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GS1 Healthcare Reference Book 2018 - 2019

Stories of successful implementations of GS1 standards

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

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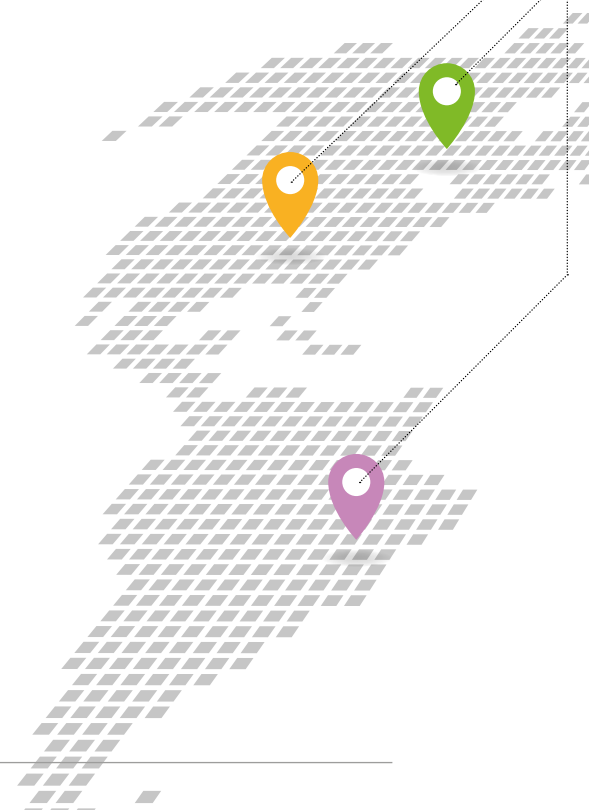
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The world is coming together to implement GS1 standards in healthcare.

With this latest edition of the GS1 Healthcare Reference Book, stories shared by healthcare stakeholders—from every part of the supply chain and from every continent—point to some significant developments. One can see the worldwide movement to using GS1 standards to help solve some of healthcare's toughest challenges.

1. There is increasing global recognition of the effect of falsified and substandard medicines.

In its 2017 report, *Global Surveillance and Monitoring System for Substandard and Falsified Medical Products*, the World Health Organization estimates "the observed failure rates of substandard and falsified medical products in low- and middle-income countries at approximately 10.5%."

Securing the supply chain through a track and trace system is seen as one of the tools to prevent falsified medicines from entering the market. This is where GS1 standards have a role.

Organised by GS1, hosted by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA) and supported by the United States Agency for International Development (USAID), the first African GS1 Healthcare Conference in May 2018 brought together more than 300 participants from 25 African countries and 13 countries outside of Africa to discuss how GS1 standards can be used to enable traceability for access to safe medicines.

Already, outcomes are being realised. The United Nations Population Fund (UNFPA) and USAID collaborated to test how the track and trace of health products with barcodes can be operationalised in the public health supply chains of Ethiopia and Pakistan. The pilots demonstrated that standardised product identification and barcodes can significantly improve accuracy over manual stock counts while significantly streamlining the stock-taking process, resulting in efficiencies. (See page 88.)

2. International collaboration is increasingly focused not only on the implementation of Unique Medical Device Identifiers (UDIs), but also on the role they can play when stored in implant registries.

When breast implants made by the French company PIP were found to contain industrial-grade silicone, the total number of women affected (about 300,000 in 65 countries) was simply an estimate since records detailing the identifier and batch of product used on each patient were often not kept consistently. Even today, it remains very difficult to find all affected patients.

GS1 standards are used by the large majority of medical device manufacturers to meet UDI requirements.

Precise and highly efficient medical device recalls rely on the ability to trace each device's UDI back to the patient via the healthcare provider's electronic health record system. Also, more and more countries are developing medical device and implant registries, including Australia, the Netherlands and the US.

At Leeds Teaching Hospitals in the UK, implants marked with GS1 standards are recorded electronically in patient records, so if a recall is needed, patients can be more quickly identified and brought back into the hospital with urgency. (See page 46.)

3. Healthcare providers are leveraging GS1 standards more and more in the clinical processes involved in patient care. GS1 identifiers encoded in barcodes have extended their reach into operating theatres, labs, pharmacies and more.

