

The Global Language of Business

GS1 Healthcare Reference Book 2017-2018

Stories of successful implementations of GS1 standards



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It's an exciting, yet challenging time in healthcare.

Medical research has advanced further in the past decade than at any time in human history. The decoding of the human genome has spurred research like never before—treatments and cures are starting to be tailored to the individual rather than the disease.

One of the greatest challenges that healthcare systems continue to face is patient safety. The report by Canadian Dr. Anne Snowdon¹, *Visibility: The New Value Proposition for Health Systems*, points to past research which indicates medical error is now the third leading cause of death in North America, behind the prevalence of heart disease and cancer.

This report suggests that medical error prevention may be strengthened by focus on the supply chain infrastructure in clinical environments —a well-developed supply chain offers the potential to protect patients by making it nearly impossible for errors to happen. It calls on healthcare stakeholders to transform their supply chain processes with GS1 standards, creating environments that are highly visible so that risks can be identified for intervention *before* errors can take place.

It's clear: The industry is listening and taking action. There's a great deal happening around the globe to improve healthcare supply chains, making them much more efficient and safer for patients.

Healthcare systems in more than 65 countries and regions are implementing GS1 standards in Australia, Brazil, Europe, Japan, Korea, New Zealand, Saudi Arabia, UK, United Arab Emirates, U.S. and many more.

Today, nearly all EU countries are using GS1 standards to identify pharmaceutical products in support of the EU Falsified Medicines Directive. The Department of Health in England is driving the implementation of GS1 standards throughout its NHS Trusts.

As of June 2017, more than 85 percent of medical device records loaded into the U.S. Food and Drug Administration's Global UDI database are using GS1 standards as the primary identifier.

And in 11 countries across Asia, Europe, Latin America and the Middle East—where no regulatory requirements exist—barcode surveys have been conducted. They identified that a significant 70 percent of medical device secondary packages and 88 percent of pharmaceutical drug secondary packages now carry GS1 barcodes.

Most recently, CEN/ISO TS 18530, the global standard for patient and caregiver identification using GS1 standards, is being implemented in a range of hospitals worldwide, sometimes as part of national programs.

Indeed, GS1 standards are being widely used today—constant progress is being made!

On the following pages, read how healthcare stakeholders are making compelling changes to their supply and clinical environments. Learn how challenges are being turned into exciting opportunities, delivering better outcomes for healthcare operations and ultimately, for patients.

Get involved in GS1 Healthcare, our global user community, at **www.gs1.org/healthcare** where you will learn from peers, participate in webinars and conferences, and be able to use all the resources available to you, as a global member.

¹ Dr. Anne Snowdon, RN, PhD and Dr. Charles Alessi, LRCP, MRC, "Visibility: The New Value Proposition for Health Systems," World Health Innovation Network, http://www.worldhealthinnovationnetwork.com/our-work/publications/15publications/155-visibility-the-new-value-proposition-for-health-systems



Healthcare provider implementation

Healthcare provider implementation

Imbanaco Medical Centre takes patient care and safety to the next level with traceability

Since 2014, Imbanaco Medical Centre has used GS1 standards to simplify and automate its clinical processes for increased efficiencies in its operations and enhanced patient safety. The hospital has launched several initiatives focused on ensuring the traceability of medicines, medical devices and other supplies—from receiving products in its central warehouse to dispensing medications at patients' bedsides—to reduce risks and errors. With its automated inventory management system, Imbanaco Medical Centre continues to assure a high-level of patient care and compliance with the patient rights of medication administration.



By José Luis Sabogal

Traceability as a priority

Imbanaco Medical Centre opened its doors to the community of Cali, Colombia in 1976. This state-of-the-art hospital has 380 beds and provides healthcare services for approximately 1.5 million patients per year. In 2016, Imbanaco Medical Centre received the "Safest National Hospital Award" for the fourth year in a row and was recognised as one of the 13 best hospitals in Latin America, according to rankings published in the América Economía magazine. One of its primary goals is to continually evaluate and adopt technologies and innovative practices to ensure a high-level of care for its patients.

Based on its Patient Safety Program, Imbanaco Medical Centre prioritises "patient safety" throughout its operations in compliance with the eight rights of medication administration: the right patient, medication, dose, route, time, documentation, reason and patient response. "Using GS1 standards has enabled us to transform our processes throughout the hospital with patient safety in mind," says José Luis Sabogal, Manager of Systems and Telecommunications. From dispensing and administering medications to patients to performing medical examinations and surgical procedures, the unique identification of single-dose medicines, medical devices, supplies and surgical instruments helps Imbanaco Medical Centre manage all aspects of patient care.

If not source-marked by its suppliers, Imbanaco Medical Centre assigns a GS1 Global Trade Item Number® (GTIN®), along with a serial number, batch/lot and expiry information for each singledosage of medicine and each medical device received into the central warehouse. The GTIN and other information is encoded in a GS1 DataMatrix barcode and applied to each.

"With this identification system in place, we can track products as they are used throughout the hospital and with patients as well as trace their origins back to each supplier," advises Sabogal. "Some of our suppliers today are identifying their products with GS1 barcodes, and for products without barcodes, we re-label these products using GS1 standards to fulfil our commitment to patient safety."

Automated inventory management

Once drugs, devices and supplies have been individually identified with GS1 DataMatrix barcodes, they are stored in one of two automated carousels or a fixed storage structure—assets that are also individually identified with standards—specifically Global Individual Asset Identifiers (GIAIs) encoded in GS1-128 barcodes.

The central warehouse schedules dispatches of products to Imbanaco's Pharmaceutical Central Service, pharmaceutical services satellites and other venues throughout the hospital. As medicines and medical devices are requested by different services within the hospital, the central warehouse and pharmaceutical service sites can easily locate and dispense these products to multiple dispensing sites for immediate access.

"As medicines, devices and supplies are distributed and administered or used by patients, their barcodes are scanned at each point of service to track their locations and progress throughout the care process," explains Sabogal. "This information is automatically integrated into our hospital's information system so that we have near real-time information and visibility into inventory levels."

The replenishment of inventory is automatically performed as inventories reach pre-determined levels. "Based on our business process management platform, data analytics and business rules, we have automated the monitoring and management of our inventory so that patient care is not compromised," advises Sabogal.



By using GS1 standards to identify a medication linked to a patient's electronic health records, it is possible to validate the five patient rights at the time medication is dispensed.

"Our goal is to make inventory always available to minimise or even eliminate delays in caring for patients. Requests for additional products are generated automatically and, if necessary, generate purchase orders for suppliers."

Based on its automated inventory and ordering system, Imbanaco Medical Centre estimates a 25 percent reduction in inventory levels at its satellite pharmacies along with a 98 percent improvement in inventory shrinkage/waste.

Patient records and sterilisation

At the same time that product information is recorded in the inventory system, it is also recorded in patients' electronic health records and in Imbanaco's billing system for invoicing. When admitted to the Imbanaco Medical Centre, each patient is presented with an identification wristband with his or her own National Identification Number.

At this moment, Imbanaco Medical Centre is in the process of migrating to the GS1 DataMatrix barcode, which allows us to identify the patient during hospitalisation and gives us instant access to the record of prescription drugs administrated to the patient, the procedures performed, and upon discharge, compiles all charges for billing purposes."

José Luis Sabogal, Manager of Systems and Telecommunications, Imbanaco Medical Centre

"During hospitalisation, the patient's identification in the DataMatrix barcode allows us to instantly access the record of prescription drugs administered to the patient, the procedures performed and, upon discharge, compile all charges for billing purposes," says Sabogal.

Imbanaco Medical Centre advises that medication errors have virtually been reduced significantly. It is also efficiently capturing all relevant costs associated with care for improved billing and accounts receivable.



By scanning the GS1 DataMatrix barcode, a medication can be dispensed and tracked throughout the hospital to the point of administration to the patient.

Imbanaco Medical Centre advises that the time needed to create an invoice for each patient has been reduced by 35 minutes to 18 minutes, improving cash flow by 55 percent. It is also efficiently capturing all relevant costs associated with care for improved billing and accounts receivable.

"By automating our processes, our caregivers can now spend more time with patients," says Sabogal.

At its sterilisation centre, Imbanaco Medical Centre has optimised the flow of sterile processing of surgical instruments and nonimplantable materials in order to maintain the highest standards of infection control.

"To achieve this, traceability is essential in the complex framework of a sterilisation centre," explains Sabogal. "Previously, we tried to track each instrument manually, which was labour intensive and not very effective. Now, we have an automated traceability system based on the efficient use of information provided by GS1 standards encoded in GS1 DataMatrix barcode on each instrument."

It is now possible for Imbanaco Medical Centre to efficiently and accurately locate each instrument in its traceability system—know which day it was used, who used it, what class of procedure was performed, and on what patient. And because each instrument is uniquely identified, Imbanaco Medical Centre can follow-up on the quality of materials and number of times used compared to the standards set by the manufacturer.

Moving forward

Imbanaco is currently working with GS1 Colombia to collaborate with pharmaceutical and medical device manufacturers and other suppliers to use GS1 standards in the identification of their products prior to shipment. "As more and more of our suppliers use GS1 standards, we will be able to save time, costs and gain efficiencies in our operations," explains Sabogal.

Another current work effort is to enable entering standardised patient identification in support of patient transfer processes, with a GS1 identifier called a Global Service Relation Number (GSRN) encoded in a GS1 DataMatrix barcode, that would help with the electronic exchange of clinical history records and the receiving of patients outside of Colombia.

"We plan to find more ways to use GS1 standards that have a positive impact on our operations, our caregivers and, of course, our patients," concludes Sabogal. "We will continue to move forward, making cultural and process changes within our health system that guarantee success."



Each medical instrument is identified with a GS1 DataMatrix barcode for traceability through the sterilisation process.

About the Author



José Luis Sabogal is the Manager of Systems and Telecommunications at Imbanaco Medical Centre and has held this position for more than 25 years. He has actively promoted technological innovation that started with the development of the homegrown version of the SIAM ERP that today has enabled Imbanaco

Medical Centre to be a key leader in the implementation of cutting-edge medical technologies in the region. His vision of the future has positioned him as a leader of committees such as the GS1 Advisory Board. Imbanaco Medical Centre takes patient care and safety to the next level with traceability - Colombia

About Imbanaco Medical Centre

Ranked among the top hospitals in Latin America, Imbanaco Medical Centre continuously strives to provide top-rate care for its patients as well as facilitating medical research. With 380 beds, this advanced hospital in Cali, Colombia provides healthcare services for approximately 1.5 million patients each year.

www.imbanaco.com

Imbanaco Medical Centre Statistical Information

55%

Creating a patient invoice has been reduced by 35 minutes to 18 minutes, improving cash flow by 55%.



A 98% improvement in inventory shrinkage/waste has been achieved based on automated ordering.



25% &

A 25% reduction in inventory levels at its satellite pharmacies has been achieved based on automated inventory management.



Order picking productivity in the satellite pharmacy has increased significantly.



Healthcare provider implementation

State-of-the-art hospital relies on GS1 standards for highly efficient and safe ways to work and care for patients

Constructing one of the largest hospitals in northern Europe has required a new approach to support process improvements and traceability. State-of-the-art technology has been a requirement for this transformation that has been more than ten years in the making. But how should a hospital plan for technology that might not have been invented yet? Following are the methods facilitated by Aarhus University Hospital and Central Denmark Region to create a foundation of global GS1 standards for innovation and technology adaption in a modern hospital. With standards in place, including EPCIS, the hospital can now easily locate the people and assets it needs to provide patients with timely and safe care.

By Henrik Stilling



Merging for modern care

Aarhus is the largest city in one of the five regions in Denmark named the Central Denmark Region, which provides healthcare for 1.2 million citizens. Aarhus University Hospital is the main hospital in the Region, providing services to patients in need of special treatments that require the highest level of expertise like heart transplants and advanced neurosurgery.

Originally, Aarhus University Hospital consisted of five hospitals. The process to merge the five hospitals into one organisation started in 2002 as part of the transformation of the entire Danish healthcare sector.

Looking back, small, local hospitals were quite common in Denmark at the turn of the century. In 2005, national and local governments decided that a structural change was needed to improve quality in healthcare services. The vision: to create fewer, more efficient hospitals with a greater level of expertise in each hospital. Another purpose was to mitigate the increasing cost of healthcare technology (and healthcare in general) due to demographic developments caused by increased life expectancy.

As a result, the governance structure of healthcare changed from small counties to larger regions in 2007. Today, each Region's government is responsible for its healthcare system and the quality of care.

To achieve the full effect of the merger, it was decided to expand Skejby Hospital to accommodate all activities from the original hospitals. Aarhus University Hospital thus became the largest hospital complex in Denmark, covering nearly 500,000 squre metres, with 10,000 employees treating about one million patients each year.

Creating the future, today

The actual building of the hospital broke ground in 2009 with planned completion in no less than eight years. Since Aarhus University Hospital aimed to be a leading hospital in research, education and innovation, this posed a great challenge when it came to implementing the latest in technology. Aarhus University Hospital realised early on that it had to be able to use new concepts, developed years in advance of the actual construction, to be incorporated into the physical structure of the buildings.

"One design requirement says a concept has to be outlined four years prior to implementation," advises Henrik Stilling, IT Architect with Central Demark Region. "However, this does not match the requirement for state-of-the-art technology. For example, when construction began, examples of the latest technology included the Apple iPod, mp3 digital audio players and mobile phones with keyboards. This was two years prior to the release of the first Apple iPad."

Great fluctuations in available devices were to be expected during the construction period. Focusing on current technology or trying to foresee what kind of technology would be available in 8 to 10 years was not a viable solution.

Making the business case

Early in the design phase, Aarhus University Hospital decided to increase the use of information technology and aim for the introduction of automation in new and existing processes. A project was initiated to gain experience from other industries and identify focus areas for investments. Secondly, a baseline was needed in order to turn the anticipated benefits into a valid business case.

One key strategy for the new hospital was the just-in-time delivery of goods. The goal was to decrease the amount of inventory in stock and to minimise storage requirements throughout the hospital. Other key concepts were to attain a high level of accountability and traceability to ensure high quality, efficiency and patient safety."

Henrik Stilling, Information Technology Architect, Central Denmark Region

While a hospital can be a very specialised business, much of a hospital's operations are similar to any business in any industry. Building and running a large hospital requires a focus on supply chain efficiency and a just-in-time delivery model. Analysis of the just-in-time delivery concept showed a general mistrust among staff that goods would truly be available on time—an issue that the science of logistics management addresses. Creating transparency in the supply chain allowing access to information on goods in transit and showing the whereabouts of goods reassures staff that supplies will be ready on time. This mitigates the mistrust.

Furthermore, the transportation industry has started to prove that global supply lines could be just as cost effective as local supply methods. Efficient delivery of goods had also shown to coexist well with traceability.

Research into potential focus areas produced different results. Some of the significant outcomes included:

- Every person in patient wards, surgery and outpatient clinics were, on average, using at least 12 minutes a day searching for items or personnel.
- The time needed to order new hospital beds and clean beds in patient wards put a heavy load on both nurses and service personnel.
- Several transports were made without goods due to a tight split between responsibilities and organisation of service personnel.
- Much of the medical technical equipment appeared to have a very low utilisation rate.

The baseline indicated that time spent "searching" as well as "registering where items were used" took an unnecessarily high toll on staff when compared to similar use cases from the logistics industry or in production scenarios with the same requirements for traceability as a hospital.

To turn the findings into future systems, obvious gaps had to be bridged, to include:

- A shared digital model describing the locations in the hospital was needed; at minimum, identities for locations would be shared.
- Events in the supply chain had to be shared between systems that were not necessarily compatible.
- A common dataset identifying items and actors needed to be introduced.





Information is available both on mobile devices and on overview touch screens.

Laying the foundation

The solution introduced a method to integrate systems that would automatically register the location and identity of a mobile object at a known time—in other words, the "what", "where" and "when."

The foundation for the method included a number of elements:

- The hospital layout was a given.
- The supply strategy would need to be designed along with the infrastructure.
- Objects like medicines, sterile goods, single-use items and reusable items would change rapidly. New objects should be easily introduced in numerous systems.
- Overview of staff and supplies would need to be made available as well as information on inventory.
- Autonomous vehicles and robots would be able to play a vital part in the daily production of the hospital.
- Major changes in the business model were expected, but only gradually introduced in its business processes.

Forty-four use cases with potential efficiency gains were identified and analysed such as automated locating and standardised object identification. Use cases helped to create a reference architecture for locating and identifying objects. $^{\scriptscriptstyle \rm 1}$

GS1 standards were found to be the best fit for many of the requirements of the reference architecture: GS1 identification keys like the Global Location Number (GLN) to identify locations and the Global Trade Item Number[®] (GTIN[®]), Global Individual Asset Identifier (GIAI) and Global Returnable Asset Identifier (GRAI) to identify objects were used along with EPCIS for sharing data about the physical movement and status of objects and products as they travel throughout the hospital and supply chain.

The relationship between objects and their locations could have been handled within dedicated business applications. However, this approach was not economically acceptable. Building a new system to register the location of an object based on each specific business need would be costly. The hospital struggled with different location models in different applications. It was also not technically possible to introduce numerous wireless tracking technologies sideby-side without creating electronic interference that could jeopardise the functionality of medical technical devices and, therefore, patient safety.

Hospital Services was selected to test the feasibility of all these concepts. The applications included patient transportation, trolley delivery, bed management, service task management (in general), a search application and methods to support patients in finding their way around the hospital. At this time, all applications were being put into full production.

A location database containing all relevant locations was also needed: Locations with a broad number of functions like bed locations, patient rooms, nurse call locations, patient reception areas and the placement of hardware needed to create real-time location data.

Streamlining processes and care

Today, each location in the hospital is identified by a GLN. A minimum level of usage is the exchange of GLN information between systems, yet a high level of metadata and location context information is available for systems. On top of the location database, a wayfinding system adds

¹ Read more about the development of the Danish Reference Architecture in the case study, "Reference Architecture enables locating objects for Danish hospitals," page 74.

routes, making it possible to be guided to a location based on its identifier. Wayfinding guides are made available to patients before their arrival at the hospital to ensure a positive experience.

EPCIS in combination with the Core Business Vocabulary (CBV) has enabled the creation of an event-based infrastructure. An EPCIS integration system has been implemented where event data is made available to multiple actors, at the same time. Business applications subscribe to events through EPCIS query interfaces and handle the supplied information to cover the needs of the individual processes supported by the applications.

Multiple locating technologies are also being used. These technologies supply tracking information through an EPCIS-capture interface in the integration system. Wi-Fi is used for devices like smartphones and computers while EPC-enabled RFID is applied for more accurate, low-cost tracking applications.

A hospital-wide EPC/RFID infrastructure with more than 1,800 gates has been placed in doorways of both existing and new buildings. This investment has reduced the cost of adding traceability to an object since EPC/RFID tags can be very cost-effective and durable. More than 20 different types of tags are in use with plans to tag more than 250,000 objects over the next two years.

Currently, the focus is locating sterile goods trolleys, trolleys in general, medical technical devices, beds and staff with more than 20,000 tagged objects in use. Locating staff is accomplished using strict terms of privacy with only a person's current position made available. The EPCIS-capture interface allows for new technologies like Bluetooth[®] beacons or ultrasound exciters to be added seamlessly.

All captured data is filtered and delivered to business intelligence applications in order to monitor a single application and be aggregated into overall production data for more in-depth reports.

Mobility is made possible by publishing standardised services. Multiple applications interact with the same set of data in multiple locations simultaneously.



More than 20 different types of tags are in use with plans to tag more than 250,000 objects over the next two years.



Currently, the focus is locating sterile goods trolleys, trolleys in general, medical technical devices, beds and staff with more than 20,000 tagged objects in use.

Significant gains in productivity and efficiency

Aarhus University Hospital has realised multiple benefits from its GS1 standards-based solutions and systems, to include:

- Quality assurance: By aggregating items with relevant data of applied maintenance and service, staff members can ensure equipment is "fit" for use and can easily manage maintenance schedules.
- ✓ Search time reduction: As much as 50 percent of the time used to search for personnel and items can be cut; on average five to six minutes per employee per day.
- ✓ Usage and capacity management: The potential for sharing equipment between units can be identified. Due to better utilisation, the number of beds is expected to be cut by at least 200.
- Transit time: The time used moving from point of origin to destination is automatically calculated with optimal transport routes and risk of congestion identified.
- Nearest employee handles task: Unproductive time is reduced when the nearest qualified employee handles a task. Time saved often exceeds 10 minutes per task.



Looking ahead

Aarhus University Hospital's decision to select GS1 standards prior to technology has enhanced the agility of the solution. "Multiple vendors have been able to provide or subscribe to data from the EPCIS platform with little or no help from Systematic, the supplier of the platform," advises Stilling.

The hospital's next priority is to expand beyond the domain of logistics by establishing the location database with GLNs as an interconnected master data system, providing location information to all lines of business within the Central Denmark Region.

An additional priority is the use of GS1 standards to support the information lifecycle for goods consumed in all hospitals in Central Denmark Region, creating a standardised information flow throughout the entire supply chain.

Finally, standardised data made available to systems on all levels has shown to support innovation and coherence. A practical next step is to make location data and relevant business events available outside Aarhus University Hospital—initially to actors within the healthcare domain and secondly for public use.

"GS1 standards is the basis for new use of existing information, and data will therefore be published through the Global Data Synchronisation Network[™] (GDSN®) to ensure general availability," concludes Stilling.



