and now operated by **Bertrand Marechal** *- Hospital Technician /Head of Logistics Information Systems and* **Veronique Jost** *- Hospital Doctor Pharmacist/Responsible for products stored on the logistic platform. This platform was the first one to use GS1 Standards.*

About the hospital

The University Hospital of Dijon is a teaching hospital of more than 1,700 beds spread over 3 sites. this is the first employer of the Burgundy region at the forefront of research with nearly 450 publications per year.

7,300 care professionals are working on 15 clinical poles to care more than 90,000 patients a year.

Everyday, nurses and doctors collect 8,000 human samples from their patients. All these preparations circulate inside the hospital from pharmacy to patient rooms, and from rooms to medical laboratory. To trace all these deliveries inside the hospital, it has been decided to identify each location inside the different wards with a Global Location Number (« GLN »). Each patient room has now its GLN with a GS1-128 barcode at the entrance, scanned for each incoming or outcoming delivery.

Ireland

eProcurement at St James's Hospital, Dublin

In 2013, St James's Hospital (SJH) embarked on a proof-of-concept (POC) project in conjunction with a number of suppliers to automate the end-to-end ordering process. The objective of the POC was to fully standardise and automate the ordering process between the hospital and the supplier. The process replaces paper-based systems and provides direct links between financial and clinical systems. The globally unique GS1 identification keys for products and locations are at the heart of this solution enabling automation and traceability. In September 2014, St James's Hospital went live with their first supplier, Cruinn Diagnostics. SJH now invites all suppliers to join the programme (which is based on the full adoption of GS1 standards).

By Vincent Callan and Pat Bailey

1995	2003	2008	2011	2012	Today	Future
Master Data Management and structured coding	Haemophilia Track and Trace project commenced GS1 Datamatrix SAP Installed (ERP & GUI)	Wireless Kanban for ward stock management	First hospital to pilot the HSE funded surgical instrument track and trace programme using GS1 standards	eProcurement project (standardised coding, and data and messaging) GTIN GLN GS1 XML 3.0	1st Sept 2014 First Supplier to GoLive Cruinn Diagnostics Communications and meetings with Top 50 suppliers	Working towards implementation of eProcurement with all suppliers Target to be first hospital fully compliant to GS1 standards Full Traceability to Electronic Health Record

Background

St James's Hospital has a long history using GS1 standards for identification to enhance patient safety, traceability and accuracy across the healthcare pathway. The success of both the Haemophilia solution to track products from supplier to patient and the National HSE (Health Service Executive) surgical instrument track and trace programme for instrument trays and endoscopes are globally recognised. Both solutions use barcode scanning to remove paper and automate the process.

Challenge

In addition to the patient safety and efficiency drivers, the economic situation in Ireland means there is huge pressure on cost savings. This combined with a change in government policy towards a "money follows the patient" model and the impending regulatory changes for pharmaceuticals and medical devices means that the time was right for St James's Hospital to step forward to address the problem.

Currently Irish public, voluntary and private hospitals have a huge task to manually reconcile paper invoices with paper purchase orders and proof of delivery dockets for the purpose of payment. Using traditional paper based systems results in an enormous paper trail. This is an error prone process which requires resources to check and audit everything to prevent any risks to patients.

The Australian government recognised and addressed this challenge several years ago. They set about establishing a model to address the standardisation of product coding, locations and product data using GS1 standards. The learnings from this standards-based national approach were taken to develop the best practice eProcurement model for Irish healthcare.

Solution

St. James's Hospital, together with its suppliers (Cruinn Diagnostics, Fannin/DCC Vital and Johnson & Johnson), implemented the eProcurement solution by starting with the standardisation of product coding by linking the existing codes to GS1 Global Trade Item Numbers (GTINs). Supplier data is mapped to an agreed minimum dataset (eg: brand name, description, unit of trade etc). This data is then uploaded by the supplier to the National Product Catalogue and is available for SJH to review and import. The second stage of the process is to exchange four electronic procurement messages using Electronic Data Interchange (EDI).

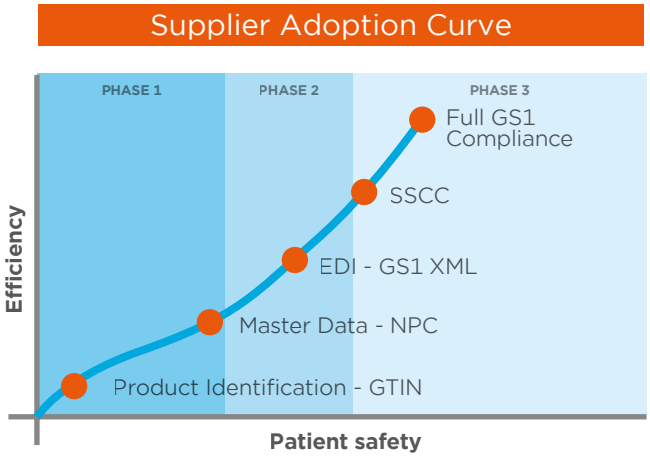
The Vision

The 2012 McKinsey* report recognises the need for healthcare to align to one global standard in order to achieve the benefits, that retail and other sectors have already demonstrated. This approach also evidence-based by the report, is the means to achieving the ultimate best practice that all hospitals aspire to - the ability to electronically and consistently record activity at the point of patient care and to have an audit trail for the purposes of efficient recall and reporting.

* Strength in Unity: The promise of global standards in healthcare

Ensuring operational efficiency and patient safety through adoption of GS1 standards

- **Unique Identifier** The Global Trade Item Number (GTIN) for standardised identification of products
- **Product Data** The Global Data Synchronisation Network (GDSN) for standardised sharing of Master Data via the National Product Catalogue (NPC)
- **Unique Location** The Global Location Number (GLN) for standardised identification of locations
- **Electronic Messaging** The GS1 XML messages for standardised exchange of business transactions messages (Purchase Order, Advance Shipping Notice, Receiving Advice and Invoice)



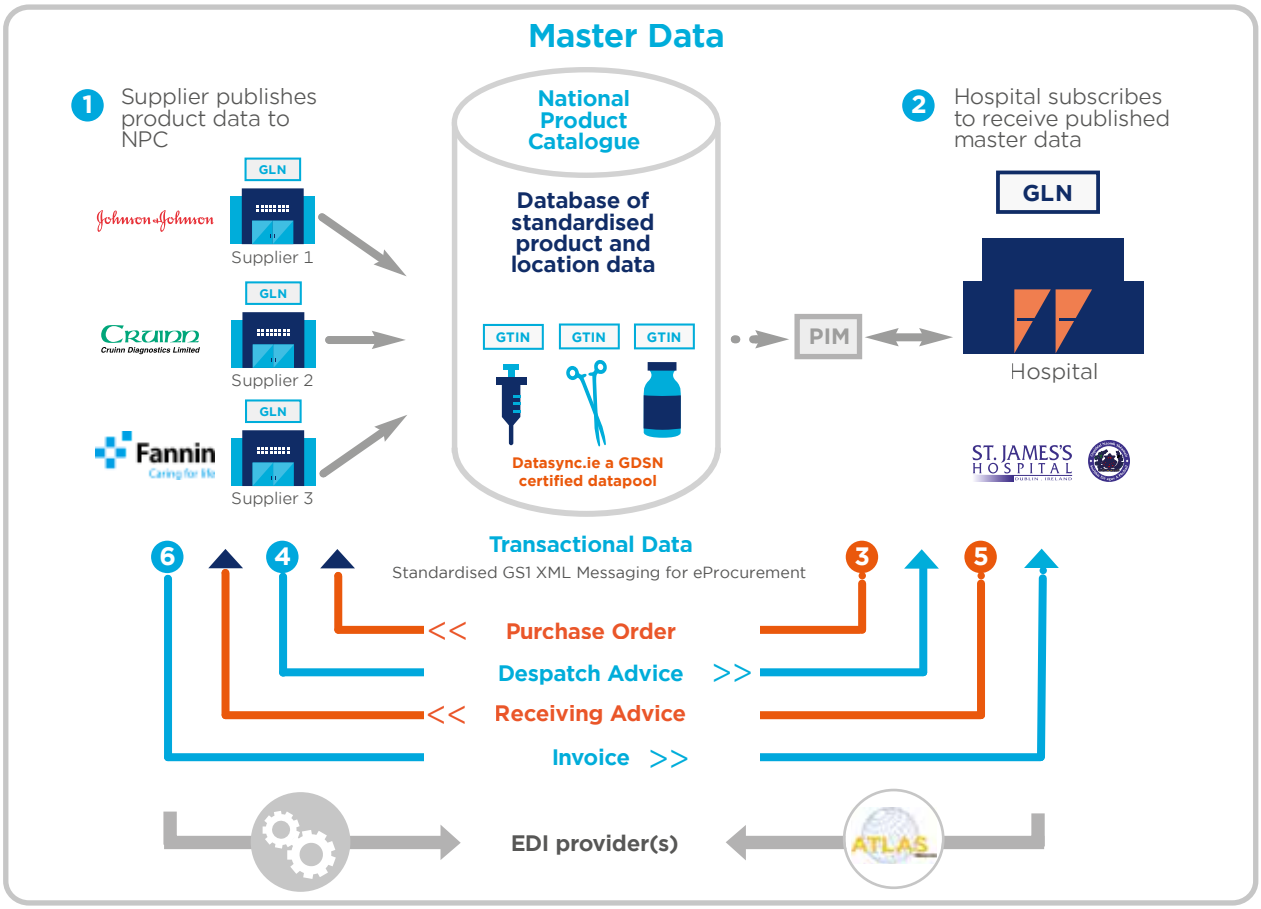
Note: the Serialised Shipping Container Code (SSCC) for standardised labelling of pallets or boxes at goods receiving is planned as part of the next phase of the project.