Nurses at Australia's Canberra Hospital are scanning GS1 barcodes on patient wristbands, clinical note labels and clinician ID cards when collecting pathology samples, resulting in a more than 40 percent reduction in wrong-blood-in-tube incidents. (.)

By scanning GS1 barcodes, Derby Teaching Hospitals now have a major database of all of their operating theatre procedures. The hospitals use GS1 barcodes to record co-morbidities. In particular, there has been major improvements in endoscopy practices based on the ability to track patient outcomes. (.)

4. Solution providers in healthcare are continuing to differentiate their offers and capabilities by integrating GS1 standards in their solutions. Healthcare providers and manufacturers alike are finding support from solution providers to be an essential factor for the successful implementation of standards.

With a need to implement a data management solution, Teleflex created a cross-functional team, including 1WorldSync and LANSA, solution providers actively implementing GS1 standards. Now, Teleflex can provide accurate, complete and validated product data to regulatory bodies and trading partners alike, including healthcare providers. (.)

5. There's growing acknowledgment that the use of GS1 standards produces a tangible return on investment, whether cutting costs, increasing revenue, preventing counterfeits or caring for patients better.

Research by the World Health Innovation Network identified returns-on-investment as high as 7:1 from hospitals in Canada, the UK and US that adopted GS1 standards in supply chain processes to strengthen health system performance. (.)

Let's come together.

- Please read more about these and other implementation case studies where learning experiences are realised and results are achieved.
- Learn how GS1 standards are improving healthcare processes around the world, making patient care better, safer and highly efficient.
- Then, join with us to make a difference in healthcare, using this reference book as a resource to help drive your own GS1 standards implementations!

By collaborating together—supply chain professionals, clinicians, suppliers, solution providers, humanitarian organisations, government and GS1—we can have a far greater impact than by working alone.

Healthcare
providers

Leveraging GS1 standards to ensure accuracy and safety of patient care at Canberra Hospital

To take full advantage of technologies available today, healthcare providers need to consider how they "capture" the identification of their patients and clinicians at the points of care. Supporting positive patient identification is especially important in busy clinical areas and where mis-identification could lead to adverse events. Using GS1 standards as the needed foundation, ACT Health and Canberra Hospital are identifying their patients and care providers for ensuring accuracy in patient-care processes throughout each patient's journey within their hospital. As a result, there has been more than a 40 percent reduction in wrong-blood-in-tube incidents based on clinicians scanning GS1 barcodes when collecting pathology samples.

By Ryan Mavin

Digitisation of healthcare

ACT Health provides healthcare services to an estimated 550,000 people in southeastern Australia. Like many parts of the world, the region's demographic is shifting towards an older profile of patients, with increased age-related, chronic conditions and heavier demand for health services. With the goal to achieve better outcomes for patients and increase patient safety, ACT Health is making significant investments in creating a digital healthcare infrastructure.

To do this, the healthcare system needed to develop a GS1 standards framework to support its digitisation of clinical processes across the ACT Health and Canberra Hospital campus. This also needed to be scalable for implementation at the new University of Canberra Hospital and Calvary Public Hospital Bruce.

Since its inception, ACT Health has worked to continuously improve its treatment of patients, identifying issues, establishing policies for prevention, and driving compliance of these policies. Yet, manual processes could only help so much. The health system found that as more and more patients needed services, there was always room for error.

"We were recognising incidents despite our efforts to implement policies to prevent them," says Ryan Mavin, Manager Enterprise Architecture Office, ACT Health. "Our wrong-blood-in-tube occurrences were above the national average. Based on an error-prone process when collecting pathology samples, there was an elevated risk of people getting the wrong treatments. Simply put: the situation was unacceptable."

Paper-based policies were not making a big enough difference. Rather, there was a need to harness the power of technology to create standardised, automated processes to support error-free patient care.

Engaging with GS1 Australia, the ACT Health team established the Location Based Services Steering Committee in 2013 and set off on its multi-year journey to transform patient care processes—starting specifically with the collection of pathology samples.

> " In the integrated world, it's hard to make a change without it having widespread impact on everything else. We needed to figure out ways to contain the impact and make the right changes with the greatest risk reduction and benefit. For us, that meant focusing on patient identification."