Staff using the overview of people and items in OR recovery.

About the Author



Henrik Stilling is the Information Technology (IT) Architect with Central Denmark Region. He is the Lead Architect for item identification and tracking. An engineer by trade, Henrik specialises in IT design focused on process management and technology adaption. He has worked in the healthcare industry since 2008.

Henrik is assigned to the Service Logistics Programme at Aarhus University Hospital and is part of the Danish national initiative on identification and traceability in healthcare.

About Aarhus University Hospital

Aarhus University Hospital is a fusion of Aarhus Municipal Hospital, Aarhus County Hospital, Skejby Hospital, Marselisborg Hospital and Risskov Psychiatric Hospital. It is built as an extension af Skejby Hospital to a size of approximately 500,000 square metres and includes the new Danish Centre for Particle Therapy. The hospital consists of 10,000 employees, 1,000 students, has 100,000 admissions per year, 850,000 outpatients per year and up to 35,000 daily transportations.

http://www.dnu.rm.dk

Healthcare provider implementation

Investing in GS1 standards helps control costs and drive highly efficient OT procedures

On 1 October 2015, the revised version of the German Ordinance on the Dispensing of Medical Devices (MPAV) came into force. One of its major requirements specifies that healthcare institutions enhance patient safety when it comes to medical devices. In the event of a product recall, a healthcare provider should be able to identify within three days all affected patients based on the model, batch or serial number of the implant as well as the manufacturer and its responsible facility. To this end, the Agaplesion Frankfurter Diakonie hospitals are implementing barcode-scanning systems based on GS1 standards to manage their clinical and administrative processes. This will allow seamless case-specific documentation, transparent cost control and the ability to quickly trace medical devices, representing a significant step forward in improving patient safety.

By Kai Piesche



From paper to barcodes

The driver of the revised version of the MPAV is noteworthy since many operating theatres' documentation procedures are still performed manually. Implants and other medical devices, complete with batch and serial numbers, are recorded in handwriting, which frequently leads to transcription errors, is extremely timeconsuming and, in an emergency situation, can even endanger patients.

Furthermore, the lack of information and communications technology, standardisation in identifying items and master data management can prove to be huge obstacles when it comes to quickly identifying patients and products in the event of a recall. For Agaplesion Frankfurter Diakonie hospitals, one of the most significant challenges centred on the management of master data. The first task of the project was to ensure that all products carried GS1 Global Trade Item Numbers (GTINs) encoded in barcodes.

We chose GS1 standards because they are most widely used to identify medical devices and they gather all information documentation required. Apart from that, we expect that GS1 standards will prevail."

Kai Piesche, Deputy Head of Purchasing, Agaplesion Central Purchasing Department, Agaplesion Frankfurter Diakonie Hospitals



At the same time, suppliers were contacted to gather the required data about each of their products and enter this information into the ORBIS system database. "When it came to choosing hardware and software, we went with the ORBIS system from Agfa HealthCare," explains Piesche. "Barcodes are scanned using code readers, or CRIDs, which communicate with the materials management system via an interface."

Taking an integrated approach

To maximise patient safety and improve efficiency, the Agaplesion Frankfurter Diakonie hospitals now rely on high-quality master data, and especially on taking an integrated approach to control and monitor hospital processes.

"We have achieved interoperability and many more benefits by scanning barcodes based on GS1 standards," says Piesche. "As a result, it's now possible to use the networked CRID modules to access the latest product data digitally stored in the materials management system. Equally important, we can also receive complete, casespecific records of every operation and cardiac catheterisation that enable traceability and transparency for cost control and as part of the patient's electronic medical record. In addition to enhanced patient safety, our hospitals are using this opportunity to increase the efficiency of their processes through the use of GS1 standards."

Here's how the new process works: The first step involves scanning every product's barcode during the order picking process at the Agaplesion Logistics Centre. When medical devices are used during an operation, the GTINs encoded in barcodes on the packages are scanned and read, again using a CRID. Then, the stored data is translated and transferred to the ORBIS system. This process not only applies to implants; the same steps are followed for all materials used, such as surgical trays, medicines and sutures. All information is recorded in patients' electronic medical records in the hospital's IT system in real time.

Thanks to the scanning process based on GS1 standards, we have put in place unambiguous, case-specific cost control for every operation and at all times."

Kai Piesche, Deputy Head of Purchasing, Agaplesion Central Purchasing Department, Agaplesion Frankfurter Diakonie Hospitals

"It's extremely important for us to be able to identify all the medical devices used within three working days as specified in the MPAV, without having to spend extra time doing so," says Piesche. "By using the barcode scanning process, we also have a real-time, case-specific overview of all materials used for each operation and clear cost control."

Worthwhile investment

By recording the information using CRID and avoiding transcription errors, the itemised list that's generated is always correct and complete. This is highly beneficial when executing the reimbursement process with health insurance companies.

"As part of the hospital's cost control measures, all materials used in each operation are determined on a case-by-case basis," advises Piesche. "With an accurate, final cost analysis for each treatment, this helps increase the hospital's revenue and, at the same time, the patient's safety. If there is an implant to be substituted because of a producer's recall, we know in a few minutes which patient must be contacted due to the MPAV. The initial capital investment of around €20,000 for hardware and software has already been recouped in the first six months of using the barcode scanning solution."



Hospitals can now scan to read each GS1 DataMatrix barcode, helping to ensure that the right medicine is being dispensed to the right patient.

About the Author



Kai Piesche is the Deputy Head of Purchasing, Agaplesion Central Purchasing Department for Agaplesion Frankfurter Diakonie hospitals. He is qualified as a nurse, anaesthetist and critical care nurse with 15 years experience working in management positions in the intensive care field with a focus

on heart surgery. Kai has also completed a degree in Health and Social Economics. About 13 years ago, he moved into hospital purchasing and since then, has worked as the Deputy Purchasing Manager at Agaplesion, responsible for strategic purchasing of medical equipment. Since September 2015, Kai has been the authorised signatory for the Agaplesion Logistics Centre responsible for developing and implementing an integrated logistics and procurement concept for all Agaplesion facilities. The implementation is planned for completion by mid 2018.

About Agaplesion Frankfurter Diakonie Kliniken GmbH

Agaplesion Frankfurter Diakonie Kliniken (FDK) is the non-profit umbrella organisation of the Agaplesion Markus Krankenhaus in Frankfurt-Ginnheim and Agaplesion Bethanien Krankenhaus in Frankfurt-Bornheim. FDK is a subsidiary of the non-profit Agaplesion gemeinnützige AG, which has over 100 healthcare-related facilities nationwide. As a Christian healthcare organisation, Agaplesion aims to provide advanced medicine and excellent standards of care coupled with Christian values. The two hospitals have a combined capacity of approximately 900 beds. With them plus the close ties to the Agaplesion Logistics Centre in nearby Obertshausen and four retirement homes, the organisation offers a wealth of expertise in the fields of medical and nursing care to the residents of the Rhine-Main area—at every stage of life.

www.agaplesion.de



Reliable medication processes for enhanced patient safety

Today's hospitals face ever-growing performance, competitive and cost pressures. As a result, innovation in healthcare processes is playing an increasingly important role when it comes to patient safety and satisfaction. To consolidate and automate their processes for more effective patient treatments and care, the hospitals of medius KLINIKEN use solutions provided by Agfa HealthCare based on globally recognised GS1 standards. The medius KLINIK Nürtingen has improved patient safety practices with help from a new approach of barcode-based medication workflow. The medication administration process is now more transparent than ever before. In addition, medication preparation and dispensing processes can be carried out far more efficiently while minimising the error rate.

M medius KLINIK NÜRTINGEN

By Gertrud Türk-Ihli

Major key for success

Digital transformation: Businesses in all industries are investing more and more in new technologies and solutions to automate and enhance their processes. Regarding digital trends in healthcare, the Wirtschaftsindex DIGITAL (Digital Economy Index) study ¹ conducted by TNS Infratest on behalf of the German Federal Ministry for Economic Affairs and Energy concluded that the healthcare industry is currently "well below average" in terms of its level of digitisation. Yet according to the survey report, Digitisation in the healthcare market, ² by the Deutsche Apothekerund Ärztebank, digital developments will be a key driver of structural change in the market and an increasingly important factor in being able to successfully compete in the future.

Treatment quality is a priority

The need for digitised solutions in the healthcare industry is becoming ever more apparent. There is a pressing demand for practical approaches and solutions that can be efficiently and flexibly implemented. medius KLINIKEN recognised this challenge as a group and reacted accordingly. Based in the district of Esslingen, medius KLINIKEN gGmbH is a hospital group with three hospitals, 1,073 beds and a staff of 2,600. Since 2001, the group has worked closely with IT experts from Agfa HealthCare to implement and use ORBIS in its hospitals as both a hospital information system (HIS) and as a medical and clinical documentation and process management system, including ERP. The system covers all departments and allows hospital processes to be efficiently managed.

Establishing a high-quality treatment workflow by digitising processes is of the utmost importance for the hospital group. However, achieving this goal is not just about implementing powerful technologies and systems, the processes should also be perfectly integrated and flow seamlessly from one to the other.

¹ https://www.tns-infratest.com/presse/pdf/presse/2016-10-20-zentrale-ergebnisse-monitoring-report-wirtschaftdigital-2016.pdf

² http://360grad.apobank.de/studie-analyse/

To this end, medius KLINIK Nürtingen wanted to implement a closed-loop medication management system—from computer-controlled prescription and validation by the pharmacist to dispensing and administration at the patient's bedside—with the least amount of resources while maximising efficiency. To optimise all workflows, the hospital decided to use GS1 standards. GS1 standards, specifically identification codes, can be encoded in barcodes that can then be applied to products' packages. When the barcode is scanned, all key information about that specific product is provided to the user and can be efficiently managed. Barcode scanning significantly increases convenience and ergonomics when it comes to monitoring medication processes, making them more transparent and standardising workflow throughout the organisation, as well as subsequently documenting them.

"The GS1 Global Trade Item Number® or GTIN® has been a familiar sight in both the clinical and materials management fields for several years now," says Gertrud Türk-Ihli of the medius KLINIKEN Information and Medical Technology Department. "The Global Service Relation Number (GSRN) seemed to be the most appropriate choice for uniquely identifying patients and employees, because it guarantees a unique and nonoverlapping allocation of patient-related services."

Barcode-based medication at the patient's bedside

When combined with the Service Relation Instance Number (SRIN), the GSRN can be used to unambiguously identify the individual dose and medication dispenser (e.g., the patient's tablet box), for a specific daily medication. This workflow that relies on GS1 standards has been in place at medius KLINIK Nürtingen since mid 2016.

Dispensers are prepared for the next day's administration of medications by the responsible hospital staff. The new GS1 standards-based system makes the medication allocation process significantly more efficient, especially since differentiating between medications is becoming increasingly difficult these days. "It was once possible to identify tablets based on their characteristic colours and shapes," explains Türk-Ihli. "Now, it is almost impossible to distinguish between the array of medications that share the exact same colour and form. GS1 standards and the performance of automatic comparisons help reduce possible errors in this area." At medius KLINIK Nürtingen, labels are applied to the dispensers that carry the GSRN and SRIN encoded in a GS1 DataMatrix barcode. When the dispenser is scanned, a medication overview for the patient and the specified date is displayed. At a glance, this shows what the patient has been prescribed and what dose of which medicine should be administered. The nurse then scans the pharmaceutical registration number (PZN) on the medication package. An automatic check is performed to ensure the medication and prescription correspond with or "match" each other.

The dispensers are then loaded. Once complete, the certified nurse scans his or her ID badge to document specifically who dispensed the medication. It is also possible to scan an additional ID badge to record the presence of a supervisor.

"The two-man rule has been a key aspect of our procedures for many years," says Türk-Ihli.

At the same time, our new processes and standards have helped strengthen this practice, enabling us to provide our patients with an extra layer of reliability. This is also in keeping with our commitment to implement the greatest possible safeguards for patients and staff."

Gertrud Türk-Ihli, Information and Medical Technology Department, medius KLINIKEN.

For several years, medius KLINIK Nürtingen has used mobile "thin client trolleys" with a 24" screen, a battery life of over 12 hours, disinfectable keyboards, tablets—basically everything required to meet the needs of a mobile digital hospital routine. The hospital staff can use the trolley to scan the medication dispensers directly at the hospital bedside and perform a final check to see if the prescription has changed.

First, the nurse or caregiver scans the patient's wristband in order to verify the patient's identity and then scans his or her ID badge to document who issued the dispenser. By using a GS1 standards-based barcode, medius KLINIK Nürtingen is able to standardise and optimise its associated processes. "It was possible to integrate the existing system for identifying staff and patients without problem," comments Türk-Ihli.



"The scanner support integrated into the ORBIS system permits an active interpretation of different codes via GS1 support. Moreover, the use of standards is essential for unambiguously allocating materials, medicines, patients and services."

Close cooperation fuels project success

The administration, staff and patients at the medius KLINIK Nürtingen have been very impressed with the GS1 standards project at their hospital. It takes just one scan to uniquely identify both the patient and the medication.

"We believe this project serves as a role model for other German hospitals," says Türk-Ihli. "The quality of documentation has improved and the efficiency of our processes has increased. It has reduced the incidence of adverse side effects and drug interactions. To a significant extent, the success of the project is due to the outstanding cooperation between the parties involved. Clinical experience, input from Agfa HealthCare as well as the expertise of GS1 Germany—all merged to create a truly successful outcome."

Traceability and real-time authentication

Thanks to GS1 standards, the medius KLINIK Nürtingen has been able to introduce an unambiguous system of identification in its medication process.

What are the hospital's plans for the future? Türk-Ihli advises that current staff and patient barcodes will be transitioned over to use GS1 standards at all hospitals. In addition, with the future availability of medication barcodes with supplementary batch, serial number and expiration date, this data will be used along with patient-related data, too. This will make it possible to perform more than just batch-specific traceability of medication to the patient. The GS1 DataMatrix will simultaneously contribute to making documentation more accurate.

Starting in 2019, nearly all prescription medicines ought to carry a GS1 DataMatrix barcode that will additionally support the authenticity of the medicine to be verified. This is stipulated in the European Union's Falsified Medicines Directive 2011/62/EU. The hospitals of medius KLINIKEN are well prepared for the introduction of the new



Dispenser with the GS1 DataMatrix barcode

regulation with their barcode-based medication workflow.

Individual doses, such as infusion solutions, drops and injections, are all labelled with the GSRN according to the five patient's rights, which are displayed on the label. Anyone who wants to be successful and stay ahead of the competition in today's world has to exploit the technical possibilities that are available. Agfa HealthCare and GS1 Germany are supporting us in doing just that."

Gertrud Türk-Ihli, Information and Medical Technology Department, medius KLINIKEN

Outstanding cooperation

In recognition of their exemplary project for the well-being of patients, medius KLINIKEN and Agfa HealthCare received the GS1 Healthcare Award 2016 in the category of "business cooperation." The award recognises successful partnerships and honours achievements that lead to greater patient safety and more efficient processes in the healthcare industry, thanks to close cooperation between medical service providers and the industry.

About the Author



Gertrud Türk-Ihli is with the medius KLINIKEN Information and Medical Technology Department. She is a qualified nurse, studied nursing management and graduated as a healthcare manager. Gertrud worked in the Information and Medical Technology Division, clinical IT systems, Module Customising

Department of the Kreiskliniken Esslingen gGmbH. She is a member of the German Society for Clinical Process Management.

About medius KLINIKEN

medius KLINIKEN is an affiliation of three hospitals located in Kirchheim, Nürtingen and Ruit that has a combined total of 1,073 beds and 2,600 members of staff, making it one of the largest academic teaching hospitals of the University of Tübingen. In keeping with its slogan, "Vertrauen.Können" ("Trust.Ability"), medius KLINIKEN strives to offer humane, local and competent medical services for the people living in the district of Esslingen. Its goal is to establish hospitals as centres of medical excellence and provide a welcoming environment for patients. The various hospitals are home to powerful medical technology, pleasant accommodations, modern infrastructure and people who offer personal and individual diagnostic services, therapies and nursing care.

www.medius-kliniken.de

About Agfa HealthCare

Agfa HealthCare is one of the leading suppliers of diagnostic imaging and computer-assisted healthcare solutions for use in hospitals and healthcare facilities around the globe. As a major player in the market for diagnostic imaging systems, the company offers analogue and digital technology as well as IT solutions that cater to the requirements of specialist doctors. Agfa HealthCare also ranks among the top suppliers of IT systems to the healthcare industry, with solutions for integrating the administrative, finance-related and clinical workflows of individual hospitals and hospital groups.

agfahealthcare.de



The Germany GS1 Healthcare Award Winner 2016



St. James's Hospital – leading global innovation in healthcare - a hospital wide approach to adopting GS1 standards

St. James's Hospital continues to lead the way by establishing the *Scan for Surgery* programme and the introduction of the automatic tracking of precious tissue samples. Both projects make use of GS1 standards-based technology to deliver improved patient safety and efficiency. These programmes follow on from other globally recognised exemplar projects carried out at the Dublin hospital.



Proven traceability

St. James's Hospital has a proven record in the implementation of national programmes that use track and trace technology to support patient safety in areas such as haemophilia treatment and in sterilisation services for surgical instruments and endoscopes. These solutions have proven that the use of global GS1 standards significantly enhances patient safety, traceability and certainty of product identification for effective and efficient product recall across the healthcare supply chain.

In recent years, St. James's has used modern barcode technology to automate the procurement of medical supplies. The awardwinning e-Procurement project went live in 2014, enabling the electronic communication of four Purchase-to-pay messages between the hospital and its suppliers. The messages use the GS1 Global Trade Item Number® (GTIN®) and Global Location Number (GLN) as common product and location identifiers, enabling the seamless sharing of messages and replacing paper-based systems. By Vincent Callan and John Cotter

Building a digital hospital

In 2015, the hospital introduced the automatic tracking of laboratory samples from theatre to laboratory using RFID (Radio Frequency Identification). All samples are tagged in theatre, and both the sample and porter are automatically tracked through the hospital to the laboratory. If the sample doesn't arrive within a specified time, an alert is sent and, if necessary, timely and corrective action is taken.

Prior to this, the tracking of samples was completely paper-based and prone to error with no visibility or assurances that the samples were delivered on time. This represented a significant risk to the hospital and to patients, which has now been addressed through this initiative.

This is a worldwide first, proving the use of passive RFID for the automatic tracking of precious samples. The GS1 identifier that uniquely identifies a member of St. James's staff—the Global Service Relation Number (GSRN)—and the identifier for a logistics unit the Serial Shipping Container Code (SSCC)—are the GS1 keys used in this project. St. James's Hospital – leading global innovation in healthcare - a hospital wide approach to adopting GS1 standards - Ireland



SJH Scan for Surgery Steering Group from L to R: Vincent Callan, Director of Facilities; Niall Hogan, Orthopaedic Consultant; Jeanne Moriarty, Clinical Director; John Cotter, Programme Director ABF (Activity Based Funding); Una Geary, Director of Quality and Safety Improvement; Neil O'Hare, Director of Informatics; Greg Magrane, Project Manager Not pictured: Simon Moores, Director of Finance; Fiona Murphy, ADON DSC/Theatre Services.

The project has since been expanded to track valuable art received by the hospital through donations. This was used to prove the application for asset tracking. The hospital has also recently gone live with the automatic tracking of vulnerable patients within the hospital which proves the patient safety benefits. Further applications are currently being planned to scale the appropriate use of automatic tracking across the hospital. The recent installation of two robotic dispensing systems in pharmacy is further testament to the hospital's innovative approach.

Scan for Surgery – a new era for patient-level data

St. James's Hospital established a *Scan for Surgery* steering group in 2016 to work on achieving better visibility of activities at the point-of-care, for both patient safety and efficiency improvements.

The hospital specifically looked at barcode scanning in the theatre, introducing technology to scan products and patients, which would:

- Improve traceability which improves patient safety.
- Improve procedure cost analytics.
- Automate re-ordering, thus freeing up time for clinical staff who had traditionally been involved in the manual procurement process.
- Improve inventory management.

89%

The hospital can now track over 89% of costs direct to the patient in theatre and estimates a significant reduction in the time spent to order products.

A significant level of stakeholder engagement was undertaken across various disciplines to ensure scanning at the point-of-care was adopted by users. The project started with the use of GS1 Scanning App to link the barcode on the product packaging to the SAP master data, proving that nearly 80 percent of the medical devices used in theatre had a GS1 barcode.

Until now we had very little visibility on patient costs behind the red line in theatre. In most cases, there was no electronic record of what products were used on which patients. That has all changed now. Combining the data from *Scan for Surgery* with existing business intelligence tools, we can now see very detailed cost analytics at a procedure level, and we can easily trace products to patients in the event of a recall."

John Cotter, Programme Director, Activity Based Funding, St. James's Hospital

Patient information 2015



Patient information 2017 Scan for Surgery



No Patient Information (11%)



The Scan for Surgery programme was introduced initially in two theatres. The GHX PowerGate point-of-care scanning system was used by the nursing staff to scan all products used during each procedure. Adoption was supported by the fact that nurses were already scanning instrument trays and blood products and they were automatically tracking lab samples in theatre using RFID technology. Therefore, nursing staff were behind the project from the beginning and the team worked collaboratively to achieve the outstanding results. Over the next few months, St. James's plans to introduce Scan for Surgery in all theatres and critical care areas of the hospital.