Stage 1: Standardised product coding and master data

The first key requirement for St. James's Hospital is the standardisation of product coding and alignment of product data with their suppliers at product setup stage, in advance of the ordering process. This ensures accuracy of the data between the hospital and the supplier. GS1 Ireland supported both SJH and the suppliers in this process.

What is the National Product Catalogue (NPC)?

The National Product Catalogue is a registry of all products sold in the Irish healthcare sector. The NPC is 'the' single source of item master data for health institutions seeking to purchase medicines, medical devices and other necessary healthcare items. The NPC is hosted by GS1 Ireland on datasync.ie, a GDSN-certified data pool. This platform enables the secure sharing of item master information such as product identifiers and descriptions, units of measure, package contents, product classification, pricing and related healthcare information. Accurate product data is critical not only for supply chain efficiency but also for clinical purposes to support patient safety.



This diagram illustrates the eProcurement model put in place by St. James's Hospital. The step 1 in the process is the publication of master data by suppliers to the National Product Catalogue. This data, such as product ID, quantity or unit of trade, is key to the successful exchange of the electronic procurement messages and full automation of the order to cash cycle. In step 2 the product data is marked and imported by SJH via the PIM (Product Information Manager). Finally in steps 3 to 6, the transactional data is exchanged via EDI incorporating the purchase order, advanced shipping notice (or despatch advice note), receiving advice note and finally the invoice.

Getting started with master data management

Supplier Action	**Assign GTIN**	The supplier determines if GTINs are available.
	Map GTIN	The supplier maps the GTINs to their product listing.
	Collect Master Data	Master data elements such as product name, description and unit of measure are collected by the supplier in line with the dataset agreed by SJH.
	Upload Data to NPC	The master data is then uploaded to the National Product Catalogue.
SJH Action	**Receive Data**	SJH receives supplier data and any subsequent updates from the NPC.
	Review and Match Data	Using the Product Information Management (PIM) tool, SJH reviews the supplier data and matches this data to the internal hospital data.
	Import Data	SJH then takes the data into their ERP system via a direct download from the PIM.

Product Information Manager (PIM)

The Product Information Manager is a software tool which allows SJH to match, review and import supplier data from the NPC.

Product data from suppliers can be populated in the hospital ERP system via a controlled and automated machine-to-machine process with no rekeying of data.

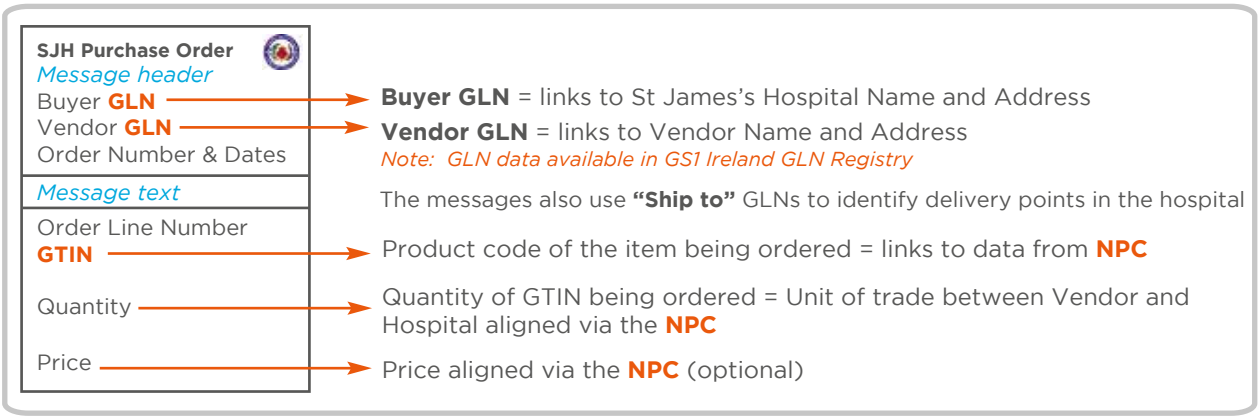
Stage 2: Standardised electronic procurement

For this process SJH engaged an EDI provider, Atlas Products, to facilitate the exchange of four key standardised procurement messages. GS1 Ireland was engaged to undertake the development of the procurement messages.

What is Electronic Data Interchange (EDI)?

Electronic Data Interchange is the electronic exchange of business information using a standardised format; a process which allows one company to send business messages such as purchase orders and invoices to another company electronically rather than with paper. EDI, based on global standards, allows the messages to be exchanged quickly, efficiently and accurately between trading partners. This second requirement eliminates the paper based processes through automated electronic communication of the transactional data between the hospital and supplier. All messages are exchanged via the EDI partners in GS1 XML Standard format.

Example of an electronic message



Getting started with order-to-invoice

Identifiers	Confirm the supplier can process the electronic procurement messages based on GTIN & GLN.
Choose EDI Provider	Typically an EDI partner is chosen to manage the translation and transmission of the electronic messages based on GS1 XML 3.0 format.
PO	SJH generates the EDI Purchase Order (PO) that is transmitted following translation by their EDI provider to the supplier. The translation to the common format is applied to each subsequent message.
ASN	Upon receipt of the order the Supplier prepares the order for shipment and responds with an EDI Advance Shipping Notice (ASN) which includes the details of the goods to be shipped to SJH.
RAN	On receipt of the goods, SJH warehouse staff compare the delivery to the information in the ASN. By confirming the receipt of goods an EDI Receiving Advice Notice (RAN) is sent to the supplier.
Invoice	The supplier generates an EDI invoice based on the information in the RAN to settle the payment process.

"The order was placed first thing this morning, the goods arrived mid-morning and the invoice was on the payment run in the afternoon with no manual intervention. The speed and accuracy of the whole process was incredible, a first for Irish healthcare."

Pat Bailey, *SAP Programme Office, SJH*

Costs

The set-up costs for the implementation of this model mainly involved (i) SJH system modifications, (ii) the engagement of an EDI service provider and (iii) participation in the product catalogue. Ongoing systems costs are expected to be no greater than current system running costs and further savings are likely to be achieved as the system is extended.