Peter O'Halloran, Chief Information Officer, ACT Health

Positive patient identification

"We needed to implement a more robust method to ensure the identification of patients and caregivers within the collection process to enable 'positive patient identification' (PPID) that is in line with the National Standard for patient identification and procedure matching," explains Mavin. "In addition, this method needed to be able to support other patient care interactions where PPID was required."

GS1 Australia helped the team to better understand how GS1 standards could help support the solution that was needed across the organisation. "GS1 introduced us to the ISO Technical Standard 18530:2014, which provided detailed workflows to assist us regarding pathology samples," says Mavin.

The ISO technical specification articulates how GS1 identifiers, specifically the Global Service Relation Number (GSRN), and Service Relation Instance Number (SRIN) can be used for patient identification and for care providers. The document then illustrates how these can be applied along with several other international standards to support good practices within a series of 30 use cases.

Creating the standards framework

The first step taken by the team was to implement GS1 identifiers as the building blocks for the PPID solution. ACT Health initially implemented GS1 identifiers with minimal integration and then built value through integrating the standards with its systems.

"In the integrated world, it's hard to make a change without it having widespread impact on everything else," explains Peter O'Halloran, Chief Information Officer, ACT Health. "We needed to figure out ways to contain the impact and make the right changes with the greatest risk reduction and benefit. For us, that meant focusing on patient identification."

The team needed to ensure that positive patient identification could only occur at the bedside by scanning the patient's wristband. To achieve this, the patient wristband's GSRN and SRIN identifier was electronically distinct from any other forms of patient identification such as the GSRN and SRIN identifier on the clinical notes labels.

"The GS1 publication of ISO Technical Standard 18530:2014 solved this problem with the use of the GSRN and SRIN," says Mavin. "The subsequent expansion of the specification to support staff/caregiver identification with the SRIN was also very useful."

- **Patient ID**: Global Service Relation Number (GSRN) + Service Relation Instance Number (SRIN)
  - Wristband
  - Clinical notes labels
  - Specimen labels
- **Staff ID cards**: GSRN
- **Location ID:** Global Location Number (GLN)
- **Product ID:** Serialised Global Trade Item Number (SGTIN)
- **Asset ID:** Global Returnable Asset Identifier (GRAI) or Global Individual Asset Identifier (GIAI)
- **Document Type ID:** Global Document Type Identifier (GDTI)

GS1 standards provide the needed identification framework for the PPID solution.

Planning was underway for a multi-year, major project to upgrade to a Patient Administration System. "Rather than wait on the new PAS, we developed a middleware solution to generate the GS1 patient wristbands that were not reliant on the upgrade and avoiding the delays that process would have introduced," explains Mavin. Today, each patient wristband includes the GSRN and SRIN identifiers encoded in a GS1 DataMatrix barcode to uniquely identify the patient and the "instance" of patient care. Labels associated with the clinical notes and specimens for a patient also include the same identifiers with subtle yet technically significant differences.
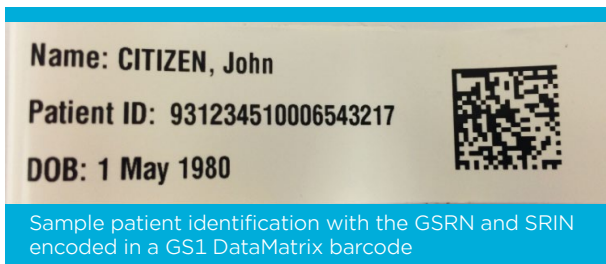
The team also worked with its existing vendors to modify the hospital's security system to print staff identification cards that used the GSRN standard. Each card includes the GSRN encoded in the GS1-128 barcode.

With any change comes challenges, yet the vast majority of caregivers and staff at Canberra Hospital appreciated the ability to work in a safer and more productive way, enabled by the PPID solution.

"Looking back, I think the biggest push back we encountered was when implementing GS1 standards on patient wristbands," recalls Mavin. "It was around the cost of upgrading our barcode scanners to support 2D DataMatrix barcodes. However, this was soon a non-issue when, put into context, it is such a small price to pay to ensure we are always working with the right patient."