Better Data, Better Decisions

Pharmaceutical and medical device suppliers are being required by regulation to barcode products by 2019 and 2020, respectively, which will support traceability at the patient-level. The UK Department of Health is mandating that all Trusts and Suppliers implement GS1 standards, which is having a positive effect on the Irish market. Also, the importance of GS1 standards adoption is recognised at a national level by the Health Service Executive (HSE). Since 2016, the HSE has been requesting GS1 information on national tenders.

This holistic approach for a hospitalwide implementation of GS1 standards with a view to increasing patient safety and operational efficiency, is a key strategic objective for St. James's Hospital. The imminent legislation for suppliers provides significant opportunity for wide scale change and benefits for Irish healthcare."

Vincent Callan, Director of Facilities Management, St. James's Hospital St. James's Hospital – leading global innovation in healthcare - a hospital wide approach to adopting GS1 standards - Ireland

St. James's Hospital is the first Irish hospital to achieve this level of patient data capture at the point-of-care, which supports patient level costing. The hospital has an ambitious timeline for the remainder of 2017 and 2018 to roll out a variety of GS1 standards-based projects. The benefits, in terms of clinical and administrative time saved, are proven.

This new way of working is giving the hospital extremely valuable data. The hospital is using this data along with business intelligence software to deliver real benefits for decision-making in relation to costs, and procurement and to underpin the hospitals commitment to patient safety.

Scan for Surgery: the process

Step 1: Business case

A joint business case was developed to illustrate the benefits, both clinical and non-clinical, that scanning at the point-of-care could yield for St. James's Hospital. The case was approved by the CEO of the hospital and the name *Scan for Surgery* was given to the project.

Step 2: Establish steering group and working group

A key success factor for the project was taking a multi-disciplinary approach that recognised the benefits to be achieved, with buy-in from all departments from the start. Two groups were created for the project, a steering group and working group that focused on strategic and tactical issues and activities. Clinicians were also active members of each team.

Step 3: Getting started - data alignment (Find the GTINs)

Industry standard for uniquely identifying healthcare items at all pack levels		
Individual Package	Multiple Unit Package	Outer Case
Ť		× 24
GTIN A	GTIN B	GTIN C
5391234560008	5391234560015	5391234560022

The starting point focused on building a registry of GTINs (barcode) for the products to be scanned in theatre. Two knowledgeable materials staff were assigned to scan all the barcodes in theatre, using the GS1 Scanning App. The app was designed to capture the barcode on the product's package (at each package level) and link it to the existing master data in SAP.

While this exercise was labour intensive, it was part of the data alignment process needed in preparation for scanning. As product data accumulates, the hospital recognised that the only sustainable way to standardise the receipt of data from suppliers was through a centralised catalogue. St. James's is now requesting GTINs in tender documents and suppliers are being asked to use the National Product Catalogue (NPC) to support a widescale adoption of GTIN information.

Step 4: Implementing the solution

Clinical engagement was vital at this point. The decision was made to implement *Scan for Surgery* in two cardio-thoracic theatres as they had a well-structured storage area for products and they also had procedure packs with one barcode for smaller items, thus avoiding complexity.

The hospital worked with GHX to optimise its point-of-care scanning software for use in theatre. The decision was made to use an existing desktop PC with flow cart and scanner, which worked well within the existing workflow of the theatre.

Step 5: Scanning and clinical workflow

Regarding "who should scan and when," the team decided that the products would be scanned by theatre staff in theatre. Steps in the workflow include:

- The scrub nurse opens the packaging, puts it in a temporary bin and sets out the products and instruments on a sterile tray.
- The surgery staff scans the patient ID label from the patient chart. There are checks carried out prior to this to make sure the chart matches with the patient's wristband.
- During the surgery, the nurse scans in all the packaging. Each time a product is scanned, the nurse can see key information relating to the product on the screen.
- The batch and expiry information are also captured from the barcode to enable recall and stock management.
- At the end of the case, the scrub nurse reviews the items scanned to confirm the case. The case is closed and saved to the patient's record. The SAP system is also updated to manage stock levels for reordering purposes.



Step 6: Business intelligence and data analytics

The data coming from the scanning in theatre is being analysed in a central repository in combination with other information relating to the patient's care. For the first time the data from theatre is real-time, complete, consistent and accurate. This information can be used to support clinical and non-clinical decisions about the patient journey in the hospital.

Proven benefits

Based on experience in the two theatres, St. James's estimates that the time of 5.5 nurses per annum could be reallocated to patient care if *Scan for Surgery* was implemented across



all 11 theatres in the hospital. This would prove invaluable due to the current shortage in nursing staff and pressures on clinical time.

Increased visibility at the point-of-care will also allow stock levels to be more efficiently managed, thus freeing up valuable space in theatre areas.

Scan for Surgery is providing visibility of costs associated with each patient, costs that were previously very difficult to assign.

St. James's can now assign over 89 percent of the costs incurred in theatre to the individual patient, enabling patient-level costing, which is a key national programme for Irish healthcare.

The real-time data from the point-of-care is also allowing real depth of procedure costing. The hospital can measure variability across consultants and is starting to look at clinical variation, an important measure for enhanced patient safety.

One of the key objectives at the start of the project was to enable recall management through the use of product information from the barcode. Scanning in theatre allows this data to be recorded easily and consistently, without manual re-keying to the patient record. This benefits patients and clinicians alike, who traditionally spent time searching through paper records. Soon after the implementation of *Scan for Surgery* in the cardio-thoracic theatre, a surgeon asked Materials Management for the cost of two different products used for the same procedure. Since the information was readily available, the surgeon was able to make the case for the more expensive item, resulting in a win for patient safety, staff time, usage capacity of the theatre and cost efficiency.

Scan for Surgery is the most exciting hospital project to date; it is transformational in nature. The opportunity to have visibility of what is happening at the point-of-care means we can make better decisions, which ultimately benefits patients."

Simon Moores, Director of Finance at St. James's Hospital

About the Authors



Vincent Callan has 20 years healthcare experience and is currently the Director of Facilities Management at St James's Hospital. He is also the Co-Chair of the GS1 Ireland Healthcare User Group (HUG) and Director of the Liberties Business Forum. 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 hospital wide implementation of traceability based on GS1 standards.



John Cotter is a Chartered Accountant and MBA with a background in Deloitte in the area of professional services and finance transformation projects. John moved to the healthcare industry in 2011 and has worked as Finance Director in Ireland's largest Paediatric

Hospital. His current role in St. James Hospital involves the implementation of systems and processes which support Patient Level Costing and decision support in an acute hospital setting.

About St. James's Hospital

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 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.

www.stjames.ie

Healthcare provider implementation



GS1 standards enable an integrated sterilisation management system for University of Fukui Hospital Surgical Centre

Since 2014, the University of Fukui Hospital (Fukui Hospital) had focused on the costeffective management of its surgical operations by using GS1 standards. The hospital has successfully achieved the traceability of surgical instruments in its surgical centre's sterilisation process by identifying each of 20,000 instruments with the GS1 Global Individual Asset Identifier (GIAI), encoded in a laser-engraved GS1 DataMatrix barcode. To date, Fukui Hospital has reduced the error rate along with the time required when assembling instruments for surgical operations by 2,000 hours per year. Fukui Hospital is the first hospital in Japan to use GS1 Global Location Numbers (GLNs) to identify each of its locations. By using GLNs as part of its surgical container setting system, Fukui Hospital has helped reduce overall operation time by 500 hours per year.

By Kazufumi Sato and Shingo Kasamatsu

UNIVERSITY OF FUKUI Faculty of Medical Sciences University Hospital

Aiming to ensure the safe use of instruments

Starting in 1999, the medical device industry began voluntarily marking GS1-128 barcodes on device packages. In 2008, the marking of barcodes had quickly spread after the issuance of the notification by the Ministry of Health, Labour and Welfare (MHLW). Currently, most medical device packages are marked with GS1-128 barcodes. Since then, little progress has been made in using GS1 standards at the unit level when it comes to hospital instruments standards that are needed for traceability.

"We wanted to prevent surgical instruments from being left in a patient's body as well as eliminate any concerns about infections via contaminated surgical instruments, especially triggered by Creutzfeldt-Jakob disease," explains Kazufumi Sato, M.D., Ph.D., and Deputy Director of the Surgical Centre, University of Fukui Hospital.

There had long been calls for safety management of surgical instruments using two-dimensional barcodes. With the aim of ensuring the safe use and traceability of instruments, the Japan Association of Medical Devices Industries (Jamdi) released the *Guideline for Marking for Two Dimensional Symbol on Steel Instruments* in 2006. This guideline defines the need for direct marking and using GS1 standards for symbol engraving, recommending the use of Global Trade Item Numbers (GTINs) plus serial numbers and direct marking with GS1 DataMatrix barcodes.

Outside Japan, the International Medical Device Regulators Forum (IMDRF) and the U.S. Food and Drug Administration (FDA) issued the UDI Guidance: Unique Device Identification of Medical Devices and the UDI Final Rules, respectively, in 2013. Both require the identification of a medical device using the UDI. For surgical instruments, UDI direct marking is expected to improve patient safety and optimise patient care.

Using GS1 standards to mark instruments

Fukui Hospital is located in the Fukui region of Japan with a population of around 400,000. It is the central hospital of the region with 600 beds and approximately 5,000 surgical operations performed annually.

From 2010 to 2014, the hospital was preparing to relocate its wards—the Surgical Centre and the Central Sterilisation Department to a new building. During this period, the hospital introduced the "integrated sterilisation management system," which through unique identification ensures traceability of steel instruments, for enhancing patient safety and the quality of infection control.

"The system enables the linkage of patient IDs, the surgical schedule and surgical instruments information within a hospital information system," says Shingo Kasamatsu, Technical Officer of the Faculty of Medical Science, University of Fukui. "For identification of surgical instruments and sterilisation-related equipment, the hospital decided to adopt GS1 standards."

Although some guidelines were already in place, such as the Practical Guideline for Operative Medicine released by the Japanese Association for Operative Medicine that recommended the use of UDI for identification of surgical instruments, there were few manufacturers that had actually implemented source marking on their products.



The hospital has successfully achieved the traceability of surgical instruments in its surgical centre's sterilisation process by identifying each of 20,000 instruments with the GS1 Global Individual Asset Identifier (GIAI), encoded in a laser-engraved GS1 DataMatrix barcode. Surgical operations require around 20,000 pieces of surgical instruments and marking these instruments must be carried out without affecting the scheduling of surgeries. Due to these factors, it was imperative to conduct direct marking in the hospital for smooth transition to the management of surgical instruments using UDI.

Today, Fukui Hospital has adopted the GS1 DataMatrix barcode as a data carrier for UDI on steel instruments. The hospital obtained the GS1 Company Prefix from GS1 Japan in order to start creating GS1 identification keys. "Because the steel instruments were already in use, we decided to apply the GIAI identification key that is used to mark assets," says Kasamatsu. "We also introduced the GLN to identify the locations of storage and use."

At the beginning of the system, the number of steel instruments marked with GS1 standards totalled approximately 18,000. The hospital spent nearly one year on the direct marking and registration of all instruments in the hospital database.

"Our system has now been in full operation since September 2015 with all 20,000 pieces of steel instruments owned by Surgical Centre identified and marked with GS1 identification keys and barcodes," says Dr. Sato. "Today, our hospital continues to mark about 18,000 pieces of steel instruments for use at outpatient and inpatient wards."

Adopting the GLN and GIAI

The hospital has also adopted GLNs to identify locations. GLNs are assigned to each operating room, every location in the surgical container storage cabinet that accommodates sterilised containers and items, fixed shelves and storage racks at the hospital wards, and more. In total, more than 1,000 of the hospital's locations have GLNs.

The GIAI is used to identify steel instruments that are already in use at the hospital and that were not source marked by manufacturers. The hospital has a laser-marking machine in place, which marks steel instruments with the GS1 DataMatrix barcode. The basic symbol size is 2.5 mm x 2.5 mm, but a rectangle form (1.3 mm x 5.0 mm) is also used depending on the shape of a steel instrument. The GS1 DataMatrix barcode is marked on two places of a steel instrument.



The surgical container storage cabinet (A) and a GLN assigned for a location in the cabinet (B).

For those instruments that have been identified and marked by the manufacturers, Fukui Hospital uses the source-provided GTINs and serial numbers as their asset numbers instead of marking them with GIAIs encoded in DataMatrix barcodes.

"We mark our instruments in two places since, by repeated washing and sterilisation, the surfaces of these instruments are gradually worn away," explains Dr. Sato. "If the marking was done at only one place, there would be a possibility that the code might become 'unscannable.' In this case, it becomes quite difficult to identify the original code. Secondly, it's easy to scan a DataMatrix barcode when two sides are marked and is very useful, especially when time may be limited during a surgery. Finally, two-place marking has been strongly recommended by the guide of Jamdi based on extensive experience for surgical instruments in Japan."

The integrated sterilisation management system

The workflow of the integrated sterilisation management system is illustrated in Figure 1. By using portable digital devices, the system allows Fukui Hospital to manage information during



each step of a surgical operation: the collecting, cleaning, sterilising and storing the surgical instruments along with preparing for operations.

As shown in Figure 1, the GS1 DataMatrix barcode that is directly marked on each steel instrument is read twice—during the collection step after a surgical operation and during assembly.

Detailed steps for reading the GS1 DataMatrix barcode and preparing for surgical operations are as follows:

- Immediately after the completion of a surgical operation, GS1 DataMatrix barcodes on the steel instruments used during the operation are read, counting all of them before the patient leaves the operating room. This ensures that all prepared instruments have been collected.
- After cleaning instruments, skilled staff members conduct a visual check, read the GSI DataMatrix barcodes again and assemble a surgery set. They ensure that all necessary instruments are in place.
- GS1 standards are used for checking at each step of the registration process of containers before sterilisation, sterilising, storage, placement and picking of sterilised containers, too.



- The hospital's surgical container storage cabinet has been developed specifically for storing containers and sets of sterilised items, and is equipped with a touch-panel monitor for displaying stock status. The monitor displays surgical operation-related information from electronic medical records in real time.
- A staff member reads the surgical operation schedule from electronic medical records using a smartphone-type portable device. By scanning a surgery ID and a barcode on a surgery cart, the shelf inside the cabinet automatically rotates and stops at the position where the necessary container is stored, allowing a staff member to pick it up easily.
- The cabinet has approximately 600 storage locations inside. Each location is assigned a GLN for identification, thereby automatically controlling its "stop" position.

Saving significant time

Specific benefits of the new system using GS1 standards include improved medical safety measures by ensuring traceability on individual steel instruments. This includes the prevention of leaving surgical instruments in a patient's body, the prevention of errors in counting, the more precise assembly of surgical sets, and the prevention of loss and unauthorised takeout. "The system enables the hospital to more easily analyse the frequency of use or turnover as well as the status of stock instruments at specified piece and set levels," says Dr. Sato. "This leads to a highly efficient stock management system and a reduction of surplus stock."

Furthermore, the analysis regarding the frequency of use by type of surgical method can help the hospital optimise the number and content of surgical sets.



Figure 1

"Experienced nurse with specilialised knowledge once assembled the steel instruments into containers," adds Kasamatsu. "Now, thanks to the new system, this process can be performed by staff members without these specilialised skills and knowledge. The assembly operation under this system is quick and accurate."

2,000

The hospital estimates the system has also contributed to a reduction of approximately 2,000 hours annually for the overall operation time, including the confirmation of steel instruments after surgery.

In addition, container storage and picking tasks, part of the preparation process for surgical operations, have become automated, paperless processes based on the real-time status of stock of sterilisation containers. Fukui Hospital estimates the time for such work has been reduced by approximately 500 hours annually. The management of steel instruments directly marked with GIAI identifiers and the management of locations using GLNs have saved a total of 2,500 hours annually. This allows nurses to concentrate on other duties, and furthermore, can contribute to a reduction of their overtime work.

For cleaners, driers and sterilisers, Fukui Hospital has a system in place that provides the operation status of each piece of equipment in real time through a monitor. This means that the cleaning and sterilisation history along with the location and utilisation history of instruments can be easily checked, thereby enabling the hospital to swiftly respond to a lack of instruments during surgery and recalls. It is expected that the analysis on instrument turnover in addition to their usage rate would further improve the efficiency of the operations.

Next steps

Fukui Hospital aims to introduce a similar system for all of its medical devices and establish a realtime traceability system. In addition, the hospital will expand the scope of traceability management to single-use medical devices and materials using GTINs that are source-marked on packaging. "We plan to take the necessary measures to ensure higher medical safety, further increase efficiencies and prevent incomplete reimbursements," says Dr. Sato.

The hospital will adopt this kind of traceability scheme to loan instruments, as well. A new system is under development to collect location information of carts in preparation for a surgical operation in real time. Using this system, Fukui Hospital will further improve the existing workflow so that it can confirm the transportation of carts in an operating room and respond to an urgent change of surgery procedure and/or operating room. "We believe that the GTIN, GIAI, GLN and other GS1 identification keys can be widely used for a variety of reasons," concludes Kasamatsu.

About the Authors



Kazufumi Sato, M.D., Ph.D., is the Associate Professor of the Surgical Centre, University of Fukui. In 1980, he graduated from the medical department of Kanazawa University. Since 2003, Dr. Sato has served as Deputy Director for the Surgical Centre, University of Fukui Hospital. He is leading the implementation

of GS1 standards in the Surgical Centre for secure traceability of the sterilisation process and costeffective management.



Shingo Kasamatsu is the Technical Officer of Faculty of Medical Science, University of Fukui. He introduced GS1 standards into the University of Fukui Hospital. He is one of the key people who spread the adoption of GS1 standards in the medical field. His interest in GS1 standards is now expanding to other GS1 keys beyond

the GTIN, GIAI and GLN.

About the University of Fukui Hospital

The University of Fukui Hospital was founded in Yoshida County, Fukui Prefecture in 1983. With 600 beds, the total number of inpatients served in 2015 was 12,551, and 5,245 surgical operations were performed by the Surgical Centre.

www.hosp.u-fukui.ac.jp





Healthcare provider implementation

Antonius Hospital makes safer medication administration a priority

The traceability of medication in the pharmaceutical sector—from production to use by patients—is important to ensure medication safety. This is why GS1 barcodes are increasingly being used at the lowest or single-unit level for medication administration. Antonius Hospital, with locations in Sneek and Emmeloord in the Northern part of the Netherlands, has implemented GS1 standards to enable the registration and administration of medicines to patients. The hospital has found that investing in GS1 standards encoded in GS1 DataMatrix barcodes is worth it for a multitude of reasons.



By Michiel Duyvendak

Preventing errors

Antonius Hospital offers a wide range of services: hospital care, home care, emergency care, care mediation and home services through a hotel arrangement. The hospital works with 3,500 people daily to provide reliable healthcare services to the population of Southwest Friesland, the Noordoostpolder, Urk and the Wadden Islands, Vlieland and Terschelling.

"In August 2011, we began the project called 'Registration of the administration of medication by means of barcodes," says Michiel Duyvendak, Hospital Pharmacist at Antonius Hospital. "The aim was to prevent registration errors as much as possible. Safe medication and patient safety are our key concerns."

According to an analysis of data maintained by the Netherland's national register of medication incidents (maintained by the KNMP/NVZA), more than 30 percent of medical incidents are related to errors in administering medication.

"Research has shown that serious administration errors can be prevented by as much as 50 percent by using barcode verification during administration," Duyvendak says.

Investing in change

In 2011, Antonius Hospital transitioned from a paper-based environment to one that is paperless. "This was a great opportunity for implementing our medication administration project," says Duyvendak. "Our motto is: 'Just do it. Don't wait till all problems have been ironed out."

Duyvendak was able to persuade the hospital's Board to back the project. "I found it was useful to share our vision as widely as possible. It also helped to reach agreement with officials such as the information manager and security officer."

In addition, the support of the Board made it possible to cut costs. The staffing costs were covered by the existing personnel budget. Bedside computers were already listed in the digital dossier.

Duyvendak continues, "We did have to request a budget for the barcode scanners, while the wireless network was included in the project budget."

Barcodes at the single-unit level

The hospital's barcode-based administration registration system went "live" at the end of 2011.

"Each dose of medication, at the single-unit level, already has or is assigned a barcode in the hospital," explains Duyvendak. "For example, consider a packaged, singular pill. When it is issued by the pharmacy, the GS1 Global Trade Item Number® (GTIN®) encoded in the GS1 DataMatrix barcode on its packaging is scanned and sent to the appropriate ward. Then the barcode on the patient's wristband is scanned just before the medication is administered."

"The display on the computer screen confirms that the right medication is being administered at the right time to the right patient. Finally, the medication issued by the pharmacy is scanned once more and registered in the system, together with information such as the batch number and the expiry date."

The barcode-based administration registration system used at the Antonius Hospital has made the administration of medications safer, improving patient safety.

"Medication is easily traced and verified now, but there is still room for improvement," says Duyvendak. If nurses forget to scan, there is no pop-up (the pop-up only appears when a product is being scanned). Our wish is that nurses always need to scan to avoid forgotten medication and to force verification with a question why the nurse is not scanning if she continues anyways (for example: there is no barcode/barcode does not work). Unfortunately this wish has not yet been honored by Chipsoft.

"In the original version of the system, the nurse had to click on the pop-up to get rid of it. This involved putting the scanner down and using the mouse to remove the pop-up before continuing the procedure, which was inconvenient. The system has now been modified so that the pop-up disappears when a specific barcode is scanned. This is much more user friendly, and motivates nurses to use the system."