Benefits

St James's Hospital embarked on this exercise based on its belief that the best approach to delivering patient safety required end-to-end process design and adherence to international standards. The benefits were known to be considerable and included:

- Improved patient safety with consequential reduction in duplicate patient procedures
- Increased ability for accurate traceability and recall
- Standardisation and increased accuracy of product information
- Elimination of inefficient paperwork and duplication of data input
- Reductions in stock holdings and level of waste stocks
- Reduction in number of credit notes generated
- Automatic invoice matching
- More efficient utilisation of supply chain management and finance resources.

Conclusion and next steps

The learnings established during the project were used to develop the final dataset and business rules which resulted in the first supplier achieving Go-Live with St James's Hospital in September 2014. Please also see the Whitepaper which has been published by St James's Hospital. The requirement for compliance to GS1 standards (see diagram) is now included in tenders and SJH is working to engage their key suppliers in this programme.

"The adoption of GS1 standards and the development of a shared product catalogue enables end-to-end traceability and full automation for healthcare supply chains. In addition, it provides the means to converge clinical and business systems which supports the 'money follows the patient' model."

Vincent Callan, *Director of Facilities Management, SJH*

About the Authors

Vincent Callan *has 18 years Healthcare experience and is currently the Director of Facilities Management at St James's Hospital and has held previous management positions in Materials Management. The Facilities Management Directorate provides a full range of non-clinical services in an integrated manner that supports the treatment of patients. Vincent has been the key sponsor for the eProcurement Project.*

Pat Bailey *is one of the leads in the SAP Programme Office at St James's Hospital. Pat has an extensive knowledge of Materials Management and business system implementation within SJH. He has played a key role in the eProcurement Project.*

About SJH

St. James's Hospital is the largest acute academic teaching hospital in the Republic of Ireland with 1,000 beds and provides a comprehensive range of diagnostic and treatment hospital services to a population in excess of 300,000 at local, regional and national level. There is a strong academic commitment with Trinity College Dublin and the Trinity Health Sciences Centre is located on site.

The Netherlands

Bernhoven: the first dutch hospital with a unique barcode on all medical devices

Bernhoven is the first hospital in the Netherlands that operates according to the GS1 Global Traceability Standard for Healthcare. An extensive international audit has shown that the hospital has a unique GS1 barcode on each medical device in the operating room (OR). The result is complete traceability, from the time a product enters the hospital to the point of use, thus improving patient safety and supply chain efficiency. All of this is accomplished via the support and cooperation of all stakeholders throughout the chain within the hospital, from management to purchasing, finance and IT departments.

By Justin Bitter and Erik van Ark

Background

Improving patient safety and adequate management were the motives for starting a project on traceability in Bernhoven, a 380-bed hospital located in Uden, The Netherlands. The goal was to achieve 100 % visibility in the internal process flow for medical devices, including better management of product recalls, improved inventory management and reduced manual processes.

Bernhoven decided first to focus on traceability of medical devices in the operating room (OR), starting with orthopaedic implants, because 40 % of medical products used at Bernhoven support this specialty. Orthopaedic implants are also characterised by a high value; showing quick results was important to lower any institutional resistance to implementing standards and provide confidence to all stakeholders of the potential benefits of traceability.

Hospital staff checking status of medical devices on internal database

Next, Berhoven started implementing the traceability process in the instrument sterilisation department and on high-risk medication in the OR.

As a starting point, Bernhoven used the business case “Patient Safety and Efficiency at the OR” (2012) which demonstrated that the investments had a return of investment within one year. This convinced the Board of Directors of Bernhoven as well as other management and key personnel

involved. It is critical to have a single shared vision to ensure the entire staff is working towards the same goal. In this way the hospital will achieve the commitment that is crucial to make the implementation a success.

Challenge

Bernhoven team winning the HPAC award. Left to right, Pieter Maarleveld (GS1 Netherlands), Justin Bitter (Bernhoven Hospital), Erik van Ark (Bernhoven Hospital), Hans Lunenborg (GS1 Netherlands), Esther Peelen (GS1 Netherlands)

One of the biggest challenges is persuading suppliers to assign a GS1 barcode with the right information: Global Trade Item Number (GTIN), batch number and expiration date for all medical devices. Not every supplier delivers its products with such codes. Nowadays, there is a variety of barcode types (those from GS1 and from other issuing agencies, proprietary, self-created codes, or none at all) present on the packaging of medical devices. In addition, there can be more than one barcode on the package, which makes it difficult for the OR staff to decide which one to scan and which to avoid. There is no consistent or uniform way to manage the receiving of medical products, which provides another layer of complexity.

Bernhoven must maintain 100 % control of its internal supply chain. For this reason, Bernhoven secured its own GS1 company prefix, used in the assignment of unique identification numbers to the products that are lacking GS1 barcodes. Around 60 % of the medical devices already do have a GS1 barcode and can be scanned right away. The other 40 % need to be re-labelled by Bernhoven until the manufacturer of these products provide a uniform barcode from GS1. In the meantime, providing a hospital-generated label and barcode enables the OR staff to handle all products in the same way. Ultimately, legislation will have to be developed to require every medical device to have a GS1 barcode.

Having a more efficient process to manage the movement and inventory of medical supplies in the OR and other clinical areas empowers staff to focus on the patient, improving the quality of care and patient safety, vs. a manual-based administrative process that may take time away from the patient.

Solution

Currently, Bernhoven is able to track and trace all items implanted in patients by their own developed digital web-based system. The system links products' GTIN with the unique patient number. Using GS1 standards, the hospital makes sure that each implant used in the OR can be scanned and that item number (GTIN), lot number and expiration date are recorded in the system, which benefits the whole supply chain. Scanning the related GS1 barcode in the OR completes the patient record and reduces the stock level automatically.

In case of a recall, the hospital is able to track and trace patients on the same day and remove the affected stock from the location in the OR department. Unnecessary harm to patients is avoided. By embracing GS1 standards, Bernhoven is also prepared for the Unique Device Identification (UDI) legislation to come in Europe.

Results

The project for traceability in Bernhoven is a success. Many benefits are achieved and costs saved.

The hospital is now able to:

- Carry out a recall efficiently without manual interference within the shortest possible time (100 % complete, including internal stock position and implants in patients);
- Reduce dependency on manual-processes and the OR staff and guarantee instant and direct registration of medical devices;
- Secure digital data storage of new and removed implants (prepare the system to link data directly to a central registry of implants, supervised by the Dutch government);
- Realise accurate registration of implants in patients in their electronic health record;
- Downsize manual work in the administrative organisation of the OR department;
- Get digital visibility of stock levels in the OR department (similar to the retail and online industries);
- Reduce inventory level;

- Reduce waste by registering expiration dates (automated checks and proactive removal of expired goods);
- Obtain accurate product data from the supplier instead of maintaining that type of information by hospital staff;
- Obtain insight in costs of used products per operation, thereby improving strategic planning and resource allocation;
- Develop analyses in the yearly financial statements of the hospital.