> " Looking back, I think the biggest push back we encountered was when implementing GS1 standards on patient wristbands. It was around the cost of upgrading our barcode scanners to support 2D DataMatrix barcodes. However, this was soon a non-issue when, put into context, it is such a small price to pay to ensure we are always working with the right patient."

Ryan Mavin, Manager Enterprise Architecture Office, ACT Health

PPID solution in action

With the PPID solution in place, a nurse or phlebotomist can now scan barcodes each step of the way when identifying a patient and the specific pathology lab test to be administered.

Here's an example of how the new process works:

- The collector (doctor, nurse or phlebotomist) selects a patient from a pending collections list. Using the ACT Health Clinical Portal displaying the specimen collection screen, he first verbally confirms the patient "is who he thinks she is" with the patient verbally confirming her name, date of birth and address.

- Upon scanning the barcode on the patient's wristband, the system recognises that the patient is not the right patient for the ordered pathology test. This is a near miss since either the collector has not sufficiently confirmed verbally the patient's identity or the wrong wristband has been placed on the patient. With this, patient safety has been preserved, and the near-miss detail is automatically captured within the system, available for analysis.

- With the right patient identified and verbally confirmed, the collector needs to scan the patient wristband. Instead, the collector scans the patient's GSRN identifier on the clinical notes label (which may be away from the patient bedside). The PPID system does not accept the patient identifier because it is not the same as the one on the patient wristband; the collector cannot proceed until the correct wristband is scanned. Once again, patient safety has been preserved, and the details of the incorrect identifier scanned have been recorded.

"This is perhaps the most significant point of differentiation for the PPID solution driving patient safety," explains Mavin. "The wrong-blood-in-tube incidents were typically a result of blood collections being taken from the correct patient, only to then become inadvertently switched with another patient's specimen before being submitted to the lab. This happens when order handling and labelling is performed away from the patient for a batch of collections."
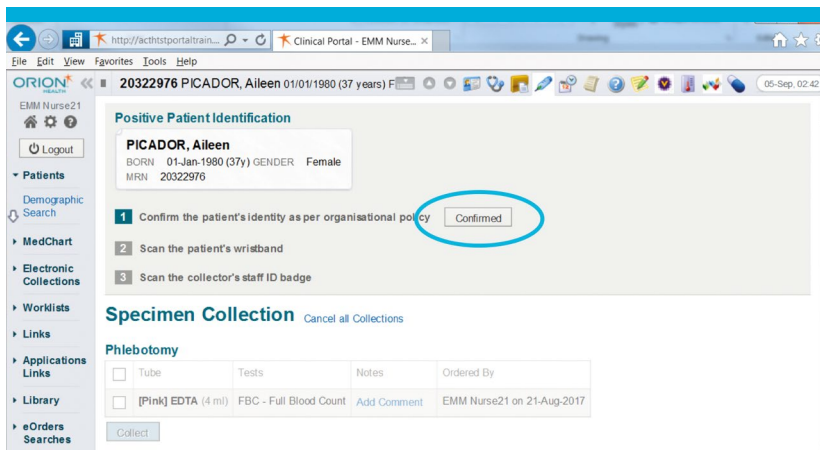
Positive Patient Identification is displayed in the top half of the screen. All collection features are disabled until the collector has successfully completed the PPID process.
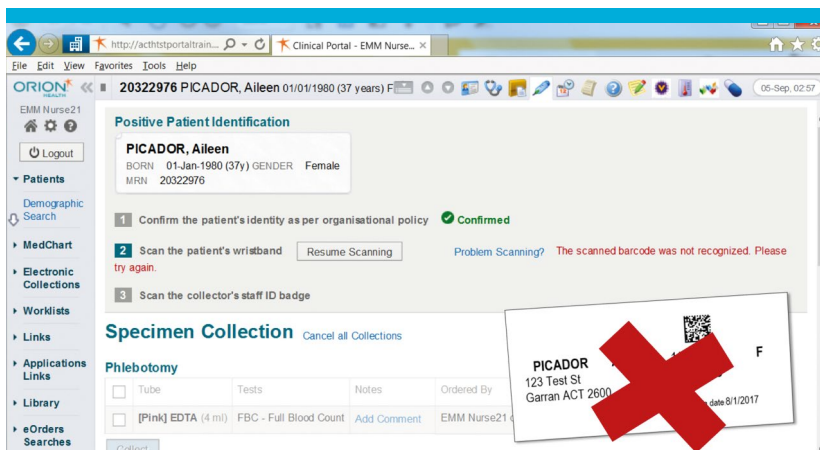
If the scanned barcodes on the patient's wristband and clinical notes do not "match," the system alerts the collector.
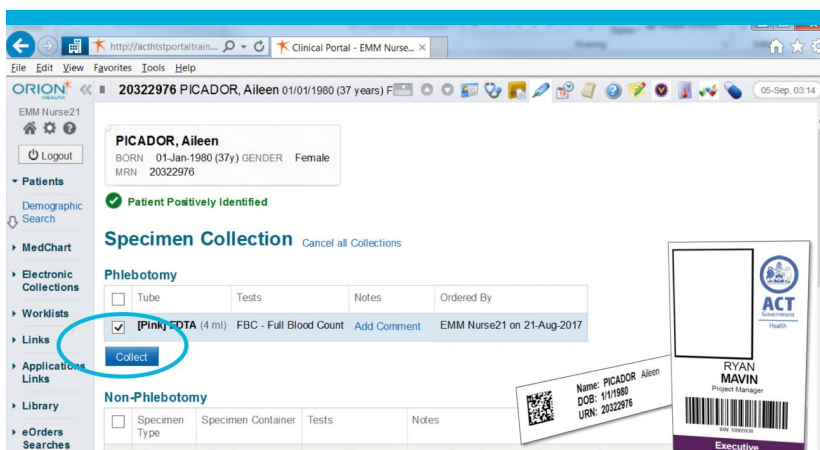
Patient safety is assured by scanning for positive patient identification each step of the collection process.