The use of GS1 standards and barcodes has also improved managing the inventory of pharmaceuticals at the hospital. Digital ordering and decision-support software now provide time for applying barcodes.

"In the final analysis, the success of the system depends on how easy it is to work with at the

patient's bedside," says Duyvendak. "Apart from the user friendliness of the software, the reliability of the Wi-Fi network is also crucial. Nurses cannot be expected to work with a system that is constantly breaking down."

Research has shown that serious administration errors can be prevented by as much as 50 percent by using barcode verification during administration."

Michiel Duyvendak, Hospital Pharmacist, Antonius Hospital

Pharmaceutical product management

Pharmaceutical product management has proven to be one of the main challenges in this project knowing which products have barcodes applied and, of those, which ones work and are effective.

"Together with GS1 Netherlands, we checked all 2,600 pharmaceutical drugs that we use to determine which manufacturers maintain and use GS1 standards correctly. We designed a barcode label based on GS1 standards for the products that did not have one. To make sure that the software works properly, uniform standards for barcodes are necessary. Only then reliable checks can be done; nurses cannot be confronted with medication that cannot be recognised."

"We work hard to convince the industry about the necessity of using standards. We are also trying to move the industry to apply GS1 standards in barcodes on each single unit of use for medicines. But we still assign barcodes on medication on a daily basis—totalling more than 200,000 single doses a year. Of course, it would be best if the manufacturers provided all products with a barcode based on this standard. Unfortunately, the industry has not yet reached this stage."

Duyvendak notes another challenge: "Some products have a barcode, yet the supplier changes the code without informing us. The result is that the medication is no longer recognised when its barcode is read. To deal with this problem, we keep a log of the registration scans and give products one of our own codes when they are not recognised. Logging also makes it possible to print out reports that show when the system is or is not working, and whether it is in use."



Legislation and safe medication

The Dutch healthcare sector has opted to use the GS1 DataMatrix barcode for the unique identification of pharmaceutical drugs. It is also possible to include additional product information encoded in the GS1 DataMatrix barcode like the batch/lot number, expiry date and more.

The NVZA (Dutch Association of Hospital Pharmacists) aims to introduce the use of the GS1 DataMatrix barcode for all medications used in hospitals, down to the single-unit level, to make the administration of medication as safe as possible. "EMR providers must also support the use of GS1 standards in the different steps of the process from pharmacy to patient," says Duyvendak."European legislation supports the use of the GS1 DataMatrix. But unfortunately not on a single-unit of use package."

The European Parliament and the Council of Ministers recently decided that all medication must comply with the European Commission's Falsified Medicines Directive (FMD), effective 9 February 2019. This directive aims to ensure that patients are never supplied with fake medicines that attempt to be passed off as real, authorised products. Manufacturers can comply with the FMD by providing each package containing a given product with a unique serial number. The GS1 DataMatrix can also be used for this purpose. However, a barcode applied on a single-unit package—the lowest level—is needed to ensure safe medication when an administration registration system is used.

Time and patience

Duyvendak recognises that change takes time and patience. "We are making significant changes in our hospital operations, which are long-term projects. After six years, we have made significant progress; yet, it can be slow. For this reason, I find it is important to share our experiences so that others can learn and perhaps implement changes faster."

"I am sort of a 'standards evangelist' and take any opportunity to share our experiences and vision at conferences and webinars. But as a small hospital, we cannot change the world. We are also part of a group that works on GS1 standards adoption together with the Ministry of Health and GS1 Netherlands to see how we can implement GS1 standards and barcodes on medication in all hospitals. A report has already been sent to the Dutch House of Representatives with recommendations for implementation. The next step is to consider how we can further implement GS1 standards and barcodes on medication together with the industry and how we can free up the needed investment."

Duyvendak hopes that the industry will adopt GS1 standards and barcodes for single-unit use of packaged medication. This is much more efficient and less error prone. "But that will cost the industry money, so that will not be easy. The industries that invest in this should be rewarded and not be punished because their products are somewhat more expensive."

Worth the investment

Even though it is a long-term project, Duyvendak recommends other hospitals "just do it." "It does not cost that much more in addition to the infrastructure that is already required at bedside. By using automated controls, keeping records and working becomes much more efficient, which provides time for applying barcodes. Also, focus on the user friendliness of the system for nursing. Finally, don't wait endlessly until everything is taken care of 100 percent, because we have to break the circle. Our patients have a right to good and safe care."

According to Duyvendak, GS1 standards and barcodes on medication are important for hospitals, but also for other healthcare organisations. "Care is shifting to the home; therefore, home care providers should work with GS1 standards-based systems. Now, they check medication manually, but automated verification with barcode scanning is better. It is efficient, effective and safer for the patient."

We started by implementing the GS1 DataMatrix. The use of this barcode makes it possible to check for expiration dates and record batch numbers for biologically produced medicines. This contributes to an increase of patient safety and a decrease of administrative burden."

Michiel Duyvendak, Hospital Pharmacist, Antonius Hospital
Duyvendak is already looking ahead: "We started by implementing the GS1 DataMatrix. The use of this barcode makes it possible to check for expiration dates and record batch numbers for biologically produced medicines. This contributes to an increase of patient safety and a decrease of administrative burden."

Benefits associated with the project for medication administration using GS1 standards include:

- ✓ Medication safety at the point of care.
- Faster and more precise recalls at single-dose level, if ever needed.
- ✓ Batch numbers of biologically produced medicinal products are being recorded to enable the traceability of these products and prevent the potential spread of contamination.
- ✓ Solutions support the continuum of patient care.

Useful tips from Antonius Hospital

- 1) Just do it!
- 2) Involve the nurses who are present at the patient's bedside.
- Pay adequate attention to the userfriendliness and compatibility of the automated system.

About the Author



Michiel Duyvendak is a hospital pharmacist working at Antonius Hospital Sneek/Emmeloord, with responsibility for Pharmaceutical Care in the hospital and nursing homes along with Logistics, Medication Safety and Electronic Medication Records (EMR). He is also an active member of the Dutch Association

of Hospital Pharmacists (NVZA) and a liaison to the European Association for Hospital Pharmacists (EAHP). Michiel is project leader of the project, "Registration of the administration of medication by means of barcodes." Michiel and Antonius Hospital received an award for this project from GS1 Netherlands in March 2017 based on their best-practices example for hospitals in the Netherlands.

About Antonius Hospital

Antonius Hospital has two locations in Sneek and Emmeloord and Home Care Southwest Friesland with 36 neighbourhood care teams. It offers a wide range of services: hospital care, home care, emergency care, care mediation and home services through the hotel. Antonius serves approximately 3,500 people daily. Both hospital and home care are accredited by NIAZ.

www.mijnantonius.nl



Antonius Hospital has implemented GS1 standards to enable the registration and administration of medicines to patients.

Healthcare provider implementation

Hospital de Cascais uses GS1 standards for seamless operations and patient safety

Built in 2009, Hospital de Cascais is a public-private partnership and one of the hospitals in the Lusíadas Saúde Group's nationwide healthcare network in Portugal. More than seven years ago, the hospital started a journey to automate its processes with GS1 standards and software solutions. Today, Hospital de Cascais can automatically replenish stock so that products are there when needed for patient care. The hospital also identifies each single dose of medication so that caregivers can scan the medication and patient's wristband for accurate and safe medication administration.

Hospital Cascais Dr. José de Almeida

Known for excellence

Hospital de Cascais has 277 beds, 33 outpatient rooms and three types of emergency care services—pediatric, general and obstetrics & gynecology. The hospital, with its team of experienced healthcare professionals, is known for excellence in patient services based on respect for the individual along with unwavering ethics, quality, competence and innovation.

In 2012, the hospital received its initial accreditation by the Joint Commission International (JCI) and achieved reaccreditation in 2015. Considered the "gold standard" in global healthcare, JCI accreditation highlights Hospital de Cascais' commitment to patient safety.

Ensuring the five rights of patients

Hospital de Cascais wanted to implement technological solutions based on GS1 standards that would support its medication administration processes for improved patient safety. The hospital also wanted to optimise its logistics processes in order to reduce costs and provide better quality of care through information technology (IT)-driven services. By Vasco Antunes Pereira

Our main goal was to aid our hospital's clinicians and staff in their daily tasks, making it easier for them to perform their responsibilities and do what they do best—caring for patients,"

Vasco Antunes Pereira, CEO, Hospital de Cascais

Hospital de Cascais was especially focused on providing its hospital staff with the tools that would help them avoid possible errors when administering medications—giving the right patient, the right dosage of the right drug, at the right time and in the right way.

Managing inventory levels in real time

In 2009, Hospital de Cascais implemented Ekanban®, BIQ Health Solutions logistics software that optimises all supply chain processes. The Ekanban solution and GS1 standards were implemented in the warehouse, pharmacy and clinical departments. With this solution, the hospital's entire logistics process was automated with staff using handheld devices. To replenish stock in each of the clinical departments, the logistics staff now receives a list of products on their handheld devices based on levels of usage. The picking list is automatically sorted according to the optimal route.

When picked, the products are sent to the requesting clinical departments and the products' inventory levels are updated. As each product is used, the staff scans via their handheld device, the GS1 Global Trade Item Number® (GTIN®) encoded in a barcode printed on the product's package. Once again, the inventory levels of used products are updated in real time.

"When a product reaches a certain inventory level, a purchase order is automatically created for replenishment," says Pereira. "By using this process with GS1 standards, we have the items on hand to ensure our patients get the best of care, in a timely manner."

Making medication administrations safer

Next, Hospital de Cascais implemented the BIQ Health Solutions PharmaTrac® in its clinical departments for greater patient safety throughout the entire medication cycle—from handling to bedside administration.

The pharmacy uniquely identifies a single-dose of medication using a GTIN and a serial number, along with the lot number and expiration date. This information is encoded in a GS1 DataMatrix barcode that is applied to the individual dose. As the medication is administered, the barcode of each dose is scanned at bedside along with the patient's identification wristband. Each patient is uniquely identified with an internal code encoded into a GS1 Datamatrix barcode on his or her wristband. By scanning both barcodes medication and wristband—"information matching" is activated to confirm if the right patient is receiving the right dosage of the right medicine, at the right time.

"An alert is activated whenever there is a potential error—if the medication is not prescribed, if the dosage is different, if the drug has expired or the batch recalled," explains Pereira. "An automated record of the medication administered and the usage is only registered when the medication is effectively and safely administered."

This process not only helps avoid potential errors in the medication administration process, it also automatically updates the patient electronic medical record (EMR) for accurate and efficient invoicing upon discharge.

Standards-based platform for seamless care

Hospital de Cascais decided to once again extend the use of GS1 standards and software-based automation in its operations by implementing MAPP[®], a mobile app platform that combines all nursing activities into a single handheld device. "The MAPP solution with GS1 standards not only provides for increased mobility and productivity for our nurses, it also supports our hospital's commitment to patient safety via barcode scanning," says Pereira.

MAPP supports patient safety by combining the hospital's software apps—PharmaTrac, BTrac®, MilkTrac® and Ekanban—into one seamless platform. The use of GS1 standards facilitates interoperability between the various processes and users.

All functions, using one unique handheld device, one integrated platform and GS1 standards, are automatically linked to the hospital's information system and patients' EMRs for a paper-free process.

"By having accurate information at hand, this significantly increases the time nurses can spend with patients and reduces time spent on updating records," says Pereira. "And it's fully compliant with HIMMS (Healthcare Information and Management Systems Society) and JCI standards."

Universal standards for interoperability

With the implementation of GS1 standards throughout its operations, Hospital de Cascais has more control over data (such as the lot numbers and expiry dates) related to all medicines and other products used in treating patients. The GTIN with the lot number and expiry date encoded in a GS1 DataMatrix barcode uniquely identifies and provides valuable information about a product. This information can then be accessed with a simple scan by Hospital de Cascais' clinicians and staff.

Since the GS1 system of standards is "open," it works independent of the software solution or supplier, thus, enabling compatibility between





systems. "The GS1 system of standards provides the 'connected tissue' of our body of automated solutions," says Pereira. "It brings together the different systems, enabling them to work together for clear interoperability."



A wealth of benefits

With GS1 standards in place, Hospital de Cascais has experienced a wealth of benefits for its operations, caregivers, staff and patients.

- Logistics staff are more productive, saving time and costs when replenishing products. The hospital has achieved greater transparency of its supply chain with reductions in stock levels and waste.
- Patients get the care they need since products are there when needed for treatments.
- Nurses can now spend more time with patients, thanks to time-saving tools at hand.
 Patient EMRs are automatically updated in real time and accurate, timely invoices are generated upon patient discharges.
- The hospital and its staff have access to more accurate medicine and product data for better decision-making and the hospital has reduced waste and costs.
- ✓ With single-dosage identification and bedside scanning, the hospital is keeping patients safer by verifying the right patient is getting the right dosage of the right medicine. Each dosage of medicine can be tracked and traced throughout the hospital processes from the point of receipt to the point of administration.

✓ The automation also facilitated to change the shift of nurses and the handover of responsibilities to the next shift to the bedside. This does not only decrease the time needed for the shift change, but also involves the patient in this process, which adds to patient safety.

Endless opportunities

Hospital de Cascais has recognised the seemingly endless opportunities of using GS1 standards in its processes. Due to the European Union (EU) Falsified Medicines Directive regulation, Hospital de Cascais plans to use GS1 standards provided on primary packages by suppliers instead of producing its own GS1 barcodes internally.

"We are confident that our suppliers will adopt GS1 standards," concludes Pereira. "Standards offer many benefits for the entire industry and especially our patients."



The hospital identifies each single dose of medication so that caregivers can scan the medication and patient's wristband for accurate and safe medication administration.

About the Author



Vasco Antunes Pereira is CEO at Hospital de Cascais, which is part of Portugal's National Healthcare System and one of the four public hospital's with private management in Portugal. In 2005, Vasco started working in the healthcare industry in different roles, from general secretary and general counsel of a large

hospital to the head of Supply Chain and Procurement at Lusíadas Saúde. In this role, he worked directly with Amil and UnitedHealth Group to maximise global negotiations and obtain important synergies for the company. Vasco is also a lawyer and has an MBA from Georgetown University in the U.S.

About Hospital de Cascais

Hospital de Cascais is considered the best hospital in Portugal in its category. It is accredited by the Joint Commission International and is the only hospital in Portugal with HIMSS Stage 6 certification and is now preparing for Stage 7 certification.

www.hospitaldecascais.pt

Time saved with GS1 barcodes

28%

17%

<u>9h</u>

Average time per patient

Average time per medication

Saved per each nurse shift



Today, Hospital de Cascais can automatically replenish stock so that products are there when needed for patient care.



Healthcare provider implementation

Implementing a health records tracking solution for a real ROI in record time

Barking, Havering & Redbridge University Hospitals NHS Trust (BHRUT) is one of the largest Trusts in East London with 950 beds in two main hospital sites—Queen's Hospital in Romford and King George Hospital in Goodmayes—6,500 staff, 950 emergency admissions each day and 600,000 out-patient appointments annually. The Trust needed to make quick and efficient improvements to its health records system after a Care Quality Commission (CQC) report challenged its approach and management. As a result, BHRUT implemented "FIND – IT," a project designed to leverage GS1 standards, barcodes and EPC-enabled RFID tags to track health records.

By Andrew Raynes

Barking, Havering and Redbridge University Hospitals

Best place to start

In 2013, BHRUT was instructed by the CQC to improve its labour-intensive health records library model. BHRUT had a limited understanding of the complex flow of its records and their whereabouts at any point in time.

Furthermore, 40 percent of all records were out of circulation at any one time and up to 10 percent were not available at clinics, leading to cancellations.

As a result, extra staff was needed to find the records, which produced significant financial challenges and resulted in poor staff morale and frustrated clinicians and patients. With another CQC inspection pending, the Trust knew it needed to make some real, tangible changes and quickly. The health records system was targeted as the best place to start.

Traceability for each health record

Based on the results from a feasibility study by 6PM, a GS1 UK Solution Partner, BHRUT implemented FIND – IT. The project encompassed a complete process change, replacing the management of records of terminal digit filing with a location-based system.

For BHRUT, this new system wasn't just a superficial add-on technology; it was a transformation programme enabled by IT and GS1 standards, which aligns with the eProcurement strategy¹ mandate issued by the Department of Health (DH). Created in 2014, the eProcurement strategy includes a range of measures to enable transparency and efficiency in NHS procurement to help support patient safety.

¹ eProcurement strategy: https://www.gs1uk.org/ourindustries/healthcare/eprocurement

The project team, led by key Trust and supplier stakeholders, established the new health records system that was launched just five months after commencement—on time and on budget. The project combined Agile and PRINCE2 project methodology and included a blended training programme for 1,300 staff.

All records and locations were identified and barcoded using GS1 standards, and approximately 65,000 Global Location Numbers (GLNs) now identify each of the Trust's locations. The GS1 identification data was encoded in EPC/RFID tags. Using 6PM's iFit software and RFID technology, the tagging of records meant that a network of stationary and handheld RFID-readers and handheld scanners could then track and locate health records at key locations around the building. "Since the system was updated in real-time as each tag was read, we can even determine the direction of each record's path as it travels throughout the hospital," says Andrew Raynes, BHRUT's Information Management & Technology Programme Director.

Tangible benefits achieved in first year

The main benefit is that records are now available when and where they're needed. The new system has also had a positive effect on both staff and patients since locating a record has become so much more efficient.

The new system has also reduced the time records spent out of the main file and has increased record filing speed.

We can now file 85 health records per hour, compared to 35 per hour before the system was implemented. "

Andrew Raynes, Information Management & Technology Programme Director, BHRUT "Before using iFit and GS1 standards, it often took 4 or more staff as many as 5 days to file approximately 2,000 records. Now, 3 staff members can file the same number of records in 1 day, allowing us to reallocate staff to fill other needs in the hospital."

The feasibility report and subsequent business case estimated a net savings of £1.4 million across 3 years; however, the Trusts is now predicting a £2.4 million return, with 84 percent of the benefits realised in the first year.

There are many benefits associated with using GS1 standards for the improved availability and traceability of records, to include:

- Improves both clinical decisions and patient experiences.
- Minimises potential legal claims and any risk of not locating health records.
- Increases the availability of records for clinical coding and audits.
- Supports the tracking of other assets such as medical devices, beds, samples and pharmaceutical supplies.
- Enables compliance with CQC recommendations and the DH retention policy, as a result of new functionality and reporting.
- Enables visibility of records throughout Trust and the performance of overall system and staff.
- Increases staff satisfaction as a result of having the right tools for the job.
- Positions BHRUT for future solutions since the needed infrastructure is now in place with support from all GS1 identifiers.

Before and after the new health records system		
Benefits	Before FIND-IT	With FIND-IT
Unfunded headcount	19	0
Creation of temporary health records	85 per day	44 per day
Unavailability of health records at clinic	<10%	<3%
Pulling records (efficiency) per hour	29	35 or 20% improvement
Filing rate (per person/per day)	90	637 or 700% increased efficiency
Total financial realisation of the business case after 3 years		84%



About the Author



Andrew Raynes is Information Management & Technology Programme Director at Barking, Havering and Redbridge University Hospitals NHS Trust. His recent achievements include the successful deployment of an RFID tracking solution that uses GS1 standards to support location-based filing for

health records. Andrew has over 18 years of experience in the health and private sectors. He has led a number of high profile projects, including the implementation of a GP-led practice at HMP Thameside on the Belmarsh Estate and the implementation of Liquidlogic, a children and adult social care system while at Leicester City Council. Andrew is also an active member of the UK Council for Health Informatics Professions (UKCHIP) and a Fellow of the British Computer Society (BCS).

About Barking, Havering and Redbridge University Hospitals NHS Trust

Working closely with partner organisations and 6,500 staff and volunteers, **Barking, Havering and Redbridge University Hospitals NHS Trust (BHRUT)** provides outstanding healthcare services to a diverse community of 750,000 people. The Trust runs two hospitals—King George Hospital in Goodmayes and Queen's Hospital in Romford—and it also serves clinics across outer northeast London. The Trust operates two Emergency Departments, one at each of the hospitals, and offers a full range of local hospital services. BHRUT is proud of its regional neuroscience centre, renowned as a centre of excellence; a cancer centre; and a Hyper Acute Stroke Unit at Queen's Hospital to provide specialist care.

www.bhrhospitals.nhs.uk



BHRUT implemented "FIND –IT," a project designed to leverage GS1 standards, barcodes and EPC-enabled RFID tags to track health records.



Healthcare provider implementation

Lancashire Teaching Hospitals NHS Foundation Trust inventory management solution leads to £3 million in cost savings

Lancashire Teaching Hospitals NHS Foundation Trust (LTH) provides health services for more than 1.5 million people in Lancashire and South Cumbria, and employs approximately 6,500 clinicians and staff. Based on the need to cut costs and improve its supply chain, the Trust decided to focus on inventory management processes for its operating theatres. LTH now uses GS1 standards for greater control and visibility of inventory levels, resulting in less product waste, reduced costs and dramatically fewer out-of-stock situations. In addition, more than 7,100 hours each year in clinical staff time has been re-allocated to patient care.

Lancashire Teaching Hospitals

NHS Foundation Trust

By lan Britcliffe

Make the best use of resources

With a vision designed to provide the latest in healthcare developments, LTH continues to improve the lives of the people it serves. Essential for the Trust's success is its continual transformation of services. Year-after-year, LTH continues to deliver quality improvements and productivity efficiencies, recently averaging 4 percent each year in savings.

One of the Trust's key aims is to make the best use of all resources—and this is where its focus on inventory and supply chain management began.