Key Performing Indicators

- Total number of medical devices registered in Bernhoven's web-based application: 9,245
- Total number of medical devices currently active: 3,477
- Total number of medical devices associated with patients: 4,761
- Total number of patients associated with used medical devices: 1,771
- Total value of current stock/inventory of medical devices in the hospital's financial statement at the start of the project: € 807,000 (non-sterile products included, value sterile stock: € 677,000)

Cost reductions

The following cost reductions were obtained:

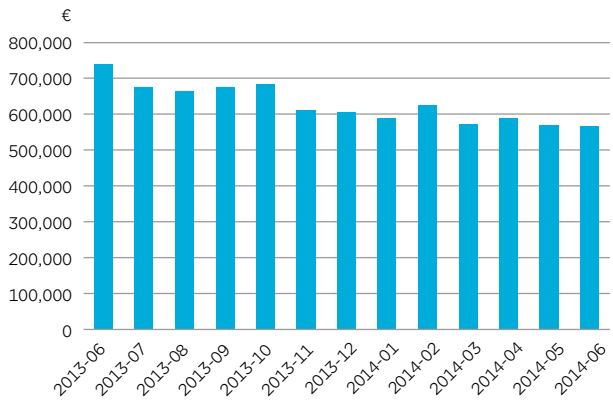
- Reduction of stock by 31%
- Reduction in stock value by 23.6%
- Reduction of waste by 72% (representing a total value of € 25,200)
- Decrease of interest based on the reduced stock value (€ 173,575- * 1.45% = € 2,517)

Conclusion and next steps

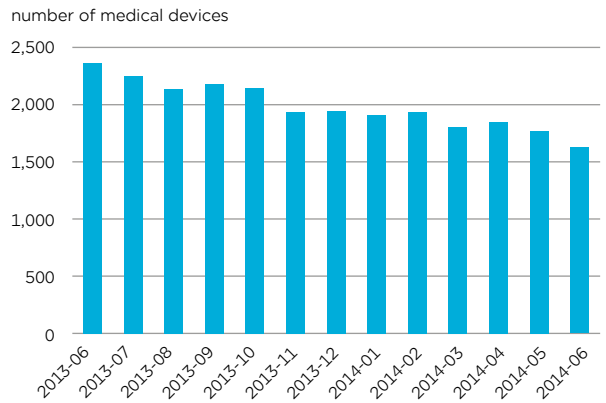
The next step of the hospital is to extend GS1 standards to other products and departments. Instrument trays will be labelled using the success of St. James's Hospital in Dublin* and its use of GS1 standards to manage its internal supply chain. To achieve closed-loop medication in the OR, high-risk medication will also be labelled. In addition, Bernhoven wants to start bedside scanning at the wards, focusing on high-risk medication first. In the radiology and cardiology departments, the Global Traceability Standard for Healthcare (GTSH)** will be applied to medical devices. As a pilot, GS1 barcodes will be introduced for assets in the OR as a proof of concept. If the project is successful, they will be applied for assets throughout the whole hospital.

Bernhoven is member of the Dutch focus group for traceability, under leadership of GS1 Netherlands. This group is now discussing with the Dutch government what can be done before the implementation of the EU-regulation on standardised barcodes. Berhoven hospital has also become a strategic partner regarding the launch of a national registry for implants. The hospital is involved in the process of preparation, providing the best vision and ideas and turning them into long-term solutions for all hospitals in the Netherlands. In the frame of this national registry, GS1 is the recommended standard for implant identification.

Stock value in the OR departement



Stock level in the OR departement



* Using an Electronic Patient Record and unique medication barcoding to deliver integrated comprehensive patient care for patients with Haemophilia.

** Global Traceability Standard for Healthcare Business Process and System Requirements for Supply Chain Traceability: This standard is the definition for GS1 healthcare members of what the process standard for traceability in healthcare encompasses and it shows the corresponding GS1 numbering, automatic identification data capture (AIDC) or data communication standards that must be in place for best practice applications.

Tips from Bernhoven if you wish to implement the process traceability of medical devices:

1. Ensure you have the correct network to help you.
2. Identify beforehand the processes that need to be improved.
3. Identify the areas that will benefit from the scanning process.
4. Involve your GS1 MO. Take advantage of their expertise and knowledge.
5. Visit a hospital that has gone through the same process.

"To support the establishment of UDI (unique device identifier), we will make agreements with manufacturers and the healthcare sector. UDI plays an important role in patient safety; it makes it easier to trace products, helps in the control of counterfeit medical products and moreover ensures that wastage is counteracted."

Source: The annual budget of the Dutch Government (2015)

About the authors

Justin Bitter *is a trained OR nurse, and manager of the OR and sterilisation departments at Bernhoven Hospital, Uden, The Netherlands. He serves as the chairman of the GS1 Dutch focus group on traceability in healthcare. In this role, Bitter is involved in improving patient safety and cost efficiency in the supply chain of hospitals by using uniform barcodes both on a national and international level. He is currently working on his PhD studies.*

Erik van Ark *(MD) is an Anesthesiologist at Bernhoven Hospital, and a member of its executive staff. He has been involved in implementation of pre-operative screening of patients, patients' logistics and re-organisation of patient-scheduling and OR-organisation. Since 2012, van Ark has served as the chairman of the OR in a dual management system in which the doctors are in the lead. He is a supporter of GS1 standards in Healthcare.*

About Bernhoven

Bernhoven is a 380-bed hospital located in Uden, and has its polyclinic in Oss, The Netherlands. Its mission is to provide the best care using modern technology and approaches. Both patients and employees (150 medical specialists and approximately 2,500 employees) take a centre stage. Together, with partner care organisations, the hospital provides comprehensive care to patients. In addition to basic care, the focus of Bernhoven is on senior care and total vascular care. Also, the hospital is well known for its Regional Pain Centre.

UK

DM Orthotics is using GS1 standards to meet regulations and transform their business

Like all companies who supply medical equipment to the U.S., DM Orthotics need to comply with the U.S. Food and Drug Administration (U.S. FDA) regulation on Unique Device Identification (UDI). By implementing GS1 standards in their manufacturing and ordering processes, they are able to meet these regulatory requirements in addition to making cost savings and improving efficiency throughout their business.

By Martin Matthews

Background

DM Orthotics Ltd is a world leader in the design and manufacture of Dynamic Movement Orthoses used in the management of neurological and musculoskeletal conditions. They provide to over 25 countries helping to improve the lives of people who face a range of physical challenges.

GS1 UK has been working with DM Orthotics to support their business processes and to help them meet expected regulations, both in the U.S. and in the UK.

Challenge

A challenge on a global scale

DM Orthotics has over 150 different types of product. The nature of the products they manufacture, and the individual needs of each patient, means that no two products they make are the same, with nearly every order being custom-built to the patient.

This level of personalisation makes their manufacturing process complex and labour intensive. There are also the challenges of meeting new and future regulations in two of their largest markets.

In the U.S., their largest market, the U.S. FDA requires all medical devices sold in the U.S. to carry a unique device identifier (UDI) and all information about each device be held in an U.S. FDA managed Global UDI Database (GUDID).

Orthoses
A custom-designed external device, such as a brace or splint, to support or assist movement of a weak or injured part of the body.

In the UK, the Department of Health has mandated the use of GS1 standards for all products and services supplied to the NHS.

There is likely to be further legislation in this area, including similar regulations being introduced in Europe for the unique identification of medical devices.

Solution

Understanding what's required

DM Orthotics worked with GS1 UK to understand what changes were required to their systems and processes to meet these regulations.

Cy Culpin, Digital Manager at DM Orthotics Ltd, has been working with the team at GS1 UK to define the systems specifications and other technical aspects of adopting GS1 standards.

DM Orthotics now uniquely identify their products using GS1 standards. Every product is labelled with:

- a unique device identifier; and
- production information, such as batch number and manufacturing date.

This information is represented in a GS1 barcode which allows the data to be captured and checked quickly using scanners.

Submitting product data to the FDA

The product data of all devices supplied to the U.S. must be submitted to the GUDID.

Given the highly customised nature of their product range, DM Orthotics are currently defining the best approach to submit product data to the GUDID. TrueSource, GS1 UK's datapool, fully supports the submission of data to the FDA GUDID.

Once they have a data submission solution in place, they will fully comply with the U.S. FDA regulations on UDI and will be in a good position to comply with the expected European regulations about medical devices.

Furthermore, DM Orthotics have gone beyond the need to just comply with regulations. Using GS1 standards, they are making efficiencies across their business operations.

Employee scanning GS1 barcode into the database.

Benefits

Transforming their entire operation

With changes required to their systems to meet these regulations, DM Orthotics took this as an opportunity to use GS1 standards even further, to transform their business and embed GS1 standards to automate their entire ordering and manufacturing processes.

Automated tracking

By implementing GS1 standards, their ordering system has been updated to identify each item with a unique order number and automatically generate a barcode whenever a new item is processed.

The order number relates back to the patient and the customer placing the order, which is then captured with scanners throughout the manufacturing process in the factory.

"I am confident that DM Orthotics will meet the regulations for UDI, in the U.S., and the NHS, in the UK, and thanks to GS1 standards, our business is set-up in the best possible way for the future."