- Only when the correct patient's GSRN identifier on the wristband is scanned can the collector proceed to the next step.

- Now that the patient's wristband identifier has been successfully scanned and match, the collector can proceed by scanning his staff identification card. Only a valid staff card with a barcode is accepted. The PPID system checks the unique identifier against the ACT Government Active Directory before allowing the collector to continue.

- Once collected, the collector checks off all of the successful collections in the eOrders system and prints the required specimen labels.

100%

Obtaining 100 percent compliance with the process and policy will ensure patient safety is preserved.

40%

More than a 40 percent reduction in wrong-blood-in-tube incidents has been achieved with remaining incidents only occurring during system maintenance periods, or with orders that have remained on paper due to patient transfers.

Error prevention is a priority

The implementation of the PPID solution has focused on the need to improve patient safety and outcomes by preventing errors while supporting clinical teams in their work.

Patients benefit from only a single sample needing to be taken. Without errors, there are no delays in results and treatment. Also, the PPID solution eliminates risk associated with the wrong results and incorrect diagnosis.

Clinicians benefit by using an automated process with electronic ordering and collection that has eliminated paper order readability and transcription incidents, reducing lab data entry efforts. The solution allows them to work more efficiently and safely collect samples, reducing the risk of errors. With the PPID solution, the use of technology helps them mitigate the impact of interruptions that occur in a normal care setting.

With GS1 standards and barcode scanning applied at the point of printing the specimen labels, this ensures the physician collecting the sample performs the steps per the organisational policy.

Mavin reports obtaining 100 percent compliance with the process and policy will ensure patient safety is preserved. More than a 40 percent reduction in wrong-blood-in-tube incidents has been achieved with remaining incidents only occurring during system maintenance periods, or with orders that have remained on paper due to patient transfers.

In pathology, clear patient identification reduces errors in labelling, reduces the amount of testing needed due to incorrect labelling, saving time and resources.

Canberra Hospital has been able to significantly reduce errors related to pathology collections, reduce the number of repeated processes and costs of pathology, and better care for patients.

Mavin concludes, "Our staff are finding the easiest way to do their jobs is now the correct way, scanning GS1 barcodes each step of the way."

Scalable solution

The overall GS1 standards framework is providing the foundation for many more process improvements where positive patient identification is key. To date, the PPID-scaled solution has been implemented across all adult wards.

The key principles defined in the initial implementation are being used in the implementation of additional projects such as the tracking of blood products to patient, breast milk matching to babies, electronic medications management and administration at bedside, and more.