Targeting tangible savings

Under mounting pressure to cut costs and discover new, better and more efficient ways of working, Trusts are facing unprecedented financial challenges and the need to develop their supply chains. After assessing its own supply chain processes, LTH decided that change was needed: to advance the hospital from a very basic supply chain model to a much more mature position.

Inventory management based on best practices is key to supply chain improvements. With this in mind, the initial focus was to introduce new inventory management processes in the highest spend area: operating theatres. LTH's goal was to provide an organisation-wide view of inventory levels with the ability to assign costs to both the individual patient and service provided.

"Our key challenges included a lack of stock control and visibility along with a shortage of management information," explains lan Britcliffe, Head of Supply Chain and E-Commerce for LTH. "We also needed to reduce waste in consumables and the costs associated with disposal and reordering. Finally, we needed better control of consignment stocks."



One of the main drivers of change was the Trust's need to realise tangible cost savings. "This had the greatest impact on our desire to transform our inventory management processes," says Britcliffe.

The Trust was also experiencing significant issues with stock management in its operating theatres. Stock was poorly controlled and there were recurring out-of-stock conditions. Clinical staff primarily managed the inventory with support from a small team of supply chain staff—a situation that was both ineffective and inefficient.

The absence of inventory control and visibility led to a shortage of management information, which created issues including product waste, excel stock levels leading to limited storage space, and the inability to trace products.

Taking control of inventory

The Trust worked with Ingenica Solutions to implement a GS1 standards-based inventory management system in the Trust's operating theatres. By using GS1 standards in its inventory management activities, LTH was able to take control of the processes, secure efficiency savings, and release valuable clinical time back to patients.

The new inventory management system uses GS1 Global Trade Item Numbers (GTINs) on most products used in operating theatres. Scanning the barcode as inventory is received, moved and used around the Trust enables key product data to be electronically captured and exchanged without manual intervention into patient administration and purchase order processing systems.

Saving clinical hours for more time with patients

The new inventory management system has helped reduce waste and inefficiencies by giving the Trust greater transparency and improved stock and data management. The data generated by the solution has helped us in many ways. Now, consumption of stock is recorded at points of use and ordering is based on actual consumption, resulting in a reduction in stock levels. In turn, this has allowed several rooms to be cleared of stock, and reassigned for clinical usage."

Ian Britcliffe, Head of Supply Chain and E-Commerce, Lancashire Teaching Hospitals NHS Foundation Trust

There is also better control and visibility over consignment implants, which as one of the most expensive items in the Trust. Costs have been cut and the likelihood that these items will become obsolete has declined. In addition, the Trust's new centralised theatre stores have made keeping track of stock much easier with automatic stock replenishment.

With greater than anticipated benefits, LTH's operating theatre department is at the forefront of effective and efficient inventory management. "One notable example is the transformation of our stock control functions that have transitioned from clinical staff to supporting materials management staff," advises Britcliffe. "This change alone has saved the Trust more than 7,100 clinical hours annually—time that has been re-allocated to patient care."

The programme has also encouraged increased communication between Trusts across the North West, not just sharing experiences of GS1 standards' implementation but also looking at additional steps that could be taken, together as a region.



The Trust has reported £3 million in costs savings from increased stock visibility.

7,100

hours each year in clinical staff time have been re-allocated to patient care.

Next steps

LTH continues to set "stretch" targets for increased clinical quality, operational developments and operational effectiveness.

To date, key benefits realised by the Trust include:

- ✓ £3 million of balance sheet adjustments recovered through stock visibility
- ✓ More than 7,100 clinical hours saved annually—the equivalent of four full-time employees
- ✓ Several rooms cleared of stock that are now available for clinical use
- Improved reliability and increased visibility of the Trust's supply chain
- ✓ Reduced inventory levels
- Minimised inventory waste
- Greater transparency ability to view stock holdings in real time, using a dynamic system
- Improved stock and data management

Following this successful implementation in the operating theatre department, the Trust has already initiated a programme to deploy the solution across both Chorley and South Ribble Hospital and Royal Preston Hospital with the goal to consolidate buying all sites.

About the Author



Ian Britcliffe is the Head of Supply Chain and E-Commerce at Lancashire Teaching Hospitals NHS Foundation Trust. He has 30 years of experience in NHS procurement and supply chain with various Trusts and has led many procurement projects, from capital purchasing to contracting, mainly in theatres and surgery. In the past

four years, Ian has led a dedicated team to implement a state-of-the-art inventory management system that is providing substantial savings for LTH and recognition from all areas of the healthcare sector.

About Lancashire Teaching Hospitals NHS Foundation Trust

Lancashire Teaching Hospitals NHS Foundation Trust is one of the largest and highest performing trusts in the UK, providing district general hospital services to 370,000 people in Preston and Chorley, and specialists care to 1.5 million people across Lancashire and South

care to 1.5 million people across Lancashire and South Cumbria. The Trust aims to be recognised as the centre for acute and specialised hospital services in Lancashire and South Cumbria, providing the highest standards of compassionate, safe care that gives patients a positive experience, excelling in research, innovation and teaching, developing staff to reach their potential, and improving the health and wellbeing of its diverse communities.

www.lancsteachinghospitals.nhs.uk



Healthcare provider implementation

Plymouth Hospitals NHS Trust implements Global Location Numbers for ready compliance and increased productivity

Plymouth Hospitals NHS Trust is the largest hospital in the UK's South West Peninsula. The Trust serves a population of 450,000 with a wider peninsula population of almost 2,000,000 people who can access its specialist services. The use of Global Location Numbers (GLNs) for location identification is one of the core enablers of the Department of Health's (DH) eProcurement strategy. By introducing GLNs now, the hospital is making sure it's on track with DH plans for compliance with GS1 standards. Add to this the productivity gains from having consistent and accurate location information.

By Theresa Gunn and Sandie Wills



Lack of consistency and confusion

The Trust's property management system was supplied by Micad, a GS1 UK Solution Partner, and contained 6,715 locations. The rules for room numbering weren't consistently applied, and where the physical numbers were attached to the doors, this led to problems when doors or doorframes were removed or relocated.

This resulted in extra work associated with renumbering locations when doors were moved, and looking for locations that had no identification label at all. The inconsistent numbering system also made it difficult to find locations without a floor plan.

"There was little or no consistency across the hospital's different software systems, with the same location being referred to differently in each system," explains Theresa Gunn, Quality Systems Manager. "The replication of data introduced the potential for information to be stored incorrectly; for example, when a cost centre changed, this information was not shared with other systems."

Matching a GLN to each location

Today, the Trust is introducing GLNs as a way of managing locations in a cost-effective and consistent way. The GLN offers a unique number that identifies every location, ultimately allowing the Trust's property management system to route information to other systems with no manual intervention.

The first stage of the implementation was to obtain a single organisational GLN prefix and Trust GLN in place.

"Since the Micad property management system holds records of all locations in the Trust, we worked to ensure that these records were 100 percent complete and accurate," says Sandie Wills, Scan4Safety Project Manager. "We supplied Micad with our GLN allocations and Micad uploaded this information into the system, matching a GLN to every location, site and space." The Micad system also holds other relevant information for each location such as department, function, GLN, GLN creation date and GLN extension owner and budget code.

Plymouth Hospitals NHS Trust also worked with Dakota Healthcare, another GS1 UK Solution Partner, to develop a mobile printing solution to help the Trust begin labelling immediately. The Dakota Healthcare Android app uses a spreadsheet exported from Micad that enables the Trust to print and visually verify the GLN labels.

Dakota Healthcare also recommended an Android tablet, which meant the Trust staff can print the labels while on-site, making sure the correct label was attached to each location.

A step-by-step approach

The initial rollout prioritised the physical locations in non-clinical areas to receive GLNs. The next step is to engage with clinical staff to ensure the effective labelling of clinical areas. Following this, the Trust will work with its inventory system suppliers to achieve system compliance.

The final stage planned is to ensure that the high priority in-Trust systems are all using GLN identifiers. In fact, the Trust has approximately 240 systems in total. Once the national GLN registry is in place, data from Plymouth Hospitals NHS Trust will help populate it.

The Trust is also working with system suppliers and managers to ensure that their systems are GS1 compliant and use the Trust's GLNs.

Saving time with a simple scan

GLNs will help the Trust achieve standardisation across and interoperability between its various systems that use location-based data.



Now, each location can be accurately and swiftly identified with a GLN and barcode in place.



Using barcoding equipment from Dakota Healthcare, Plymouth could efficiently label each of its locations with a GLN encoded in a barcode. "Our staff will save valuable time since labels with barcodes will be available at every location," says Gunn. "A simple scan of the barcode is all that's needed to identify the location quickly and accurately, instead of manually entering data."

With GLNs, the Trust has now standardised the naming and labelling approach for its physical locations. "There will be much less time spent looking for rooms," says Wills. "Productivity will increase since there will be much less ambiguity and confusion associated with ownership and occupany of locations and rooms."

Overall, Plymouth Hospitals NHS Trust has a complete record of its spaces with the needed governance in place to ensure future compliance.

A simple scan of the barcode is all that's needed to identify the location quickly and accurately, instead of manually entering data."

Theresa Gunn, Quality Systems Manage, Plymouth Hospitals NHS Trust

About the Authors



Theresa Gunn is the Quality Systems Manager at Plymouth Hospitals NHS Trust. She has 15 years of experience working with the Micad Property Management system.



Sandie Wills is the Scan4Safety Project Manager at Plymouth Hospitals NHS Trust. She is a Prince2 qualified project manager working on the Scan4Safety programme at the Trust. Prior to this position, Sandie worked as a Project Manager within IT for more than 10 years and has over 30 years of experience in the NHS.

About Plymouth Hospitals NHS Trust

Plymouth Hospitals NHS Trust is the

largest hospital in the UK's South West Peninsula, providing comprehensive secondary and tertiary healthcare to almost 2,000,000 people who can access the Trust's specialist services. The area served is characterised by its diverse and aging population, giving Plymouth Hospitals NHS Trust the opportunity to innovate in services for the elderly.

www.plymouthhospitals.nhs.uk



Suppliers and GPOs



Suppliers and GPOs

Bionnovation transforms its operations and achieves global growth with GS1 standards

Headquartered in Bauru, Brazil, Bionnovation Biomedical is a Brazilian company that specialises in dental implants and biomaterials for the medical and dental markets. The company supplies distributors worldwide with innovative products and the latest technologies designed to meet the growing demands of their markets. Expanding into the U.S. and other important international markets, Bionnovation wanted to improve the distribution of its products as well as comply with the U.S. Food and Drug Administration's (FDA) Unique Device Identification (UDI) regulation. The company now uses GS1 standards to uniquely identify each of its dental implants and other products. As a result, Bionnovation has achieved end-to-end product traceability throughout its global supply chain, reduced order fulfilment errors to zero, improved productivity and inventory management, and further demonstrated its commitment to innovation for customers.

Bionnovation b i o m e d i c a l

By Jeferson Tavares

Delivering dental health worldwide

Bionnovation was formed with the vision of bringing smiles back to people's faces. As a provider of dental implants and biomaterials, Bionnovation works daily to ensure that highquality dental health is accessible to everyone.

The company's product line is comprised of implants, prosthetic, surgical and instrumental components as well as biomaterials, which are products that aid with bone regeneration. From the receipt of raw materials to the distribution of products to customers, all steps in Bionnovation's production process are executed, verified and recorded according to certified procedures based on Good Manufacturing Practices.

High performance and accelerated growth has spurred its predominant market share and

impressive sales in Brazil and in international markets—with its resellers and customers. "To successfully conduct business in global markets, we needed greater control over the distribution of our products as well as the ability to address the U.S. FDA's UDI regulation," says Jeferson Tavares, Systems Analyst. "We decided to implement GS1 global standards as a necessity of doing business."

Traceable, accurate shipments

Working with GS1 Brazil, Bionnovation is now identifying each of its individual products with a GS1 Global Trade Item Number® (GTIN®), batch/ lot and expiry date information—all encoded in a GS1 DataMatrix barcode. To identify and track cartons of products, the company uses GS1 standards.



To identify and track cartons of products, the company uses GS1 standards.

"We can now track cartons and even the individual products as they travel to distribution sites and, ultimately, to resellers and customers' locations," say Tavares. "This has allowed us to gain visibility into and improvements in logistics operations."

Tavares and his team developed a new logistics process that relies on GS1 standards and the company's ERP system to confirm the accuracy of orders and subsequent shipments.

"Prior to shipping an order, our logistics employee pulls up the customer's purchase order in our system," explains Tavares. "To validate the shipment, he scans the GS1 DataMatrix barcode on each product's package. The system then compares the products scanned to the products listed on the order. If a product is missing or if a product is part of the shipment and should not be, the system alerts the manager so that he can take immediate action to correct the order before it's shipped. If the products in the shipment match the products listed in the purchase order, the system confirms its accuracy."

Putting smiles on customer faces

Even in its initial stage, the new process enabled by GS1 standards is helping Bionnovation eliminate shipment errors and avoid the associated costs. "We have found that errors in order shipments have been reduced to zero," shares Tavares. "Mistakes made in filling orders meant our company had to pay all costs associated with re-working the order as well as transport costs back to the customer."

By scanning products' DataMatrix barcodes, logistics workers can now more easily and quickly check orders, thus boosting their productivity.

Overall, we have eliminated human error in the checking process that, in turn, has helped us improve stock management and achieve precision in stock inventories".

Jeferson Tavares, Systems Analyst, Bionnovation Biomedical

GS1 standards have also helped Bionnovation address critical FDA UDI requirements for applying globally unique product identifiers to all medical devices placed on the U.S. market. "By using the GTIN in the GS1 DataMatrix, our company complies perfectly with the FDA's mandate, allowing us access to the large American market," says Tavares.

"What's most important is that our customers are very satisfied. When they receive our orders, they can trust that these orders are accurate and complete," says Tavares. "When tracking the status of orders, we are much more agile and can respond even quicker than before. We're putting 'smiles on our customers' faces' with our improved level of service."

As a pioneer in using GS1 standards, Bionnovation continues to win the respect of customers and trading partners alike. "GS1 standards are helping us take advantage of new business opportunities and gain new credibility in an exciting global market—now, that's something to smile about!" concludes Tavares.



By using the GTIN in the GS1 DataMatrix the company complies perfectly with the FDA's mandate.

About the Author



Jeferson Tavares is a Systems Analyst with Bionnovation. He has more than 20 years of experience in information technology. Jeferson graduated with a degree in Information Systems from Faculdade FGP in São Paulo, Brazil.

About Bionnovation Biomedical

Bionnovation Biomedical was created with the purpose to make accessible the benefits of dental implants to everyone. The company provides advanced solutions for the replacement of dental elements and tissue reconstruction with a product line comprised of implants, prosthethic, surgical and instrumental components and biomaterials. In short, Bionnovation's 83 employees work to bring a smile back to people's faces.

www.bionnovation.com.br



Suppliers and GPOs

Prati-Donaduzzi invests in GS1 standards for traceability of medicines in Brazilian healthcare

For nearly 25 years, Prati-Donaduzzi has built its reputation on a foundation of producing quality medicines, respect for its employees and a commitment to ethical business practices. In 2014, the pharmaceutical manufacturer started using GS1 identifiers encoded in GS1 DataMatrix barcodes to identify its pharmaceutical drugs at the single-dose level. As a result, Prati-Donaduzzi has realised the value of fractionable medications, enabling traceability throughout the healthcare supply chain, increasing efficiencies within its own operations and for its healthcare providers, and improving the care and safety for patients.

By Walter Batista



Focusing on safety

Prati-Donaduzzi is well-known as a leading drug manufacturer, focusing on generic brand medications as the largest supplier for healthcare providers in Brazil. The company is constantly investing in infrastructure, professional training, research and development, and innovation in order to expand its product line. In 2016, Prati-Donaduzzi was recognised by Infraero, a national public company, for logistics efficiency and received the "Automation Award" from GS1 Brazil.

While Prati-Donaduzzi recognises the needs of its customers, the company is also focused on improving safety practices for patients. In 2014, Prati-Donaduzzi started to use GS1 standards in support of its customers—private and public hospitals—and the RDC 80/06 regulation that governs the manufacture and trade of fractionable or single-dose medications.

"On July 2014, we received a complaint from the Hospital de Clínicas' pharmacy (HC UNICAMP) about the Amoxicillin 500mg tablet," recalls Walter Batista, Prati-Donaduzzi's Commercial Director. "The pharmacists showed us how they were having difficulties in unitising our blister packs since the tablets were diagonally placed. Furthermore, they had to repackage and rework all of our medications, adding time and costs to their operations."

Addressing customer needs

In the following month, Prati-Donaduzzi received a request to visit Alemão Oswaldo Cruz Hospital in São Paulo to discuss fractionables. Once again, Prati- Donaduzzi met with pharmacists who demonstrated the need for single-dose medicines and how this would enable the traceability of each unit of medicine.

"We got to know more about the GS1 DataMatrix barcode used by the hospital and other large hospitals throughout Brazil," says Batista. "We requested help to assess the possible implementation of GS1 standards, including the DataMatrix barcode. Our next step was a visit to Dr. Nilson Mata at Israelita Albert Einstein Hospital, which led us to the experts at GS1 Brazil."

With support from the company's senior management, Prati-Donaduzzi launched the use of GS1 standards for single-dose identification and labelling. Prati Donaduzzi's Group packaging company, Centralpack, performed several tests and studies.

"On September 2014, just three months after being approached by HC UNICAMP, we attained our GS1 certification to use DataMatrix barcodes on the blister packs for the anti-inflammatory drug, Diclofenac Sodium," says Batista. "We were the first national pharmaceutical company to implement the GS1 DataMatrix barcode in aluminum blister packs for solid oral drugs in single doses."

Importance of single-dose identification

Today, Prati-Donaduzzi identifies each single dose of its medicines by using GS1 standards specifically the GS1 Global Trade Item Number[®] (GTIN[®]), batch/lot number and expiry date, encoded in the GS1 DataMatrix barcode.

"We believe that unique identification at the item and single-dose levels is extremely important since pharmaceutical drugs can seriously impact patients if there is an administration error," explains Batista. "In addition, if we include individual identification in all of our medications, we can improve the efficiencies of recalls (if ever needed) and provide personalised customer service."

Prati-Donaduzzi is also leading the way by sharing its experiences and the need for traceability with others in the Brazilian healthcare industry. The company hosted a breakfast at ANAHP (National Association of Private Hospitals) in São Paulo to discuss the issue, "Fractioning and Traceability in Hospitals."

"All of São Paulo's private hospitals attended with about 110 healthcare professionals in attendance," says Batista. "After the event, we extended our discussions about the standardisation of single-dose identification to public hospitals and agencies." By implementing GS1 standards, it has helped us realise greater efficiencies in our operations and especially improved safety practices something that is clearly recognised by our partners and customers."

Walter Batista, Commercial Director, Prati-Donaduzzi

Growing with traceability

Prati-Donaduzzi has always understood the importance of being aligned with the most modern management practices and technology and especially their impact on customer satisfaction.

"We have made and will continue to make substantial investments in these areas by aiming to continuously improve our performance," says Batista. "By implementing GS1 standards, it has helped us realise greater efficiencies in our operations and especially improved safety practices—something that is clearly recognised by our partners and customers."

"We understand productivity benefits are experienced gradually," continues Batista. "However, we also understand that increased productivity gains are forthcoming with increased safety controls, which has become more effective over time."

Prati-Donaduzzi also points out the growing requirement in Brazilian's healthcare market for traceability enabled by the DataMatrix barcode. "Our overall financial results have been very positive," says Batista. "Recognised as a pioneer, we have been able to enter new markets more easily (such as private hospitals) since we are able to track our medicines at every point in the supply chain—from their arrival in the hospital's warehouse, in its pharmacy, in nursing stations, and ultimately, in the administration of medications to patients. Using standards has helped us reduce administration errors as well as increase control of our inventory."

Public and private hospitals are also benefiting from Prati-Donaduzzi's implementation of single-dose identification. "The use of the GS1 DataMatrix barcode has helped our hospitals save costs by approximately 30 to 42 percent since they no longer need to perform unitisation," says Batista. "We need to be constantly evolving to meet our customers' needs," concludes Batista. "Using technology and standards helps us differentiate our company in a highly competitive global marketplace. Our customers realise that we have a choice, and we choose to leverage GS1 standards for the benefit of all."



"The use of the GS1 DataMatrix barcode has helped our hospitals save costs by approximately 30 to 42 percent since they no longer need to perform unitisation."

Walter Batista, Commercial Director, Prati-Donaduzzi

About the Author



Walter Batista is the Commercial Director at Prati-Donaduzzi. Mr. Batista graduated with a law degree from Universidade Estadual de Goiás (UEG) and a Masters in Business Administration (MBA) degree in Strategic Management and Marketing from Fundação Getúlio Vargas (FGV). He completed the

Executive Development Program (PDE) conducted by Fundação Dom Cabral (FDC) and an MBA in Strategic Pharmaceutical Management from Fundação Instituto de Administração (FIA). Mr. Batista has been active in the pharmaceutical industry since 2004 and at Prati-Donaduzzi since 2008.