Martin Matthews,
Managing Director of DM Orthotics Ltd

Real-time traceability

This has enabled DM Orthotics to gather valuable insight into the efficiencies and pinch-points along the process from an order being received to an order being fulfilled, allowing real-time improvements to be made, from staff training requirements to coping with different levels of demand.

A template for best practice

DM Orthotics have so far implemented this level of automation to a portion of their product range. This 'test and learn' approach has allowed them to make tweaks and amendments to their processes along the way and understand the benefits of using GS1 standards without disrupting their global operations. They have already seen a positive impact to their business, beyond simply meeting regulatory compliance.

Using this approach means that DM Orthotics now have a template for best practise and are planning to roll out the same level of automation, using GS1 standards, across the rest of their product range.

Now they have seen how using GS1 standards can improve the flow of information through their business, they have taken traceability a step further.

Not just products and processes, but people too

Not only are orders uniquely identified, but people are too. DM Orthotics identifies each member of staff in their factory, using GS1 standards.

Touch-screen and scanning technology has been installed throughout the factory to enable every product and member of staff to be identified at each stage of the manufacturing process. This is achieved by scanning barcodes on each product and staff ID card as an item moves along the process.

This gives DM Orthotics visibility over who's working on a particular order at a particular time.

Conclusion and next steps

- **U.S. FDA UDI compliance**
  Implementing a solution to submit product data to the GUDID, by the deadlines outlined by the FDA, will allow them to fully comply with the UDI regulations in the U.S.

- **Roll out GS1 standards to the rest of their product range**
  Using the template and best practices that have been identified through the initial phase, DM Orthotics plan to implement the use of GS1 standards across the rest of their product range.

- **Integrating their dispatch and accounts systems**
  DM Orthotics are planning to integrate their dispatch and accounts systems to the new automated processes. This will enable complete end-to-end visibility across their entire business from receiving an order, to invoicing and receipting payments.

Before implementing GS1 standards, DM Orthotics' ordering and manufacturing processes were paper-based and required substantial time and effort in manually keying and rekeying data into multiple systems.

It was difficult for them to monitor orders through the manufacturing process. The amount of manual data entry, inaccuracies of information and varying types of external order numbers, meant that orders were difficult to keep track of and manage.

The requirement to use GS1 standards has enabled DM Orthotics to make improvements to their business processes throughout their entire order and production systems, over and above meeting regulatory compliance.

By using GS1 standards, they have reduced the amount of time spent by staff processing orders and rekeying order information onto different systems. This has enabled a marked improvement in efficiency, as an order now moves automatically through the order and manufacturing systems and is identified, captured and shared through the entire process.

About the author

Martin Matthews *is Managing Director of DM Orthotics Ltd.*

Martin qualified in 1981 from Salford College of Technology as an orthotist and specialises in paediatrics and scoliosis management.

In 2009 he graduated from the University of East Anglia with a research Master of Philosophy degree investigating the effects of DMO leggings on children with cerebral palsy. He has developed the Dynamic Movement Orthoses over the past 15 years. He lectures at University of East Anglia and has written numerous scientific papers. He partners with a number of Universities to ensure continued innovation and development of the business.

About DM Orthotics

DM Orthotics was founded in 2005 by Martin Matthews. The company has grown into an international business with distributing partners in 25 countries.

U.S.

Louisiana hospital system achieves the “touchless order” via GS1 standards implementation

Franciscan Missionaries of Our Lady Health System (FMOLHS) is currently engaged in a two-year pilot to develop a high performance, streamlined and automated supply chain, in large part via the implementation of GS1 standards. Like many hospital systems, FMOLHS aims to eliminate human error and bad data while putting into place supply chain processes that are automated from end-to-end - from the time an order is placed through its materials management information system (MMIS), to the delivery of the product, use of the product at the patient bedside and accurate recording of the product in the patient’s electronic medical record. In 2014, FMOLHS achieved what was previously considered by the U.S. healthcare industry as “mission impossible” – it processed the Touchless Order with zero errors, and has since replicated the process with additional suppliers.

By Sandi Michel

Background

Based in Baton Rouge, La., FMOLHS is the leading healthcare provider in the state of Louisiana. For many years, hospitals in the United States have been working towards establishing a true “Touchless Order” process, a major goal of supply chain management. FMOLHS leveraged lessons learned and best practices of other leading hospital systems, including Mercy, Mayo Clinic and others, and achieved the milestone in the summer of 2014 with its first supplier partner, Cook Medical, and did so ahead of schedule. In addition, the hospital system developed a repeatable process for use with additional supplier partners, including BD, Johnson & Johnson, Abbott Laboratories, Terumo Medical, Bard and Medtronic, to automate the order process from end-to-end and without human touch. FMOLHS expects to implement the Touchless Order for additional suppliers in the months ahead.

Challenge

The current era of accountability across the healthcare system means that all of healthcare must pull together to provide quality care to patients, reduce healthcare costs and improve the health of the community at large. However, a hospital cannot achieve operational excellence if it uses faulty data. Accurate, consistent data is important to every function within the hospital, as it impacts quality of care provided to patients, the safety of the products used in the delivery of that care and the security of the supply chain. With healthcare’s ongoing reliance on electronic communications and business transactions, the very foundation of quality healthcare rests with sound, accurate and reliable information every step of the way.

Solution

GS1 standards in a fully automated supply chain wrapped with sound business processes work together to enable improved patient safety, supply chain security, and critical information sharing each step of the way (from manufacture to patient use and beyond). Standardised data provides countless predictable and unpredictable benefits.

Having a clear view of the supply chain leads to improvements in every area that a product touches, including inventory management, contract management, claims and reimbursements, patient care and records management, among others. The information can be used for U.S. Food Drug Administration actions, such as product recalls, post-market surveillance and counterfeit abatement efforts. Standardised data also supports regulation, such as U.S. FDA Unique Device Identification (UDI) and pharmaceutical product serialisation, as required by the Drug Supply Chain Security Act. Standards also support many industry priorities as well (Meaningful Use, Triple Aim, and others.). At FMOLHS, the transition to Touchless Order has been much smoother than the team at FMOLHS had originally expected.

FMOLHS started implementing GS1 standards with Cook Medical in May 2014, and its first go-live order was processed successfully on July 7, 2014. The order was 100 percent touchless, meaning that FMOLHS was able to create a purchase order, submit it, receive the product at its central dock, scan it into their IT systems, send receipt acknowledgement, receive and pay the invoice, and have the product accurately delivered within the hospital, all without manual entry.

- Global Location Number (GLN): Location Identification

Standardised location identifier that replaces custom account and location numbers.

- Global Trade Item Number® (GTIN®): Product Identification

Standardised product identifier that replaces custom product numbers. Manufacturers are moving toward adopting a standardised product identifier to ensure accuracy of product information at every level of packaging throughout the supply chain.

- Global Data Synchronisation Network™ (GDSN®)

Source of standardised product information. With this network, all supply chain partners will be able to access identical, up-to-date, reliable product data efficiently. The GDSN plays an integral role in the adoption of GTINs. Healthcare organisations can use the GDSN to store and share product information for faster standardisation and better communication across the industry.

FMOLHS GS1 standards implementation project phases

- Completion of pilot and key decisions
- Document project activities and processes
- Identify and communicate with parallel projects (e.g. launch of FMOLHS’s new, centralised distribution center and alignment with ROi)
- Closure plan, including internal certification of system readiness certification
- Rollout (for Cook Medical, FMOLHS is entering monitoring phase. In this phase, will conduct analytics for financial and other benefits)
- Transition to Operations (30-60 days post pilot)

A few basic steps

Working closely with Cook Medical, FMOLHS went through a few basic steps to implement GS1 standards, specifically the Global Location Number (GLN) to identify locations and the Global Trade Item Number® (GTIN®) to identify products. This process is now being replicated with other suppliers:

1. FMOLHS established its hierarchies and registered the GLN for its facilities. The information was shared with Cook Medical, which now uses GLNs instead of customer numbers created in house. Cook also shared their GLNs with FMOLHS.
2. FMOLHS tested all of its transaction points using GLNs. This step involved working with data translator partners to ensure EDI transactions were being processed using GLN information.
3. FMOLHS coordinated efforts with its MMIS provider (Infor v. 9.1.03) to ensure that their software was able to accommodate GLN information. For now, this involved simply setting up a transaction table within the system. Future versions of the software will contain GLN and GTIN fields.
4. FMOLHS conducted round trip order processing tests (successfully), and then implemented the orders live.