It's clear: There is an overall transformation of systems and processes happening at ACT Health and Canberra Hospital with patient safety and outcomes as a priority.

> " Our staff are finding the easiest way to do their jobs is now the correct way, scanning GS1 barcodes each step of the way."

Ryan Mavin, Manager Enterprise Architecture Office, ACT Health

About the Author

__Ryan Mavin__ is Manager of the Enterprise Architecture Office, ACT Health and has worked within the IT Industry for more than 20 years. For the past six years, Ryan's focus has been in Healthcare, implementing electronic systems to streamline clinical interaction and information capture for ACT Health. Ryan is passionate about IT interoperability, delivering better patient outcomes and enabling the industry to adapt to the challenges of an aging population. Prior to joining the ACT Government, Ryan held lead roles covering all aspects of system development and implementation as a vendor to the Finance and Gaming industries.

About ACT Health

__The ACT Health Directorate__ (ACT Health) aims to deliver the best possible healthcare and health-related services in Australia, through its public hospitals: Calvary Hospital, Canberra Hospital, and the University of Canberra Hospital; Community Health; Mental Health ACT; Capital Region Cancer Service; Aged Care and Rehabilitation Service and Population Health, including the Health Protection Service.

www.health.act.gov.au

CAISM and Cristália partner together for increased patient safety, improved processes and reduced costs

The Women's Health Hospital – CAISM UNICAMP (CAISM) has always been concerned with the safety of patients. With this goal in mind, the hospital decided to improve the management of medicinal products. To help with this challenge, CAISM established a partnership with Cristália Produtos Químicos Farmacêuticos Ltda. (Cristália), a manufacturer of quality pharmaceutical products. Cristália enabled CAISM to make significant process improvements by using GS1 standards applied on the primary packaging of medicine. By scanning GS1 DataMatrix barcodes, CAISM can now automatically capture important data that identifies the item—specifically the Global Trade Item Number® (GTIN®), batch number and expiration date. The hospital can more effectively manage the hospital pharmacy resources, enabling internal traceability—from the receipt of medicinal products in stock to their administration at patients' bedsides.

By Nice Maria Oliveira da Silva
and Paula F. Magalhaes de Souza

A need for complete data

"Our hospital needed to administer medicine in individualised or unit-based doses," says Nice Maria Oliveira da Silva, Clinical Pharmacist with CAISM. "We were concerned about patient safety and wanted to be able to trace all medicines within our hospital."

The hospital needed to answer questions like:

- What patient took which drug?
- Which batch was it?
- What was the expiration date?
- Which manufacturer was it?

In case of a patient's adverse reaction, CAISM required the ability to quickly double-check the process associated with the administration of the medicine and investigate the situation thoroughly.

"Previous GS1 EAN-13 barcodes on medicines would only provide us with the product's identity, but not additional information for traceability," explains Silva. "We needed complete information provided by the GS1 DataMatrix barcode—a GTIN, with the batch number and expiration date. So, we contacted Cristália and told them about our challenge."

CAISM presented to Cristália its concerns about all the work performed within its hospital pharmacies and its goal to mitigate the risk of

error in preparing, dispensing and administering pharmaceuticals to patients.

"Most of our products are hospital drugs," says Paula F. Magalhaes de Souza, Production Director from Cristália. "CAISM requested that we label our products with globally standardised codes for primary package-level identification that would enable the preparation, dispensing and administration processes in the hospital in an automated way."

"Our partnership with GS1 Brazil was essential since they gave us all the information necessary to implement and validate the GS1 DataMatrix barcode," advises Souza.

About 70% of medicinal products used by the CAISM hospital have GS1 DataMatrix barcodes applied by the manufacturers.

Automating processes

To develop a system and adapt that system to each production line was our major challenge," says Souza from Cristália.

"Before partnering with Cristália, all medicines used were labelled with EAN-13 barcodes by the CAISM pharmacy team," says Silva from CAISM. "So, our main challenge was to create a solution that could guarantee the safety of the patient and the hospital, from the receipt of the product to the dispensing of the medicinal product to the patient. It was a solution created practically from zero."

Simultaneously, with the implementation of GS1 DataMatrix barcodes on primary packages by Cristália, the CAISM Pharmacy Service, in partnership with the hospital's IT Service, developed software compatible with GS1 DataMatrix barcodes.