About Prati-Donaduzzi

In the late 1980s, Pharmacists Luiz and Carmen Donaduzzi started a pharmaceutical manufacturing plant in Recife, Brazil. By 1993, the company had relocated to the city of Toledo, along with their partners, Celso Prati and Arno Donaduzzi, and with support from the municipal and state governments. Nowadays, Prati-Donaduzzi is well-known as a leading drug manufacturer, focusing on generic brand medications as the largest supplier for public agencies in Brazil.

www.pratidonaduzzi.com.br



In 2014, Prati-Donaduzzi started using GS1 identifiers encoded in GS1 DataMatrix barcodes to identify its pharmaceutical drugs at the single-dose level.

Suppliers and GPOs



Legrand strengthens its commitment to customers and quality with single-dose identification

Laboratorios Legrand produces, develops, markets and exports pharmaceutical products, based on international standards and best practices in manufacturing and logistics. A long-time user of GS1 standards throughout its operations, the company is now using GS1 standards, encoded in GS1 DataMatrix barcodes, to uniquely identify single doses of its branded pharmaceutical, Omeprazol. Based on positive pilot results with Valle del Lili, a prominent hospital, Legrand plans to extend the benefits of using GS1 standards to include other product lines and business transactions in the near future.

By Giovanna Higuera García



Innovation and quality

For more than 30 years, Laboratorios Legrand (Legrand) has focused on innovation and quality to grow and distinguish itself in the worldwide pharmaceutical industry. Headquartered in Bogotá, Colombia, Legrand was the first national pharmaceutical manufacturing plant to attain Good Manufacturing Practices (GMP) certification status, granted by INVIMA, Colombia's National Food and Drug Surveillance Institute. With more than 550 employees, Legrand is committed to the health and well being of Colombians.

"At Legrand, our commitment to customers and patients can be summed up in our motto, 'We do well what makes you well,'" says Giovanna Higuera García, Chief of Planning.

"We continuously work to improve our processes so that we can consistently deliver quality pharmaceuticals for advancements in health. With help from GS1 standards, we can implement and ensure best practices throughout our value network."

Always at the forefront

Since 2015, Legrand has worked side-by-side with its healthcare providers and pharmacies to implement and use GS1 standards to uniquely identify its medicines, enabling traceability throughout the company's marketing, distribution and dispensing processes.

In 2016, the company re-affirmed its certification in GMP and, at the same time, expanded its use of GS1 standards to include the unit or singledose level. "We are always considering ways to be at the forefront in the market," says Higuera. "We found that many of our customers wanted to be able to identify the medicine—the actual unit of medicine—administered to patients and managed in their inventory systems. We stepped up to the challenge."

Working closely with GS1 Colombia, Legrand decided that a GS1 Global Trade Item Number[®] (GTIN[®]) with batch number and expiry date encoded in a GS1 DataMatrix barcode would be used to uniquely identify each single dose of each of its medicines.



Phased planning and testing

For the implementation, Legrand took a phased approach to include a pre-implementation, planning stage and then a testing phase with one of its key customers, the Valle del Lili Foundation, a 500-bed hospital located in Cali, Colombia.

For approximately three months, the company conducted planning sessions, trained its staff and worked on establishing the systems needed to create and print the GS1 DataMatrix barcodes on dosage-level packages.

"We not only focused on the systems and technical aspects of printing the GS1 DataMatrix barcodes, we also modified our logistics processes and ensured everyone was trained on these changes to ensure a smooth transition," explains Higuera.

One of the challenges during implementation was establishing automated systems to facilitate the control, traceability and safety of the drug preparation process. Higuera advises, "Many of the information systems are in the design and preparation phase, to achieve proper registration, control, labeling, dispensing and administration of the pharmaceutical service. We know that this takes time but is finally a process, which will improve over time."



Legrand has modified its processes and best practices to include using GS1 unique identifiers and other valuable information encoded in the GS1 DataMatrix barcode on each dosage of Omeprazol.



Hospitals can now scan to read each GS1 DataMatrix barcode, helping to ensure that the right medicine is being dispensed to the right patient.

Collaborating for confirmation

During the implementation phase, Legrand tested the new process and GS1 DataMatrix barcodes on dosage-level packages. "We collaborated with Valle del Lili and identified one of our own medicine brands—Omeprazol—to conduct the pilot," says Higuera. "The result was highly satisfactory. Valle del Lili could easily scan and consistently read the GS1 DataMatrix barcodes on the Omeprazol dosages when administering medication to patients."

And with each scan, thanks to the implementation of GS1 standards, Legrand's customers like Valle del Lili can now realise benefits within their own hospital operations such as improvements in inventory management, resource efficiencies and patient safety.

For example, Valle del Lili has reported that by using GS1 standards within its operations such as single-dosage GS1 DataMatrix barcodes, it has experienced a 50 to 75 percent reduction in obsolete inventory and 15 to 30 percent reduction in inventory levels.¹

"With the implementation of GS1 identification at dosage-level standards in place, we can now trace our medicines to not only the individual hospital, but also to the individual patient to whom it was administered," says Higuera. "This is a powerful capability."

^{1 &}quot;Valle del Lili improves patient safety with automated inventory management," pages 28-30, GS1 Healthcare Reference Book 2016-2017: https:/www.gs1.org/healthcare/ reference-books

Legrand strengthens its commitment to customers and quality with single-dose identification - Colombia



Looking ahead

With the objective of optimising production times, materials and its associated costs, Legrand is now looking to extended the benefits of using GS1 standards to several of its branded medicines manufactured in two of its distribution centres. "We plan to work with GS1 Colombia and other hospitals for continued compliance in implementing standards," says Higuera.

Legrand is also considering extending the use of GS1 standards to include the labeling on their manufactured products and for other clients. It plans to automate transactions by including GS1 standards in the electronic exchange of documents, such as purchase orders and dispatch notices.

"We will continue our drive toward innovation and quality," concludes Higuera. "With GS1 standards, many improvements are possible in today's healthcare environment."

About the Author



Giovanna Higuera García is the Chief of Planning at Laboratorios Legrand where she has been for more than 14 years. Ms. Higuera is a public accountant with specialisation in Management and Financial Management. She has contributed to the development of Laboratorios Legrand to become one of the most

important laboratories in Colombia.

About Laboratorios Legrand

In 1986, Laboratorios Legrand was formed with the acquisition of the production plant and licensing agreement for products of the pharmaceutical company, Lepetit de Colombia SA, a subsidiary of the multinational group, Dow Chemical Company. Today, the company produces, develops, markets and exports pharmaceutical products, based on international standards and best practices in manufacturing and logistics. Headquartered in Bogotá, Colombia, Legrand has more than 550 employees who are committed to the health and well being of Colombians.

www.laboratorioslegrand.com

Suppliers and GPOs

Resah leverages reliable healthcare product data to improve patient safety

French hospitals are today challenged by new regulations that require them to track and trace all healthcare products. As a result, pharmacists in these hospitals need reliable and complete trade item data for greater knowledge about the products they use and for improved patient safety. Réseau des Acheteurs Hospitaliers (Resah)—the second largest French group purchasing organisation (GPO) that purchases for 320 care providers in France—requested that all its suppliers send synchronised trade item data through the Global Data Synchronisation Network[™] (GDSN[®]). This measure is expected to save time and money for hospitals and pharmacies while ensuring better data quality and greater patient safety.



By Vani Barsoumian

In need of quality data

Health professionals need complete and accurate data related to healthcare products for efficient processes—order-to-cash, inventory management and dispensing of the products they use every day. In fact, the quality of data received is especially critical when it comes to ensuring the quality of patient care and safety.

For more than 10 years, French hospitals have been very aware of this need and have attempted multiple times to synchronise product information with their suppliers and their points of care.

Now, Resah, a major GPO of health products in France, has succeeded in its project of data synchronisation between suppliers and healthcare providers.

To start, the company created a task force comprised of stakeholders all along the value chain who were concerned about issues related to the quality of their product information. The group included representatives from medical device manufacturers (B.Braun, Bio-Rad, Vygon), a pharmaceutical laboratory (Roche), a solution provider that specialises in information systems for hospitals (MiPih), a pharmaceutical database (CIP), hospital pharmacists (Hospitals of Argenteuil, Saint-Denis and Groupement Hospitalier de l'Est Francilien), the medical service of the French Army (Service de Santé des Armées) as well as GS1 France.

The objective of the task force was to collect users' needs that would conform to regulatory prerequisites with the aim of getting responses from manufacturers.

The Resah task force was initially focused on the definition of two data models: one for medical devices and the other for pharmaceutical drugs. The data model for medical devices took into account the list of data elements requested by the U.S. Food & Drug Administration's (FDA) Unique Device Identification (UDI) regulation.

The task force then enhanced the data model with other useful information needed by pharmacists and healthcare providers for the efficient receipt, storage and management of pharmaceutical drugs and medical devices. Regarding the data model for pharmaceutical drugs, the task force retained the regulatory data in France and the necessary information for pharmacists. The two data models integrated all of this mandatory information required by GS1 standards for the exchange of trade item data via the GDSN.

Exchanging information via data pools

Once the two data models were defined, Resah organised tests to exchange trade item data through the GDSN. It partnered with one of the major solution providers for hospitals in France called MiPih, based on the company's expertise in providing ERP-based solutions for healthcare providers. Today, MiPih information systems solutions support more than 600 French healthcare providers in their day-to-day activities, effectively mastering the integration of product data in its current solutions.

MiPih's role was essential for the tests. The company developed a data pool based on GS1 technical specifications and connected to the GDSN. The data pool was designed to receive data from suppliers through the GDSN and then distribute this reliable information to any existing and future hospital member of Resah. A data pool called "eCatSanté" (means "e-catalogue in healthcare") has been developed by MiPih and can now provide hospitals with product records directly from manufacturers.

The initial tests through the GDSN took place in September 2015 with successful exchanges of complete trade item data realised in October 2016. On 1 January 2017, Resah officially announced the launch of eCatSanté to all of its suppliers.

€65 to €10 🗖

All along the value chain, GS1 France estimates costs are reduced from €65 to €10 per product record, in terms of data management costs.

Benefits of data synchronisation

The initiative is compliant with recent European and French regulations related to e-procurement. The use of an electronic catalogue is now recognised by authorities as a possible way to organise tenders.

In terms of benefits for data recipients and the quality of the care, a parliamentary report from the British Department of Health¹ had anticipated by 2015 that each hospital equipped with such a tool could realise up to \notin 3.5 million a year in savings.

Initial results in the French hospitals show that synchronised trade item data decrease the workload of administrative staff—two percent of assistants can thus be reallocated to other activities.

All along the value chain, GS1 France estimates that costs are reduced from \notin 65 to \notin 10 per product record, in terms of data management costs.

The advantages for manufacturers are also numerous. A standard data model enables them to reduce the number of product record formats sent to their customers. Above all, manufacturers can control their data.

Thanks to synchronised data exchanges, manufacturers know precisely who can request and access their product data. Finally, the system makes it possible to provide pharmacists in hospitals with reliable, up-to-date and complete information.

For the next steps of its initiative, Resah plans to extend this system of data exchange to most of its suppliers, including those in foodservice and laboratory supplies.

¹ Interim Report, by Lord Carter of Coles: https://www.gov. uk/government/uploads/system/uploads/attachment_ data/file/434202/carter-interim-report.pdf



About the Author



Vani Barsoumian is a project manager at Resah, with 10 years of experience in hospital management. She leads projects aimed at improving the performance of purchasing activities in hospitals. Vani leads the eCatSanté project, organising healthcare stakeholders and working to harmonise and

optimise data management related to healthcare products (pharmaceuticals and medical devices) in hospitals. Vani graduated with a Masters degree in Healthcare Economy from Paris-Dauphine University and with a University degree in Hospital Management.

About Resah

Resah is a public group purchasing organisation in France that supports high performance for all actors in the healthcare, medico-social and social sectors, thanks to mutualisation and professionalisation of purchasing and logistical activities. Its activities are organised around two major areas of services: as a purchasing group and as a resource and expertise centre.

www.resah.fr

Suppliers and GPOs

Delivering life-saving treatments and end-to-end traceability for patient safety

Johnson & Johnson Supply Chain (JJSC) is comprised of more than 63,000 professionals worldwide who support the global supply chains of Johnson & Johnson's business segments—from planning and sourcing to manufacturing, logistics and deployment. When delivering medicines to healthcare providers and patients around the world, JJSC in Germany is leading the way to ensure the authenticity and safety of these drugs with its serialisation programme, supporting the European Union (EU) Falsified Medicines Directive. Using GS1 standards as a foundation, JJSC is confident that compliance can be simplified as more and more European countries adopt the GS1 common language of business.

By Dirk Van den Wouwer, Christiane Puellen-Lanckohr and Marian Omtzigt

Johnson Johnson SUPPLY CHAIN

Global compliance strategy

Dirk Van den Wouwer, EMEA End-to-End Traceability Leader with JJSC, is responsible for the serialisation and traceability programme of all products manufactured in the EMEA region (Europe, Middle East and Africa) and distributed throughout the world.

"Since we serve the global marketplace, we must comply with all of the different regulations in the different regions and countries—something that could be quite complex," says Van den Wouwer.

As the EMEA regional lead for the global serialisation and traceability programme, Van den Wouwer is making sure that all JJSC production and distribution sites including processes and systems, are ready for the EU Falsified Medicines Directive (FMD) 2019 deadline.

An integral part of the company's global compliance strategy is GS1 standards.

"We are using GS1 standards, a combination of serial numbers and GTINs (GS1 Global Trade Item Numbers) in barcodes to uniquely identify each product," says Van den Wouwer. "This allows us to track and trace the packaged product, from our manufacturing site to any patient, in any country across the globe."

We have invested and continue to invest in standard operating procedures, common platforms and GS1 standards to help us simplify processes to speak 'one business language' in our multinational environment. The more global the healthcare supply chain becomes, the more it is a 'must' to work with standards."

Dirk Van den Wouwer, EMEA End-to-End Traceability Leader, Johnson & Johnson Supply Chain

Compliance could be greatly simplified if one set of standards was accepted and used in the various

countries in which we do business."

Christiane Puellen-Lanckohr, Director of Business Quality, Janssen Germany

Simplifying complexity

Van den Wouwer explains why JJSC has chosen to use GS1 standards globally. "In the healthcare industry, supply chains have become increasingly complex and vulnerable to falsified medicines. We have invested and continue to invest in standard operating procedures, common platforms and GS1 standards to help us simplify processes—to speak 'one business language' in our multi-national environment. The more global the healthcare supply chain becomes, the more it is a 'must' to work with standards."

Complexity is also a growing challenge in healthcare provider environments. The use of specialised drugs for targeted treatments of specific diseases has meant an increase in the number of medicines used—and an increase in the exposure for falsification. To keep patients safe, regulations across the globe like the EU's FMD are requiring the serialisation of drugs.

Yet, Christiane Puellen-Lanckohr, Director of Business Quality for Janssen Germany, the pharmaceutical company of Johnson & Johnson in Germany, advises "implementing the FMD regulation across different countries with different interpretations of the legislation can be complicated." She says, "Compliance could be greatly simplified if one set of standards was accepted and used in the various countries in which we do business."

As we rollout traceability across Europe, having common standards in place and used will help us stay on track and schedule."

Dirk Van den Wouwer, EMEA End-to-End Traceability Leader, Johnson & Johnson Supply Chain

Ensuring interoperability

Indeed, without a common approach, managing the labelling and packaging of drugs that are bound to as many as 32 countries in the EU, European Economic Area (EEA) and Switzerland could be costly and time-consuming.

"This is why we—across JJSC—are using GS1 standards to provide a common foundation for product identification and traceability," says Van den Wouwer. "This will help us improve efficiencies, lower costs, reduce errors and ultimately, save time when meeting regulatory deadlines."

While GS1 standards are global, some countries have their own national numbers used in their reimbursement systems. To support interoperability, GS1 has created a standard that allows it to capture that national number in addition to the GTIN in the barcode.

"In Germany, we had the option to use a GS1 compliant number or another in-country alternative," comments Van den Wouwer. "When establishing our traceability pilot, we chose the GS1-compliant number since it works within the GS1 system of standards, simplifying our crossborder business operations."

Marian Omtzigt who is the Serialisation Business Process Manager EMEA adds, "Using GS1 standards makes good business sense. There was no need to adjust or modify our systems or packaging processes, which saved us significant costs and time. The national number and GTIN are 'encoded' in the same barcode so that both can be read with a single scan to identify the package as it travels through the supply chain—a benefit for us and our customers."

Today, the majority of worldwide countries are accepting and using the GS1 standards. "As we rollout traceability across the globe, having common standards in place will help us stay on track and schedule," says Van den Wouwer. "Furthermore, we will be able to implement within a relatively short timeframe the mandate to publish our serialised GTINs in the European Hub system."

Learning early with pilots

In support of the FMD, JJSC took a leadership role in 2011 to work with the European Federation of Pharmaceutical Industries and Associations (EFPIA) and other innovation-based pharmaceutical manufacturers to help with the creation of the European Stakeholder Model (ESM), ensuring as such the design, development and establishment of the European end-to-end verification system that enables medicines to be verified at the point of dispensing.

JJSC was also instrumental during the vendor selection process, helping to establish a quality system for the European Medicine Verification Organisation (EMVO) and European Hub.

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Marian Omtzigt, Serialisation Business Process Manager, EMEA Johnson & Johnson Supply Chain

At the end of 2015, JJSC tested its end-to-end serialisation and verification process in Germany. The German pilot focused on six products, produced in two manufacturing plants.

Serialised GTINs encoded in barcodes were applied to packages, published in the European Hub, Europe's centralised data distribution system, and then downloaded to securPharm, Germany's national medicines verification system.

As packages arrived in the 400 pharmacies that were part of the pilot, they were successfully authenticated via the European Medicines Verification System.

"With this pilot in Germany, we proved that our system and standards work from end to end," Van den Wouwer explains. "We built close partnerships with the European Medicine Verification Organisation and those who manage securPharm. By piloting the process, it helped us learn 'on the go' so that we can share and leverage our experiences in the next pilots that we will conduct."

One notable lesson learned is the need to publish master data in the European Hub system with the expectation that master data requirements may differ from country-to-country in the future. With this in mind, JJSC is now planning the next pilot, to include more products in more sites, and with master data requirements as a pilot priority.

"With growing confidence and plenty of lessons learned, we will continue to implement this new serialisation process 31 more times before 2019," says Van den Wouwer.



In its pilot, JJSC proved that its system and GS1 standards worked to provide traceability from manufacturing to pharmacy.



Planning with confidence

While this may sound overwhelming, Van den Wouwer points out that it doesn't have to be.

If a single standard was applied across all countries, JJSC could start immediately adjusting its systems and artwork for all products and packaging to accommodate a highly efficient rollout of the new FMD-compliant serialisation process.

Yet, the FMD framework allows for small differences regarding the type of unique identifier, which means necessary artwork changes and other actions cannot truly begin until those decisions are in place for a specific country.

Even with this uncertainty, Van den Wouwer and his team are confident in meeting the 2019 deadline. "We have plans in place on how to move forward with our systems, processes and retrofitting the different lines in our manufacturing sites. Yet, as critical regulatory information for changes such as artwork move further out in time, this 'snowplow effect' could turn a relatively straightforward, standards-based process into a more and more complex one."

Ready for the world

As new regulations emerge in other parts of the world, JJSC will be ready with GS1 standards.

"At JJSC, we have built an enterprise-wide set of capabilities, leveraging GS1 standards for worldwide regulatory compliance," says Van den Wouwer. "As regulations evolve across the globe, we will be able to more easily and quickly report to regulatory authorities."

At the same time, Van den Wouwer stresses that "the value of GS1 standards extends far beyond compliance—simplified processes, lower cost of ownership, shared systems and quality data."

"Perhaps the biggest advantage is the common language that enables a common system for interoperability across companies, industries and even countries," explains Van den Wouwer. "With the FMD as a backdrop, I'm confident that we will come together in Europe with patient safety as a common goal and GS1 standards as a common language."

About the Authors



Dirk Van den Wouwer is the lead for EMEA serialisation and traceability for JJSC. With more than 25 years of experience, Van den Wouwer has held various leadership positions in supply chain management, program management, global planning and business process development. He holds masters degrees in Engineering

with specialisation in Operations Management and Logistics.



Christiane Puellen-Lanckohr is a pharmacist and has worked in the pharmaceutical industry for more than 23 years, primarily in Quality with experience in Pharmacovigilance, Regulatory, Supply Chain and Commercial. As the director of Business Quality with Janssen Germany, she is committed to

ensuring quality practices are part of the company's operations for targeted outcomes.



Marian Omtzigt is the Serialisation Business Process Manager EMEA with JJSC. She works with the JJSC Brand Protection and Supply Chain Visibility organisations, engineering, manufacturing and distribution centres to influence and direct Johnson & Johnson's global serialisation strategy.

About Johnson & Johnson Supply Chain

Johnson & Johnson Supply Chain encompasses four segment supply chains (Pharmaceuticals, Consumer Products, Medical Devices, and Diabetes & Vision Care) that cover planning, sourcing, internal and external manufacturing, Customer Logistics Services and the Supply Chain Strategy and Deployment. Additional enterprise-wide functions that are part of Johnson & Johnson Supply Chain include Quality & Compliance, Environment, Health, Safety & Sustainability and Engineering & Technical Operations.