Cook Medical has assigned a Global Trade Item Number (GTIN) for each of its products, and is now requiring customers to transact using GTINs going forward. FMOLHS received the GTIN for the items used, and loaded that information into the MMIS. The FMOLHS team verified that all the product attributes were accurate, and that the information in the hospital information system matched with Cook’s descriptions for consistency. Once all the records that contained GTINs were in the MMIS, FMOLHS was able to submit orders using GTINs. For four weeks, the FMOLHS team monitored every electronic order closely, and every single automated order was processed accurately.

The GTIN piece is very important, because it is through these transactions that FMOLHS is supporting FDA UDI. Capturing GTIN allowed FMOLHS to know where the product went once it was in the hospital, which improves patient safety, security in the supply chain (to prevent counterfeits, for example) and for potential product recalls. As hospitals launch initiatives to track patient outcomes and population health, knowing when and where a specific product was used and on which patients will become even more critical.

Benchmarks

It is important to look at before/after scenarios to evaluate effectiveness of any business process change. To that end, FMOLHS has established benchmarks to assess metrics in the following areas:

- Accuracy in purchase order, invoicing and payment.
- Revenue reporting factors (charge accuracy, claims processing efficiencies, real-time product usage and consumption, automated replenishment, demand-driven supply chain, and point-of-use systems and processes).
- Inventory management (value of inventory on hand, reduction in inventory, re-labeling activities, recalls, expiration date management).

Conclusion

The journey to the Touchless Order has resulted in FMOLHS finally having a complete, accurate and up-to-date item file for our materials management processes.

As FMOLHS embarks on this exciting transition with other partners, it does so knowing that the long-time healthcare ideal of a fully automated supply chain is now within reach. With the Touchless Order, what seemed like an unattainable vision just a few years ago is now a reality that the hospital experiences everyday. In short order, it could become "business as usual" for the healthcare system.

For those hospitals that have been hesitant or have been delaying their efforts for any reason, a significant lesson learned for FMOLHS is that as intimidating as implementation may seem at the beginning, the adoption of standards is completely "doable," no matter the size of the hospital system.

These standards are the foundation of our ability to order supplies error free, and track the product all the way from order to dock to patient, and beyond." Sandra Michel, director of supply chain systems and quality.

Sandi Michel, *Director of supply chain systems and quality. FMOLHS*

About the author

Sandi Michel *is Director of Systems and Quality, MMIS, Implementations, and Audits at Franciscan Missionaries of Our Lady Health System in Baton Rouge, Louisiana. She currently leads the implementation of GS1 global data standards and a team of Supply Chain Analysts.*

About FMOLHS

Based in Baton Rouge, the Franciscan Missionaries of Our Lady Health System is the leading health care innovator in Louisiana. They bring together outstanding clinicians, the most advanced technology and leading research to ensure that patients receive the highest quality and safest care possible.

This commitment is grounded in a history that is more than 100 years old, but reflected today by its strategic vision of transforming healthcare through superior performance and excellent patient care.

Government initiatives

Australia

NSW Health continues to benefit from its implementation of GS1 standards

NSW Health is the largest public health system in Australia and had been reliant on manual processing of procurement information using several methods and from various sources. These processes led to inaccurate, unreliable and variable sources of information and posed a deterrent to business growth. They were not conducive to system-to-system integration, essential for procurement process efficiencies.

In 2005, NSW Health adopted GS1 Australia's global data synchronisation network compliant data pool, GS1net – known as the National Product Catalogue (NPC) in the Australian healthcare market – as its optimal and compliant solution to facilitate the exchange of accurate, timely and synchronised data across its supply chain.

The NPC has enhanced the quality of data within the NSW Health procurement information system. The established processes by GS1 Australia provide system architecture improvement to ensure the solution is flexible in terms of accommodating industry endorsed additions and improvements over time.

by Valentino Bulaon

Background

The NSW public health system is world-class, consisting of approximately 220 public hospitals, 105,000 dedicated staff (FTE) and 15 Local Health Districts (LHDs) - eight servicing the Sydney metropolitan region and seven servicing rural and regional NSW.

HealthShare NSW was established in 2007 to deliver efficient non-clinical and corporate shared services for NSW Health and is the largest public sector shared services model in Australia, with an annual operating budget of more than $1 billion.

With approximately 6,400 employees, HealthShare NSW processes 72,000 purchase orders per month and 8,000 accounts payable invoices daily.

Challenge

NSW Health was reliant on manual processing of procurement information. Procurement information was obtained from a myriad of sources, such as phone calls, emails and paper catalogues creating double handling and costly reprocessing.

Budget control, contracting and tendering had also become a major concern with diminished reporting capabilities due to inconsistent system information and sources that did not support the production of reliable spend-trend reports.

Valentino Bulaon, *NSW Health's Procurement and Catalogue Information Manager.*

Each week, 18,000 purchase orders were being processed, of which 45 to 55 % were free-text, i.e., requiring manual entry by both clerical and clinical staff. This contributed to invoice processing on-holds estimated to be valued at $10 million per week.

NSW Health realised inaccurate, unreliable and variable sources of information posed a deterrent to business growth and were not conducive to system-to-system integration, essential for procurement process efficiencies.

Solution

NSW Health set itself a task to identify a solution designed to meet a specific set of criteria. The solution sought needed to:

- support service improvement through the provision of accurate procurement data;
- have the ability to monitor procurement activities, analyse trends, influence buyer and supplier behaviour, and ensure compliance to NSW Government policies;
- generate savings for NSW Health through reduced manual processes, reduced data errors and subsequent processes required to rectify errors;
- support the roadmap to making procurement business intelligence available across the state through a shared system;
- contribute to NSW Health standards for intelligence gathering and analysis.

In 2005, working with the National eHealth Transition Authority NeHTA, NSW Health was involved in identifying GS1 Australia's data synchronisation network compliant solution - the NPC as its solution.

Today the NPC is a repository of master data and presents as the "central source of truth" for procurement purposes. Suppliers who own and maintain the data pertaining to their products, enter product information into the NPC. The entry of data is based on global standards and is validated for quality control and accuracy. Standards governing how and what data is entered, inclusive of category and health item codes, assist delivery of consistent and accurate procurement information.

The NPC uses global standards governing unique identification keys, including the Global Trade Item Number (GTIN) which uniquely identifies each product at all layers of packaging, and the Global Location Number (GLN) which uniquely identifies the physical, operational and legal locations of trading partners. A separate system, GS1 Locatenet, a central directory of GS1 Global Location Numbers (GLNs), enables the matching of NSW Health Location GLN to receiving Trading Partner GLN.

The NPC met the NSW Health solution criteria as it enabled system-to-system access to accurate procurement information directly from data owners, thereby addressing data quality issues and removing reliance on manual processes. In addition, the NPC data supported the automated processes NSW Health wanted to implement, including data extraction, linking, validation and the subsequent data push to procurement information systems.

NSW Health uses the Bizcaps Master Catalogue Information System, which enabled integration between the NPC and the NSW Health internal systems.

The GS1 Australia Data Services Support team was of great assistance to HealthShare NSW when the NPC project was implemented and continue to provide ongoing support. Ongoing consultation with these specialists is strongly recommended.

Valentino Bulaon, *NSW Health's Procurement and Catalogue Information Manager.*

Post the NPC implementation, NSW Health applied an image project designed to enhance the user ordering experience. It chose GS1 SmartMedia as one of two options available to NSW Health suppliers to populate product images on the NPC and supplement the NPC data. GS1 SmartMedia is a whole of industry solution that fulfils the need for a single repository of valid, up-to-date multimedia files, other digital assets and basic product data attributes, allowing easy sharing with trading partners and seamless integration with the NPC.

Benefits

Implementing the NPC has addressed the key issues deemed as deterrents to business growth, such as inaccurate, unreliable and variable sources of information. The NPC data has proven essential to system-to-system integration required to deliver procurement process efficiencies.

The NPC has enhanced the quality of data within the NSW Health procurement information system. Once the full system-to-system integration is complete, invoices ”on hold” resulting from free-text ordering are expected to be drastically reduced if not eliminated altogether. The average time spent for the requisitioning process is expected to also reduce. Additional time savings are to be realised through reduced time spent rectifying wrong deliveries and returns.

Manual data processing undertaken by hospitals and NSW Health business units during the cataloguing requisitioning, purchasing, warehousing and accounts payable processes, have almost been eliminated through automated vendor product data updates. In turn, this has enabled the introduction of robust data control tools, with auditable and comprehensive reporting capabilities, sound work flow processes for improved management of the state catalogue.

The NPC incorporates industry standard specifications which supports seamless integration of internal systems. The established processes by GS1 Australia provide system architecture improvement to ensure the solution is flexible in terms of accommodating industry endorsed additions and improvements over time.

Conclusion and next steps

NSW Health plans to expand system-to-system integration to other non-health specialised procurement information systems across the state. This will maximise the use of global standards for unique product identification and data in cataloguing, spend trend analysis and product traceability.

It is important to share with others what the implementation of GS1 standards can achieve when coupled with a dedicated vision.

NSW Health is receiving national recognition for its success in making its procurement processes more efficient using GS1 standards.

GS1 global standards now form the key components of NSW state cataloguing, requisitioning, purchasing, accounts payable and state spend reporting. As of December 2014, the NPC holds the catalogues of more than 460 supplies, and shares data with each of Australia's seven State jurisdictions across Australia in addition to a number of providers (private hospital providers).

The NPC enables trading partners to have accurate, real time information in their systems upon which to base decisions. If any changes are made to one company's database, the change is automatically sent via the NPC to all trading partners.

The important work undertaken in electronic data validation, synchronisation and integration between the NPC and the Health Information Master File (HIMF) and related NSW Health procurement contract, financial management and electronic clinical systems is of national significance as an exemplar of Electronic Healthcare Supply Chain Reform.

Paul Broadbridge, *Supply Chain Manager at the National E-Health Transition Authority (NEHTA).*

About the author

Valentino Bulaon *is Catalogue & Procurement Information Manager for HealthShare NSW.*

Valentino is responsible for a number of successful procurement projects and ongoing programs. These are the establishment, implementation and administration of the NSW Health Supply Chain Information System incorporating the Health Quality Reporting System and Clinical Product Evaluation Registries; the state catalogue that is associated with the National Product Catalogue; and the integration of a number of data systems with NSW Health's Master Catalogue Information System. These projects paved the way for NSW Health's successful implementation of national and global data nomenclatures and GS1 Global Standards in the management of its supply chain. Previously, Valentino held a senior role in NSW Health and led the implementation of whole of NSW Health procurement reforms, including the successful pilot and rollout of the Electronic Tendering System.

About HealthShare New South Wales

HealthShare NSW is a statewide organisation established to provide shared services to support the delivery of patient care within the NSW Health system. The organisation employs more than 6,400 people and is the largest public sector shared services model in Australia.

Turkey

Turkey implements first successful national Pharmaceutical Track and Trace System (ITS) for a safe and reliable supply chain

The Turkish Pharmaceutical Track-and-Trace System (ITS) is the infrastructure constructed to track and trace all units of a pharmaceutical product in Turkey. Uniquely identifying the drugs with a GS1 Global Trade Item Number (GTIN) and a serial number held in a GS1 DataMatrix barcode enables the tracking of each drug unit as it travels across the supply chain; the barcode is scanned at each step by supply chain stakeholders that physically handle the product. That data is then captured and sent to the ITS database. The data captured provides a Chain of Custody or Chain of Ownership (CoC/CoO) of the product (also known as its pedigree). ITS was the first successful application of a "Pharmaceutical Track and Trace System" in the world and is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients. The sale of counterfeit drugs, reimbursement fraud, drug theft and barcode scams are therefore made more difficult.

by Prof. Özkan Ünal

Background

Pharma counterfeiting is a major problem worldwide and over the last few years, the number of counterfeit drugs has increased. Ongoing education of the public, and stricter laws governing the control of the products, so far are not making a significant impact in combating the issue. As counterfeiters become more sophisticated, pharmaceutical manufacturers and their trading partners need to improve the safety and security of the pharmaceutical supply chain.

In Turkey, all stakeholders have licenses issued by the Turkish Medicines and Medical Devices Agency (TMMDA). After obtaining the TMMDA scientific committee's permission, the data is registered in the ITS system. The Agency also defines the price of a drug; 91 % of drugs in Turkey are paid for through the reimbursement association of the state, making the state the biggest customer of the pharmaceutical industry in Turkey.

Challenge

The main challenge in Turkey was to ensure and guarantee the reliable supply of drugs to patients. Turkey's drug supply, like most countries, was at risk of illegal activities that could seriously impact public health and safety, ranging from theft and diversion of legitimate drugs to counterfeiting. Turkey needed to find ways to prevent the sale of illegal drugs, smuggled drugs, or counterfeit drugs and fight reimbursement fraud, among other threats to the safety and security of the supply chain.

The challenge was:

Solution

The solution is traceability, which is defined as full, end to end, actionable visibility of finished pharmaceuticals in healthcare globally, from point of production to point of use.

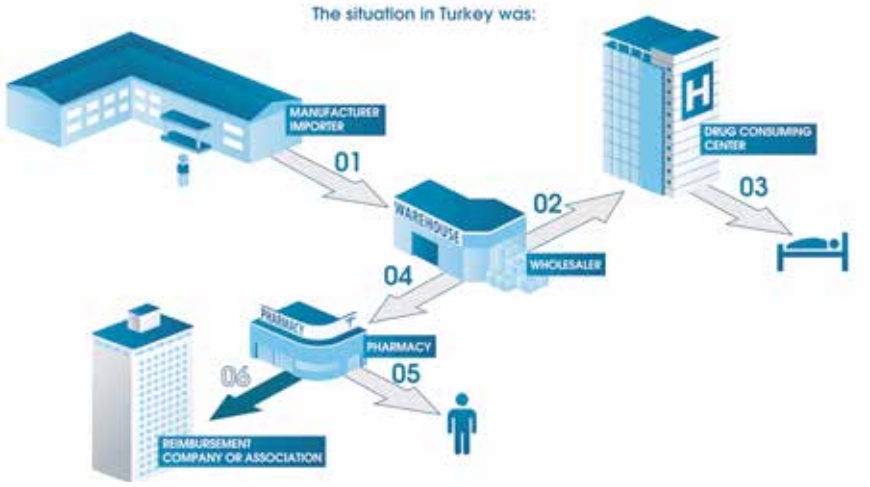
That is why Turkey developed their own Pharmaceutical Track and Trace System, known as ITS. In addition, Turkey built a centralised repository to provide a single location that all the stakeholders must use to notify all activities related to the movement of a drug through the supply chain. With such a central management system in place, the ITS can track and trace a drug by using its serial number from the point of manufacture to the point of dispense. By serving as the single source of true data in the pharmaceutical supply chain, ITS has become a fully interoperable, electronic, serialisation-based track & trace system for pharmaceuticals in Turkey, and can serve as a model for other countries looking to establish a similar model.

PTS and ITS

ITS is limited to tracking and tracing the secondary level of packaging of the drug, however as the majority of drugs sold, bought and transported is done via cartons, boxes, palettes, Turkey developed the Package Transfer Service (PTS), a centralised file sharing platform to track and trace the shipping level. PTS provides an electronic language (PTS XML) that can be used between the stakeholders to share the data related to their shipment and/or exchange.