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Dirk Van den Wouwer, EMEA End-to-End Traceability Leader, Johnson & Johnson Supply Chain

Suppliers and GPOs



Piloting traceability of prescription drugs with GS1 standards

The U.S. Food and Drug Administration's (FDA) 2013 Drug Supply Chain Security Act (DSCSA) requires that the pharmaceutical industry implement end-to-end traceability by 2023. As trading partners, Johnson & Johnson Supply Chain (JJSC) and AmerisourceBergen (ABC) chose to implement and test GS1 standards-based solutions in a real-world pilot to meet the deadline for interoperability. While GS1 standards have created a hierarchy that reaches down to the product level for serialisation, several industry entities have voluntarily chosen to use GS1 EPCIS (Electronic Product Code Information Services) to fully meet the intent of the regulation. EPCIS allows trading partners to exchange data in concert with products as they move through the supply chain. The industry pilot between JJSC and ABC did just that, with actionable and repeatable results.

By Matt Sample, ABC, and Mike Rose, JJSC



A prescription for clear vision

When it comes to pharmaceutical traceability, ABC is in the thick of it as a wholesaler positioned between more than 450 pharmaceutical manufacturers and more than 60,000 customers, including pharmacies and healthcare providers. In addition to its core distribution services, ABC is also a private label manufacturer, re-packager, 3PL service provider and specialty pharmacy, operating at the origin, middle and end of a vast global supply chain.

Naturally, compliance is a critical issue for the pharmaceutical industry. The DSCSA, which was signed into law on 23 November 2013, requires the industry to institute an electronic, interoperable system to identify and trace by 2023 certain prescription drugs distributed in the United States.



ABC and JJSC agreed that a traceability pilot that involved serialisation of individual products would provide valuable information for the industry. The collaboration highlights the importance of having a robust, well-implemented serialisation platform—one that opens up a host of future supply chain and commercial capabilities, enabling the delivery of a reliable supply of highquality products and other services to customers.

Both companies saw this pilot as an opportunity to not only help develop the industry solution, but also provide insights that may help customers leverage it beyond just compliance to benefit them and their patients.

ABC and JJSC are long-term members of the GS1 Healthcare US Initiative¹, the voluntary user group

¹ GS1 Healthcare US Initiative: https://www.gs1us.org/ industries/healthcare/initiative



implementing global standards to address patient safety and deliver supply chain efficiencies. With "the global language of business" supplied through GS1 standards, traceability mandated by DSCSA is exceedingly easier.

To enable serialised product identification and end to end traceability, the Janssen Pharmaceutical Companies of Johnson & Johnson have opted to leverage GS1 standards. At the saleable level, a Global Trade Item Number® (GTIN®) with a serial number is encoded in a GS1 DataMatrix barcode to establish global uniqueness. This unique identification allows trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

Let the pilot begin

ABC and JJSC decided on a four-week pilot program in a live production setting, excluding the several months of planning that preceded it. Beginning at the point of manufacture, a GS1 DataMatrix barcode, containing a serialised GTIN, batch/lot number and expiration date, was applied to each lowest saleable unit. The lowest saleable units were packed into cases, creating a parent/child logical hierarchy, commonly referred to in the supply chain as an "aggregation."

Product cases were then loaded onto a pallet or other logistics units, establishing yet another level of the aggregated hierarchy. At supply chain points downstream from packaging, automated vision systems or manual barcode scanners read the GS1 DataMatrix barcode to capture the GTIN, serial number, batch/lot number and product expiration date.

GS1 EPCIS was used to record business events associated with the serialised GTIN at various critical points along the supply chain, including commissioning, packing and shipping, followed by receiving and unpacking by the buyer.

Serialised product was moved from manufacturing to distribution, and once the wholesaler placed an order and the truck departed, JJSC issued an EPCIS message containing the serialised GTINs and aggregated hierarchies contained in the shipment. This provided the ABC distribution centre with the details of the specific products that were on their way.

When the shipment arrived, the EPCIS events and inference of the aggregated contents allowed



ABC to confirm receipt—without opening a single case—of every single item that had begun its journey at the manufacturing site. Using the EPCIS standard as a foundation provides for a more streamlined, interoperable process, as systems using it are designed with similar data requirements across the supply chain. Providing DSCSA-compliant EPCIS files that include master data for material attributes, as well as valid Global Location Numbers (GLNs) and GTINs, helps the process go smoothly.

Benefits beyond compliance

Serialisation and traceability can also bring value to the businesses above and beyond regulatory compliance. Leveraging GS1 standards helps improve patient safety and provide a means to investigate counterfeit and diverted products. It improves internal and external supply chain integrity.

With the implementation of serialisation and traceability, a serialised product can be traced from a manufacturer to the end customer, and used to further ensure that patients and customers receive quality, genuine products. Additional benefits such as being able to more effectively manage and verify returns are a bonus.



Key members of the ABC pilot team include (left to right): Matt Sample, Alex Philips, Josh Sutherland, Pat Burress and Girish Sethuram (scanning).

With GS1 standards, specifically the use of GLNs and GTINs, identification of a product and its unit of measure will become clearer to the entire supply chain. In the future, there's also immense value in utilising GTINs for ordering processes.

Lessons learned

This pilot helped JJSC and ABC to validate and challenge end-to-end business processes and architecture, identifying ways to improve their processes for successful end-to-end traceability. It also showed how important it is for companies' internal management systems and traceability processes to perform in unison. For instance, JJSC found that its products were arriving on ABC's loading docks before product data arrived, because of the way JJSC had batched its data transmissions. This led them to challenge and reconfigure old ways of thinking. The pilot was a reminder of how many processes and IT systems the company has in play, and the need to synchronise them.

The pilot also proved that a missing element of data—whether it's a dosage form or a single letter in the description of the product can drastically impact the efficiency of the pharmaceutical supply chain, potentially leading to disruption for patients. A profound emphasis on cleansing existing master data and establishing robust data governance will be crucial to success going forward. Data formatting issues—how others are encoding data using GS1 standards—are crucially important, as is thorough testing with the right amount of volume in production.

Something as seemingly simple as labelling requires careful consideration. A case displays multiple labels—a Healthcare Distribution Alliance (HDA) label, a two-dimensional (2D) matrix label, another put on by transport and logistics, among others. This can be a source of confusion at stops along the supply chain. Glare resulting from shrink wrap and flashing lights can also impede automated barcode capture; damage to cases can compromise label readability. For example, ABC found it was putting the 2D barcodes in the most vulnerable spot on the packaging, so that was changed for improved readability.

As a result of the pilot, JJSC and ABC are working with both GS1 US and HDA to update labelling guidelines. The pilot clearly demonstrated that this is not a casual exercise; it is a business transformation project, not to be underestimated.



Practice makes perfect

The exchange of data between businesses takes some massaging in the real world. It's advisable to start now and repeatedly test and practice implementing standards-based serialisation and traceability processes, while there's still time to work out the kinks.

Trading partners will also need to establish a clear understanding of exceptions—how often they occur, how to deal with them and what will be deemed acceptable by the regulator (in this case, the U.S. FDA). Exceptions are a reality, especially with niche products, and the industry will need to know how to deal with them.

Robust communication is imperative. For this initiative to be successful, trading partners up and down the supply chain must collaborate and communicate. Collaboration is critical to helping companies align on objectives and resolve issues. By keeping the lines of communication open and continuing to develop and refine industry standards together, we will all be prepared to fulfil DSCSA requirements and continue to provide safe and effective medicines to our patients.

The key to success in meeting any instance of regulatory compliance really comes down to collaboration. It all rests on the willingness of industry partners across the supply chain to work toward consensus and then drive to adoption. This pilot has been a stunning example of true partnership as we move to establish a meaningful standard that serves our industry and protects patients.

The key to success in meeting any instance of regulatory compliance really comes down to collaboration. It all rests on the willingness of our industry partners across the supply chain to work toward consensus and then drive to adoption. This pilot with JJSC has been a stunning example of true partnership as we move to establish a meaningful standard that serves our industry and protects patients."

HEATHER ZENK, Vice President, Secure Supply Chain, AmerisourceBergen

Revelations of the pilot

- **The natural order of things.** The GS1 GTIN is not only foundational, but has tremendous value to enhance ordering processes and unit of measure ambiguity in the future
- The devil is in the details. What may seem like an inconsequential piece of data can derail communications between trading partners. Clean, quality data is imperative.
- **Timing is everything.** Make sure data transmissions precede product arrivals
- **Too much information.** With multiple labels on a case, be sure to follow labelling guidelines of those who have gone before; industry leaders share their expertise through the GS1 community
- Not trivial, transformational. Treat this as the business transformation that it is. Assign proper resources in time, investment and decision-makers
- The Carnegie Hall approach. Start now and practice, practice, practice
- **Take the chance.** This industry transformation presents the unusual opportunity of sharing best practices among partners, customers and even competitors
- **Everyone wins.** Bask in the benefits. End-toend traceability also helps trace counterfeit and diverted products, and delivers supply chain integrity and safe medicines for patients.



Key members of the JJSC pilot team include (left to right): Rebecca Hehnly, Thomas Pizzuto, Rosemary Hampton and Chris Reed.



EPCIS allows trading partners to exchange data in concert with products as they move through the supply chain. The industry pilot between JJSC and ABC did just that, with actionable and repeatable results.

About the Authors



Matt Sample is Senior Director of Secure Supply Chain at AmerisourceBergen. He is currently the business lead for the serialisation efforts at AmerisourceBergen and is responsible for managing all current and future DSCSA operations. Matt has over 15 years of experience in the medical device, pharmaceutical and

life sciences industry; working both for manufacturers, wholesalers and for a large consulting firm. He has held various roles in the areas of product development, lean six sigma, business system implementation and operational leadership. His most recent responsibilities have included leading a global medical device serialisation effort, device UDI implementation and, until joining AmerisourceBergen, he was the serialisation overall program lead at a mid-size pharmaceutical company.



Mike Rose is Vice President of Supply Chain Visibility with Johnson & Johnson Supply Chain (JJSC). He is responsible for leading JJSC's supply chain visibility program that is an enabler to delivering exceptional customer experience while improving supply chain effectiveness and integrity. Mike's responsibilities

include product identification and traceability, which includes serialisation and traceability, GS1 standards adoption, Unique Device Identification, and Global Data Synchronisation Network.

About the Companies

About AmerisourceBergen

AmerisourceBergen maintains partnerships with global manufacturers, providers and pharmacies to provide product access and efficiency throughout the healthcare supply chain. AmerisourceBergen is part of the largest global generics purchasing organization, the leading specialty pharmaceutical services provider, and the partner with more community and health system pharmacy relationships than any other. From product commercialisation and distribution to pharmacy, provider and manufacturer solutions, AmerisourceBergen is a leader patient care.

www.amerisourcebergen.com

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Government initiatives

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Government initiatives

Reference Architecture enables locating objects for Danish hospitals

Technologies to keep track of the location of people and physical objects, whether indoors or outdoors, are continuously improving and quickly reaching maturity. The ability of locating objects and people provides for a wide range of opportunities for healthcare providers to significantly improve the efficiency of their operations. The National Reference Architecture is serving as a common framework for information technology (IT) projects in Denmark's healthcare, enabling the automatic location and identification of objects. Its goal is to make it easier to exchange location-related information and to capitalise on investments in location-related systems. In short, the reference architecture aims to drive significant improvements in hospital operations with many related benefits for patient care. Also the *National Reference Architecture* points to standards such as the GTIN, GRAI, EPICS to support exchange of locating information.

By Lars Østrup Leiding



Providing guidance in Danish healthcare

In 2015, the Danish Health Data Authority and Danish Regions agreed to extend an existing reference architecture published by the Danish Regions covering all healthcare providers throughout Denmark. The Danish Health Data Authority established a working group with representatives from municipalities, regions and the Ministry of Health, with support from GS1 Denmark, resulting in the National Reference Architecture for Object Locating and Identification. The national reference architecture was completed in October 2016, with an English version made available in April 2017.¹ The Danish Health Data Authority ² has the task of creating coherent health data and digital solutions for patients and clinicians, research and administrative purposes within Danish healthcare. Thus the Danish Health Data Authority authorised by law to approve standards within healthit. Reference architectures describe architecture and points to standards within areas of strategic interest.

¹ http://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammerog-retningslinjer/referenceaktitektur-og-it-standarder/ referencearkitektur/object-locating-and-identification-1,-d-,0,-d-,4,-d-,3_en-public.pdf?la=da

² The Danish Health Data Authority can approve standards according to an executive order. Read more here: http://sundhedsdatastyrelsen.dk/da/ rammer-og-retningslinjer/om-referencearkitekturog-standarder/referencearkitekturer.

A call for a common solution

Danish healthcare providers continuously look for ways to provide high-quality patient care while better managing their time, resources and costs. Although patients feel safe in the Danish healthcare system, avoidable mistakes still occur. By improving logistics processes, healthcare providers can tap into an important source of efficiency improvements for their operations as well as avoid errors for greater patient safety.

Hospital staff can also spend a significant amount of time trying to locate other people, equipment and other assets. Time, effort and costs are expended in stocking goods and equipment; yet, savings could be realised if health services were more effectively shared and coordinated.

Streamlining a healthcare environment is certainly a difficult task since much of what takes place during a normal day in a hospital is inevitably unplanned. When unplanned activities override planned ones, people, equipment and assets that should be in one location, are suddenly needed to solve a problem in another.

It comes as no surprise that automatically identifying and locating these people, equipment and assets is essential to ensuring more efficient processes—for planned and unplanned events. With support from healthcare IT systems to help locate vital staff and equipment, healthcare providers can better plan, coordinate and use their resources.

Since enabling technologies are being developed rapidly and in many different directions, it is important that competences are adopted to avoid being locked into specific solutions. New technologies will create new possibilities for a better and more effective and efficient healthcare environment; therefore, it's critical that the healthcare industry respond to new developments in a way that allows us to develop "in the same direction."

Cross-sector services across regions and municipalities are becoming an increasingly important priority, which means that cross-sector equipment and services will be more prevalent in the future. It's expected that this development will gain momentum in years to come, adding pressure to the challenges mentioned above, and underscoring the need for a common approach. It comes as no surprise that automatically identifying and locating these people, equipment and assets is essential to ensuring more efficient processes—for planned and unplanned events. With support from healthcare IT systems to help locate vital staff and equipment, healthcare providers can better plan, coordinate and use their resources.

Alignment for all IT systems

The National Reference Architecture supports all IT systems that enable traceability for healthcare providers. It establishes targets and a framework, so that the various healthcare stakeholders can align and develop a traceability solution together and achieve interoperability.

The reference architecture provides a layered architecture. Included in the architecture is an integration system model that receives and presents identification data via an identifier such as a Global Trade Item Number® (GTIN®), Serial GTIN, Global Returnable Asset Identifier (GRAI) and Global Individual Asset Identifier (GIAI) along with location data identified by a GS1 Global Location Number (GLN), using established GS1 standards like EPCIS for creating and sharing event data.

Currently, the systems that produce location data and the systems that use the location data are not interoperable. With the reference architecture, an increase in usage with fewer integration problems is expected.

In short, the reference architecture helps provide a common and robust set of opportunities for introducing object-location systems, allowing healthcare providers to take advantage of the huge potential provided by these solutions.



Creating value in many ways

The National Reference Architecture is helping to achieve Denmark's vision and goals for increased efficiencies in its healthcare provider system. The reference architecture is comprehensive, ensuring its viability in supporting future, new business requirements and changes in the ever-changing healthcare environment.

This flexibility requires using globally approved standards, so that interdependencies between applications, technologies and external factors are minimised. The reference architecture ensures a "decoupling" between applications and their underlying technologies and infrastructure. For this, applications and technologies must be able to evolve independently of each other and without major interdependencies.

To describe the value created by the reference architecture, the following use cases provide some examples:

- Improved inventory management in the home healthcare sector with easier and more precise inventory processes, including the retrieval of equipment on loan
- Locating the nearest member of staff in order to assign a specific task in the home healthcare sector
- Better planning of service tasks by making it easier to find workers for specific tasks in hospitals
- Learning from analyses of location data to optimise transport routes and inventory management in hospitals
- Getting a notification when a dementia patient leaves a specific area and being able to locate this patient quickly
- Using location data on a national basis for research and planning, in particular
- Locating diverse pieces of healthcare equipment on loan for retrieval, avoiding the loss of equipment and associated expense of replacements

A number of benefits

Using the reference architecture has proven to deliver (and will continue to deliver) a number of benefits for healthcare providers and their IT systems, including:

 Simplifying systems integration, making it easier for systems to communicate with each other

- Facilitating access to location data and its value
- Delivery of a platform for reusing methodologies and software components across systems
- Providing a conceptual framework for communicating about object location and identification
- Serving as an inspiration for new systems or changes to existing systems, so that the data available is used in the best possible ways
- Providing a guideline for requirement specifications in the procurement of IT solutions
- Increased reuse and reduced operational problems associated with integration of systems
- Serving to substantiate standards approvals by the Danish Health Data Authority

The National Reference Architecture is helping to achieve Denmark's vision and goals for increased efficiencies in its healthcare provider system.

About the Author



Lars Østrup Leiding, Enterprise Architect with the Danish Health Data Authority, has 10 years' experience in Enterprise Architecture. He works whithin interoperability and standardisation. Lars is engaged in strategic initiatives for creating a modern health sector and take part in the development for the new

common public architecture in Denmark. Lars holds a MSc. in Physics and Computer Science and is TOGAF certified.

About the Danish Health Data Authority

The Danish Health Data Authority is responsible for creating coherent health data and digital solutions that benefit patients and clinicians as well as research and administrative purposes in the healthcare sector. As such the Danish Health Data Authority provides health data about activities, finances and quality to healthcare professionals in regions and municipalities as well as citizens and other relevant users. It strengthens the overall digitisation; and promotes a coherent data and IT infrastructure in the healthcare sector focusing on data security.

http://sundhedsdatastyrelsen.dk/da



SNOMED and GS1: Harmonising standards to benefit New Zealand healthcare

Globally, the Systemised Nomenclature of Medicine - Clinical Terms (SNOMED CT) and GS1 standards uniquely identify medicines, using standardised numbers for both clinical and supply chain purposes. Work is underway to harmonise and make these systems interoperable. The New Zealand Health Information Standards Organisation (HISO) has mandated a national medicines terminology for New Zealand and defined standards for using SNOMED CT and GS1 Global Trade Item Numbers (GTINs) to manage health information and enhance clinical decision-making outcomes. The challenge is to drive efficiencies and improve outcomes by harmonising GS1 and SNOMED CT standards. A first step is a cross listing of New Zealand Medicines Terminology (NZMT) and GTIN-based information into both their respective clinical and supply chain systems. Through a pilot involving a sample selection of pharmaceutical manufacturers, GS1 and the New Zealand Universal List of Medicines (NZULM) have demonstrated that GS1 and SNOMED CT identifiers can be harmonised and leveraged to benefit the NZ healthcare sector through enhanced, more informed clinical decision-making, leading to improved patient safety outcomes. Learnings from this pilot and recommendations for the rollout of the pilot to all suppliers are presented.

By David Mitchell

Introduction

Leveraging international best practices

Internationally, two major not-for-profit standards development organisations have worked collaboratively to implement and support global standards for clinical and supply chain purposes.

SNOMED International develops and administers the SNOMED CT terminology, which provides standardised clinical terminologies and concepts. GS1 is the "global language of business" that enables unique identification, data capture and sharing of that data to increase supply chain efficiency and service delivery.¹

In 2010, SNOMED International and GS1 signed a Memorandum of Understanding and agreed to collaborate to make their respective systems harmonised and compatible.²

¹ GS1 New Zealand Profile document

² SNOMED International briefing paper, 5 August 2015



Through a pilot involving a sample selection of pharmaceutical manufacturers, GS1 and the New Zealand Universal List of Medicines (NZULM) have demonstrated that GS1 and SNOMED CT identifiers can be harmonised and leveraged to benefit the NZ healthcare sector through enhanced, more informed clinical decision-making, leading to improved patient safety outcomes.

In 2013/14, GS1 and SNOMED International agreed to develop principles for linking SNOMED CT and GTINs within a country.²

Most recently, in April 2016, a new collaborative agreement between GS1 and The International Health Terminology Standards Development Organisation (IHTSDO) was signed to support the interoperability of health information systems globally.³

The objective was to facilitate links between the clinical information in clinical records (SNOMED CT) and point of care systems (using the GTIN), to ensure patients receive the correct medicine.³

Applying at a national level

This case study outlines a New Zealand pilot project between GS1 and the New Zealand Universal List of Medicines (NZULM) to harmonise clinical and supply chain-related systems in the healthcare sector.

In New Zealand, the Health Information Standards Organisation (HISO) supports and promotes the development and adoption of health information standards for the health system.⁴ HISO links with the international standards community through:

- SNOMED International for SNOMED CT
- HL7 New Zealand for HL7 standards
- GS1 New Zealand for GS1 supply chain standards⁴

HISO has endorsed:

- SNOMED CT as the national clinical terminology.⁵ As part of this, HISO mandated the development of the New Zealand Medicines Terminology (NZMT) within the NZULM as the national SNOMED CT based medicines terminology.
- GS1 standards for automated product identification for all medicines, including barcodes, the GTIN product identifier and other associated data definitions (commonly referred to as Application Identifiers or Als).⁶

Recently, HISO also endorsed to:7

- Use the GTIN as the medical device identifier for all supply chain purposes.
- Support the programme to develop a unique device identifier (UDI) standard based on the GTIN as the device type identifier.
- Support the SNOMED International project to develop a medical device model and terminology using SNOMED CT.
- Establish a SNOMED CT-based medical device terminology for clinical documentation and decision support.
- Record GTIN and other UDI data elements (e.g., the Global Location Number or GLN) in clinical documentation for product traceability.