The manufacturer produces the finished goods, uniquely identifies them and includes a GS1 DataMatrix containing additional information: the Global Trade Item Number (GTIN), expiration date, serial number and batch/lot number. The goods are then packed in boxes which are labelled with a barcode which could be a GS1 barcode. After the shipment is prepared, the manufacturer sends a “manufacture notification” message to ITS and creates an XML file containing pertinent data for the units in the container; this data is then uploaded via an XML file to the PTS. This is the first record that begins the CoC/CoO of the drug pack.

After the shipment is delivered, the wholesaler downloads the XML file from PTS, and scans the shipment to verify that it matches the shipment received and sends the purchase action to ITS. The ownership of the drug then changes from the manufacturer to the wholesaler. The same procedure is followed by the retail pharmacy or hospital after sending their order. The wholesaler sends the sale notification to ITS and uploads the XML file to the PTS. The buyer (retail pharmacy or hospital) downloads the XML file from PTS, and uses the information from the drug packs to notify the purchase action to ITS. For hospitals,



GS1 DataMatrix included on secondary packaging.

the consume notification is done right before opening the drug pack which symbolises the end of the product's "life" and is marked as such in the system. The pedigree ends at this stage which prevents this drug from re-entering the supply chain. In the retail pharmacy setting, after getting the prescription from the patient, the retail pharmacy provides the drug pack to the patient and electronically sends the invoice to the reimbursement association. The reimbursement association queries the sale from ITS and verifies that the information sent by the retail pharmacy is correct before reimbursing the retail pharmacy.

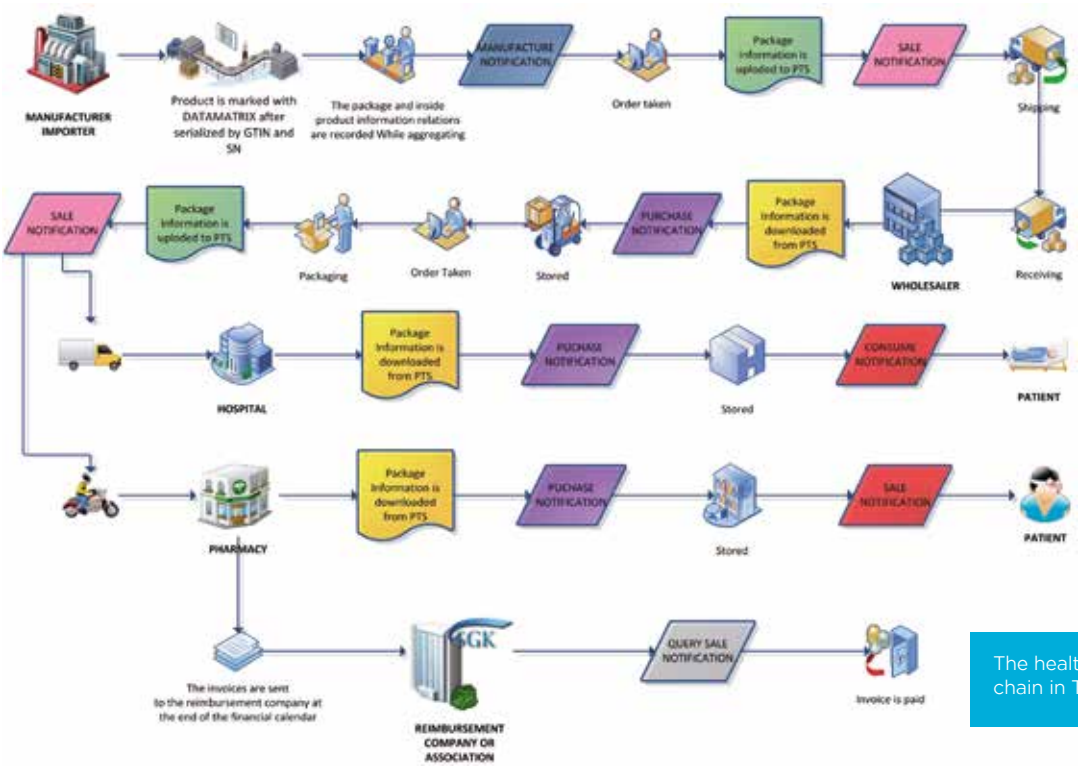
Benefits

Turkey has more than 40,000 stakeholders included in the ITS system and has tracked and traced more than 10 billion drug packs. On a daily basis, there are more than 45 million transactions through the system. The system response time is 0,02 seconds per transaction, and its performance record is outstanding, with an uptime ratio of 99,999%!

Turkey's main goal was to ensure the reliable and safe supply of drugs to patients. By implementing a traceability system, Turkey has achieved that and more. The system has contributed to Turkey's ability to combat the sale of counterfeit and smuggled drugs, prevented illegal sale of drugs, barcode scams and also drug thefts. Results of Turkey's efforts have been tremendous, and in these five areas alone, the nation is seeing savings of 1 billion US dollars annually. By considering that pharmaceuticals is a ten billion dollar annual industry in Turkey, this is a significant saving. In addition, the electronic system has streamlined supply chain processes, saving time and increasing efficiencies. With the system in place, the Turkish government also has data tools in place to support its fight against the selling of narcotics on the black market.

The nation is seeing savings of 1 billion US dollars annually.

The product recall process is also greatly improved. The government can conduct more complex recalls more quickly, as the product



The healthcare supply chain in Turkey

data is housed in one place. It is now possible for the government or manufacturers to issue a recall for a batch or a half batch of a drug from just the affected stakeholders (vs. the entire drug production or across the entire supply chain). The recall can be conducted in more specific ways as well, such as stopping a transaction at the point of sale or following the movement of the recalled product backwards in the supply chain. Once a recall is issued in the system, the recall takes effect instantly and no entity can challenge the recall.

The product data captured in the system is valuable, and can be used to support rational use of medicines, create administrative reports, monitor the industry and prevent tax fraud, among other uses. Faster decisions and more consistent estimates can be made by using this instantly updated data.

Conclusion and next steps

Outcomes and benefits of the system have been an inspiration for other industries and countries. In fact, the Turkish government anticipates applying nationwide track and trace systems for other industries, such as medical devices and food sectors.

The Turkish Medicines and Medical Devices Agency recently made significant investments in a project that aims to track and trace medical devices and cosmetics.

Also, Turkey is working on ways to further enhance its approach to traceability. A new, innovative project is investigating a rule-based approach, which may provide a modifiable and dynamic structure. Such a structure would provide the ability to the existing system to be customised with respect to various regulations, serialisation standards and technologies. With this innovation in place, the system could accommodate any country's regulation and trace any kind of packaged product, without the need of redevelopment. Furthermore, with this innovation, the system can also be used as a harmonised and an interoperable region-wide traceability system.

Turkey's government and pharmaceutical industry stakeholders are working to increase safety and security in the pharmaceutical supply chain to prevent theft and counterfeiting and other illegal activities, and have gained many additional benefits as a result. Turkey's traceability system can provide a model for other nations looking to establish a central repository for drug information that can be used to meet CoC/CoO goals.

About the author

Prof. Özkan Ünal, *was born in 1966 in Zara, Sivas. He graduated from Ankara University Faculty of Medicine in 1989. Dr. Ünal was Radiologist at Ataturk University Faculty of Medicine in 1994. He is the President of Turkish Medicines and Medical Devices Agency since December 2014.*

About ITS

The Pharmaceutical Track & Trace System (ITS) has been planned in order to track drugs and the most related products to drugs and it tracks the products within the scope of "Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use." It enables to define the locations of the products in the supply and distribution chain. It is possible with the help of the electronic product code to track each transaction of the drugs in the supply chain beginning from the production or importation. Accordingly, with the DataMatrix printed on the drug packages, it is possible to report the incoming and outgoing of the products, so that the last location, time and status of the product can be saved and stored in a live data source.

About GS1

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, healthcare providers' solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies. GS1 Healthcare members include over 60 leading Healthcare organisations worldwide.

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

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