HISO intends these initiatives to ensure that medical devices can be safely prescribed, dispensed and administered and be properly ordered, distributed and tracked.⁷

Most recently, in April 2016, a new collaborative agreement between GS1 and International Health Terminology Standards Development Organisation (IHTSDO) was signed to support the interoperability of health information systems globally.

^{3 &}quot;New Global Collaboration between GS1 and SNOMED International" press release, 22 April 2016: https://www.gs1. org/articles/1875/new-global-collaboration-between-gs1and-ihtsdo

⁴ HISO website, http://healthitboard.health.govt.nz/health-itgroups/health-information-standards-organisation-hiso

⁵ http://healthitboard.health.govt.nz/standards/endorsedstandards/snomed-ct-endorsement

⁶ http://healthitboard.health.govt.nz/standards/endorsedstandards/gs1-standards

⁷ Medical Device Terminology and Identification Standards, http://healthitboard.health.govt.nz/hiso-1002422016medical-device-terminology-and-identification-standards



Standards-based New Zealand healthcare initiatives

The New Zealand Universal List of Medicines (NZULM)

The NZULM provides the national medicine list and associated core information about those medicines including indications, contraindications, adverse effects and dose forms.

The NZULM currently combines product information from:

- New Zealand Medicines Terminology
- Medsafe (medicine regulatory information)⁸
- PHARMAC (medicines subsidy information)⁹
- Pharmacode (a proprietary New Zealand pharmacy product identifier)¹⁰
- Supplier data

The NZMT data model has seven concepts allowing medicines to be described and identified at all levels of abstraction.

The Containered Trade Product Pack (CTPP) describes the physical product and is the point

of linkage between the NZULM conceptual world and the physical world.

The National Product Catalogue (NPC)

GS1 New Zealand's implementation of the GS1 Global Data Synchronisation Network (GDSN) is known as the National Product Catalogue. Suppliers load item master data information into the NPC and then publish it to their data recipient(s). The NPC is based on GS1 standards, with the GTIN as the mandatory product identifier.

Challenge

The challenge is to connect the New Zealand clinical and supply chain worlds and drive greater efficiencies and better outcomes for the healthcare sector by harmonising and integrating GS1 and SNOMED CT standards.

The key to harmonising the data sources is for GS1 New Zealand and NZULM to incorporate the CTPP SCTID and GTIN in their respective databases.

⁸ Medsafe - New Zealand Medicines and Medical Device safety Authority - www.medsafe.govt.nz

⁹ PHARMAC - Pharmaceutical Management Agency - www. pharmac.govt.nz

¹⁰ Pharmacode is administered by the New Zealand Pharmacy Guild - www.pgnz.org.nz



Solution

The interface between the NZULM and GS1 can be summarised in this way: 11



The key to harmonising the data sources is for GS1 New Zealand (GS1NZ) and NZULM to incorporate the CTPP SCTID and GTIN in their respective databases. Mandatory listing of CTPP SCTID in the NPC and GTIN in the NZMT data field will be the first step in creating a link between the NZULM and GS1NZ¹². These key data elements form the bridge between the two systems and open the way for more extensive mapping of the NZULM and NPC listings in the future.

Harmonisation pilot project

GS1NZ and the NZULM collaborated to test the process of integrating supplier product data from the GS1 National Product Catalogue into the NZULM clinical database.

Project objective and expected benefits

The overall objective is to enhance patient and clinician safety in the future by improving medication management, dispensing and medicine administration at the point of care. The immediate objective was to create reference data that serves both clinical and supply chain purposes.

The main benefits of undertaking the project are to provide the following: $^{\rm 13}$

- Greater value for existing suppliers on the NPC. Pharmaceutical suppliers who currently have data loaded to the NPC will be able to publish their product information to the NZULM.
- Greater value for existing users of the NZULM. Accessing market and product information from the NPC via the NZULM will make clinical systems easier to use and provide greater utility.
- Enhanced patient and clinician safety when administering medication and improve stock management.

¹¹ Mitchell, David, "NZULM: GS1Net harmonisation" presentation, GS1 Healthcare User Group Conference, September 2015

¹² SNOMED CT Identifier for a product from the NZULM.

¹³ Project scope document, business case section, 30 January 2015

Implementation approach and progress

The pilot project involved three phases:

Phase 1: Access, set up and testing. During this phase, the NZULM was set up as a data recipient of the NPC. While the overall aim was for multiple data attributes to be incorporated into the NZULM database, the importation of GTINs took priority, with other attributes to be agreed upon and incorporated at a later stage. Likewise, the CTTP SCTID was identified as the key attribute, which suppliers needed to complete and populate in the NPC. The CTPP SCTID will match the NPC data associated with a GTIN to the NZMT in the NZULM database. GS1 New Zealand provided support by downloading the test data from the NPC for importing into the NZULM. The aim was to assess the upload process and review the data presentation in the NZULM database.

Phase 2: Training and utilisation of the NPC recipient (NPC-R). GS1NZ trained NZULM personnel to download supplier data from the NPC using what is known as the "NPC recipient tool." Workload concerns led the NZULM to a decision to use a sFTP connection. This connection ensures electronic messaging of item master data updates would be automatically placed into the NZULM sFTP mailbox. This process is still in pilot mode and as such has not been fully utilised. Additional training will be provided by GS1 New Zealand to enable the NZULM team to interpret NPC XML messages and incorporate them into their NZULM database.

Phase 3: Collaboration with suppliers. A small sample of pharmaceutical suppliers with existing NPC catalogues were identified and invited to participate in the pilot project. These suppliers were chosen because of the quality and volume of their data in the NPC. They were each asked to add the CTPP SCTID code against each of the GTINs in their NPC catalogue and were provided training by GS1 New Zealand on how to publish to the NZULM as a data recipient.

The result was the incorporation of previously unpublishable GTINs into a newly introduced data field in the NZULM, along with the existing CTPP SCTID code.

Learnings from the pilot project

To date, key learnings from the project are:

- Supplier understanding of the NZULM is limited. Consequently, the NZULM will now likely provide a supplier guide and a "getting started" pack to educate and empower suppliers to verify NZULM-to-NPC mappings for their products.
- Managing data quality is a critical but a time-consuming task. The process of assisting suppliers to map product listings was refined as the pilot progressed. The most efficient approach was for the NZULM to provide a list of NZULM listings and CTPP SCTID codes for the supplier. This made it easier for suppliers to populate the field in their NPC catalogue and subsequently publish data to the NZULM. The NZULM also highlighted the need to support suppliers with difficult to map products. Data errors¹⁴ can occur, especially where the product identifier data is manually entered into the systems. Importantly, a system to electronically upload data as well as a quality management system is needed to prevent errors entering both databases.
- New business processes are required. Not all products have NZULM listings and it is important to add new NZULM listings when gaps are identified. In the long-term, a new process of incorporating medicine registration and GTIN allocation and importation into the NZULM could streamline the overall process for suppliers.

Future steps

The next step is to develop a strategy and framework for rolling out this initiative to the wider healthcare community. The key themes for improving the process include:

1. Define the future NZULM data set

The additional NPC attributes to be provided to the NZULM in future will be determined. They are expected to include the following NPC supplier data elements:

- Product availability dates
- Expiry date
- Trade item description
- NZ Business Number (NZBN, which is essentially a GLN)

¹⁴ Between 2% and 5% in the test series.



2. Provide suppliers with assistance

Reducing supplier workload is essential. Providing a supplier process guide, a list of pre-mapped medicines for verification where possible, training to understand the NZULM and management of any data gaps will lessen the burden on suppliers.

3. Make better use of the NPC recipient tool and sFTP mailbox

GS1 and NZULM will work together to enhance NZULM skills on downloading data from the NPC recipient tool, subscribing to suppliers' NPC catalogues and using the sFTP mailbox to manage supplier updates efficiently. The NZULM will develop tooling to accept updated data and incorporate it into their database automatically.

4. Business process development for mapping is needed

To ensure correct mappings between CTPP SCTID and GTIN, a quality control process will be developed to cover the various use case scenarios (e.g., new, obsolete listings). This will take into account the full workflow processes from suppliers applying for consent to distribute right through to incorporating the additional healthcare attributes into the NPC and importing them into the NZULM database.

Conclusion

The successful sharing of the GTIN between the two systems has demonstrated that GDSN: NZULM interoperability is technically achievable in fulfilling stated clinical and supply chain outcomes. GS1 New Zealand and NZULM have proven that these important standards can co-exist in different systems and interoperate and be leveraged to benefit the entire NZ Healthcare Sector.

The pilot has greatly assisted the international work effort in aligning GS1 and SNOMED standards to develop international guidance principles on linking.

About the Author



David Mitchell is trained as a pharmacist and has extensive experience in the New Zealand healthcare sector having worked in the pharmaceutical industry, health sector advocacy, and health informatics as well as working for a period in a senior role with Statistics New Zealand. He currently is Lead Terminologist with New Zealand Universal List of Medicines and

also practices part-time as a community pharmacist.

About the Organisations

About SNOMED

SNOMED International is a not-for-profit organisation that owns, administers and develops SNOMED CT. SNOMED CT is a clinical terminology created by a range of healthcare specialists to support clinical decisionmaking and analytics in software programs.

www.snomed.org

About NZULM

The NZULM is New Zealand's national medicines list for universal use across the health and disability sector. The NZULM provides an up-to-date and trusted, onestop-shop of core and commonly used information about medicines (and other products and devices where appropriate) for New Zealand. The NZULM brings together medicines information from Medsafe, PHARMAC and the Pharmacy Guild into a single standardised product, utilising the "common medicines language" in the New Zealand Medicines Terminology (NZMT).

www.nzulm.org.nz

About HISO

The Health Information Standards Organisation (HISO) supports and promotes the development and adoption of fit-for-purpose health information standards for the New Zealand health system. HISO works with health providers and shared services organisations, clinical and consumer groups, software vendors and industry bodies, the academic community, the wider government sector and other standards development organisations. HISO links with the international standards community through the International Health Terminology Standards Development Organisation (IHTSDO) for SNOMED CT, and through HL7 New Zealand for HL7 standards.

www.health.govt.nz/about-ministry/leadershipministry/expert-groups/health-information-standardsorganisation



Improved clinical and supply chain data for medication management enhance both patient and clinician safety.

Government initiatives



Improving patient safety and efficiency in the NHS

In 2014, the Department of Health mandated the use of GS1 standards as part of the National Health Service (NHS) eProcurement strategy. Called *Scan4Safety*, the programme to rollout GS1 standards across the acute care sector in England has since grown, and is now in the early implementation phase with six acute NHS Trusts selected as demonstrator sites. The adoption of GS1 standards allows for the unique identification of every patient, every product and every place across NHS acute Trusts. This will help to improve patient care and safety, efficiency, patient experience and support the standardisation of clinical best practices.

By Steve Graham



Make a significant difference

Scan4Safety is now supporting the NHS to improve the delivery of patient care and to drive process standardisation and efficiency to protect frontline care.

The *Scan4Safety* programme emerged out of a series of high-profile, ambitious and centrally led initiatives designed to enable England to become a global leader in the provision of digital health and care services that improve patient safety and transparency.

Published in 2013, *Better Procurement, Better Value, Better Care* was the precursor to the eProcurement strategy and set the scene for the drive to adopt GS1 standards in the English NHS. Lord Carter's report—*Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variations*—built upon the measures outlined in the 2014 NHS eProcurement strategy. It highlights that investment in digital platforms, improved staff organisation and a standardised approach to purchasing will make a significant difference in the way the NHS operates and could make a notable contribution to savings of up to £5 billion per year.

In February 2016, the Department of Health announced the six NHS acute Trusts in England that are now acting as *Scan4Safety* demonstrator sites, proving the benefits of the use of GS1 and PEPPOL standards. The six sites have received a share of £12 millon in funding and are documenting the benefits, as well as the challenges they encounter from using the standards.

GS1 UK is supporting the Department of Health to embed GS1 global standards across the NHS.

Degrees of readiness

Due to the size and complexity of the NHS, the main challenge is how to achieve the range of efficiencies outlined in the NHS eProcurement strategy. There are varying degrees of "readiness" across NHS Trusts, which differ in size, services offered, level of technology adoption and size of the population they care for. This requires a collaborative approach to implement GS1 standards.



Five achievements

What has been achieved so far?

1. Ministerial sponsorship

GS1 standards have been included in NHS policies for some years, although their wide scale adoption has been patchy. In 2014, the NHS eProcurement strategy received endorsement from the Parliamentary Under Secretary of State for Health, Dr Daniel Poulter MP.

This level of endorsement, coupled with clinical and professional support from both inside the NHS and from suppliers, has driven the *Scan4Safety* programme forward and given credibility to the work as it is rolled out to individual NHS Trusts.

2. NHS Trusts commitment

Across England, each NHS Trust is managed by a board of senior healthcare executives who make strategic and operational decisions. In support of the programme, each Trust was asked to nominate a senior executive to act as GS1 lead sponsor for its organisation. Over 80 percent of Trusts now have nominated leads to sponsor GS1 adoption in their organisations.

This level of engagement is evidence of a growing commitment by Trusts to adopt GS1 standards. It shows that Trusts are serious about harnessing the potential efficiency and patient safety benefits.

80%

Over 80% of Trusts now have nominated leads to sponsor GS1 adoption in their organisations.

3. Suppliers and technology and service providers commitment

In addition to the momentum that has built across the NHS for *Scan4Safety*, many suppliers to the NHS are also now engaged with the programme and working to adopt Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) across their product catalogues and operational estates. The commitment of suppliers is fundamental to the success of the programme, so as to ensure that products Through the *Scan4Safety* programme, the Department of Health has made available a fund of £12 million in order to demonstrate the anticipated benefits from the implementation of GS1 and PEPPOL standards into a healthcare environment.

designed for patient care enter hospital environments labelled correctly and traceable from their sources.

In addition, the commitment of technology and service providers that support the identification, capture and storage of information related to patients, products and places, is vital if the benefits of *Scan4Safety* are to be realised across the whole healthcare system in England. Commitment from this group has been similarly encouraging and has enabled the rapid realisation of benefits in the six demonstrator sites.

4. Central funding

Through the *Scan4Safety* programme, the Department of Health has made available a fund of £12 million in order to demonstrate the anticipated benefits from the implementation of GS1 and PEPPOL standards into a healthcare environment. This has kick-started the programme through an initial bidding round that ended with six NHS acute trusts being selected to implement the standards and document and record every benefit and every learning—every step of the way.

The expectation is that once the benefits have been proven, it will be easier to drive implementation across the rest of the NHS acute care sector in England.

5. Core enablers and primary use cases for implementing GS1 standards

Recognising the potential size and scope of the work involved for Trusts to fully adopt GS1 standards, the *Scan4Safety* programme accepted the decision to break up the task and, in the first instance, is promoting the use of GS1 standards across three core enablers.



The adoption of GS1 standards allows for the unique identification of every patient, every product and every place across NHS acute Trusts.

Three core enablers

The core enablers include:

1. Every person: patient identification

Globally unique identification of patients enables accurate and consistent identification at every stage of care and for relevant information to be captured and stored in an electronic patient record. This is seen as a major addition to patient safety and data quality in the NHS.

2. Every product: catalogue management

Scan4Safety has committed to delivering common coding for products across all aspects of healthcare based on GTINs. This will be delivered through the establishment of a national datapool service for the NHS, acting as a single route for data between the GS1 Global Data Synchronisation Network (GDSN) and all Trusts. Using this approach, Trusts can easily access accurate and transparent product information, enabling more accurate ordering, improved product availability and lower operating costs, as well as increasing efficiency and enabling the delivery of improved patient care.

3. Every place: location numbering

A single location numbering system, used by all Trusts and their suppliers, provides for the unique and unambiguous identification of every physical and operational location within the healthcare system. It enables the consistent identification of exactly where material and equipment is delivered, by whom it was received and where it was stored. The aim is that the information will extend to include where patient care events occur and which specific suppliers or partners were involved in the supply chain.



GS1 standards enable everything that happens to a patient to be recorded accurately and with minimal impact on patient or clinical staff.

The structure of the delivery of the *Scan4Safety* programme in NHS Trusts revolves around four "Ps." These are patient, product, place and process, relating to the three core enablers plus the addition of the vital step of process management and change, which is imperative if the GS1 and PEPPOL standards are actually going to be used. Therefore, the programme identity: *Scan4Safety*.

Alongside these three core enablers, *Scan4Safety* is first focusing on the implementation of GS1 standards to support three main applications or use cases. Concentrating activity on just three applications in the first instance, this will help to maintain focus on the adoption of GS1 standards in a healthcare environment of the size and complexity of the NHS.

Three applications

The three main applications or use cases are:

1. Purchase to pay

Automating purchase to pay processes and increasing the adoption of electronic, machineto-machine transfer of business transactional information, such as purchase orders, advance shipping notices and invoices, reduces the number of errors in these documents and avoids time delays.

2. Inventory management

Evidence to date suggests that one of the largest areas of opportunity for potential cash and efficiency savings is in the area of inventory management. Applying a common approach to the management of inventory across a hospital and making stock visible to all areas, reduces the overall level of inventory required by a Trust. At the same time, it increases the confidence of nurses and doctors in the availability of stock when needed for patient care.

3. Product recall

By linking improved product and location identification with better inventory management and the relationship of products to patient care events, product recalls can be executed easier and faster. This radically improves the visibility of the locations of medical devices used in patient care and significantly reduces the amount of time clinical front-line staff spend locating and processing returns.

Healthcare Advisory Board

GS1 UK has facilitated the coming together of industry leaders, senior clinical staff and regulators from across healthcare in UK to form the Healthcare Advisory Board. The board's aim is to improve patient safety, reduce regulatory non-compliance and realise cost savings from operational efficiencies across the NHS through the adoption and implementation of GS1 standards. It aligns support and engagement activities and ensures coordination across healthcare in the UK.

Healthcare User Group

GS1 UK, key healthcare users and industry stakeholders regularly meet to discuss the implementation of GS1 standards across healthcare in UK—particularly in the NHS. These sessions support the tactical application of GS1 standards, are forums that provide advice and technical expertise and encourage best practices across Trusts as well as manufacturers and suppliers.

Engagement with trade associations

The NHS eProcurement strategy states that ultimately, every supplier of every product and service in the NHS must adopt GS1 standards over a period of time. With potentially more than 50,000 suppliers of the NHS—from medical device suppliers to cleaning products and foodservice operators—embedding GS1 standards into the supply chain is a complex challenge.

Engagement is ongoing, through a series of regular meetings, with all the leading trade associations to drive awareness, education and support for the adoption of GS1 standards. Where appropriate, this is then being supplemented with direct engagement of major international manufacturers and distributors.

Numerous benefits

Adopting these three core enablers and the three main applications will allow Trusts to provide accurate and real-time records, reduce "neverevents" and drive patient- and activity-level costing.

Accurate and real-time electronic records

GS1 standards enable everything that happens to a patient to be recorded accurately and with minimal impact on patient or clinical staff.

For example, critical standard operating procedures (SOPs) can be implemented using handheld scanners or suitably equipped trolleys and would require the nurse to scan the patient, their own identity, the current location (for example, a bed bay or recovery room), the products administered and the equipment used. This would provide an accurate and real-time record of exactly *who* did *what* to the patient, *when* it happened and *where* it took place.

Having detailed and accurate electronic records will enable the identification of areas where outcomes are worse than should be expected and allow remedial action to be taken.

Prevention of never-events

Through the effective use of technology, GS1 standards also enable "what is about to happen to a patient" to be recorded accurately and with minimal impact on clinical staff, through use of barcodes and RFID (Radio Frequency Identification) tags. This can be checked against the patient record to make sure "what is about to happen" is correct, before it occurs.

For example, the implementation of ePrescribing enables the scanning of the patient, the equipment and the products that are going to be used to be checked against the prescribed treatment in the patient record. This means any potential errors can be identified and prevented before they are prescribed.

Patient- and activity-level costing

Having an immediate, accurate and detailed electronic record of what was actually involved in a treatment makes it easier to code everything correctly and ensures that Trusts are correctly compensated for the work they do, through the system of national tariffs. Trusts can also accurately compare payments received with the actual costs they incur, so they can financially plan more effectively. These benefits can be transformational for cash flow.

Since the 2012 McKinsey report, *Strength in unity: the promise of global standards in healthcare*, the benefits of GS1 standards in healthcare have been widely accepted. In the UK, the programme of work that is well underway is demonstrating these benefits and efficiency gains, while at the same time, supporting the NHS to build a better, patient-centred, health service that is ready for the future.

About the Author



Steve Graham leads the NHS eProcurement policy at the Department of Health in England. He developed the NHS eProcurement Strategy, published by the Department of Health in May 2014, and leads a small team focused on delivery of Scan4Safety, a project to implement GS1 and PEPPOL

standards in the NHS, working with six NHS Trust demonstrator sites and the NHS supplier base. Steve previously led the Innovative Technology Adoption Procurement Programme for the Department of Health, focused on increased adoption of medical technologies to improve patient outcomes while reducing costs. He has significant private sector experience, including: procurement roles in manufacturing; commercial director for the hospital division of a European pharmaceutical wholesaler; and director for an innovative supply chain finance solution provider.

About the Department of Health (DH)

DH is a ministerial department, supported by 15 arm's length bodies and a number of other agencies and public bodies. The department employs 2,160 staff who work in locations across England.

www.gov.uk/government/organisations/departmentof-health



GS1 Healthcare Reference Book 2017-2018



GS1 Healthcare Reference Book 2017-2018

About GS1 Healthcare

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 70 leading Healthcare organisations worldwide.

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

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