"It was now possible to implement our Electronic Hospital Dispensing System," advises Silva. "As a result, the processes that involve the printing of medical prescriptions, collection of hospital admission copies, and the preparation and manual checking of primary packages have been optimised."

> " We have experienced major process and accuracy gains with medicinal products coming to our hospital with GS1 DataMatrix barcodes. We have been able to register them once in our system and, from that point forward, the system identifies the drug, the batch number and expiration date, and whether the medicinal product matches the prescription. All of this provides the patient with greater safety."

Nice Maria Oliveira da Silva, Clinical Pharmacist, CAISM

Major gains for patients and processes

"We have experienced major process and accuracy gains with medicinal products coming to our hospital with GS1 DataMatrix barcodes," says Silva. "We have been able to register them once in our system and, from that point forward, the system identifies the drug, the batch number and expiration date, and whether the medicinal product matches the prescription. All of this provides the patient with greater safety."

Additional benefits for CAISM include:

✔ **Optimisation of resources and time:** The hospital no longer needs to print extra copies of medical prescriptions nor does the Pharmacy Service team need to internally apply barcodes on medicines.

Furthermore, the hospital has enhanced the efficiency of its processes, including the preparation of drug products, traceability and dispensing. Now that prescribed medicines are viewed directly through the electronic dispensing system, as soon as the medical prescription is finalised, the preparation of medicinal products is performed by reading the GS1 DataMatrix barcodes. As a result, the hospital has streamlined these processes for significant savings of time and resources.

✓ **Increased patient safety:** When the GS1 DataMatrix barcode is scanned, the information encoded in the barcode is automatically checked against the medical prescription. If there is a difference, alerts are issued as a way of preventing errors. Also, since the drug is labelled by manufacturers (and not by the hospital), this helps minimise potential errors that may occur if the drug was repackaged and relabelled in the hospital.

✓ **Assisted risk management:** By scanning GS1 DataMatrix barcodes, the hospital has increased its agility when identifying batches that may have deviated from its quality standards and recalled by ANVISA, the Brazilian Health Regulatory Agency. CAISM has also gained traceability of each dose of a drug to each patient.

✓ **Reduced costs:** The identification of medicinal products by GS1 DataMatrix barcodes has sharply reduced the process of re-packing and re-identifying Cristália's products within CAISM, reducing costs associated with these processes, exposure of the product to the external environment and maintaining the product in its original package. Currently, out of 800,000 drug product items a year in solid, oral and injectable dosage forms, 70 percent or 560,000 units of medicinal products are being delivered with GS1 DataMatrix barcodes on manufacturers' packages. Therefore, CAISM's pharmacy no longer needs to apply barcodes for the vast majority of medicinal products used in the hospital. The hospital estimates a cost reduction of R$15,000 and time savings of 945 hours per year.

70%

or 560,000 units of medicines are being delivered with GS1 DataMatrix barcodes on manufacturers' packages. Therefore, CAISM's pharmacy no longer needs to apply barcodes for the vast majority of medicinal products used in the hospital. The hospital estimates a cost reduction of R$15,000 and time savings of 945 hours per year.

✓ **Improved processes:** CAISM has improved its stock management process with less human intervention in the process, and a reduction of contamination risk and errors in the administration of drug products to patients. In addition, there has been an automatic write-off in inventory and a reduction in inventory problems.

✓ **Traceability:** Using the GS1 DataMatrix barcode, it is possible now to track the flow of medicinal products within the hospital, automatically registering the drug when it is administered at the patient's bedside, the date and hour of administration, and the caregiver who performed the administration.

" For us, this has been a source of pride. It's an acknowledgment of our work, our strong partnership with our clients and hospitals and, above all, knowing that we're contributing to the safety in the dispensing and use of drugs with patients. That's our main reason to be happy."

Paula F. Magalhaes de Souza, Production Director, Cristália

A source of pride

"For us, this has been a source of pride," says Souza from Cristália. "It's an acknowledgment of our work, our strong partnership with our clients and hospitals and, above all, knowing that we're contributing to the safety in the dispensing and use of drugs with patients. That's our main reason to be happy."

"The hospital is now able to trace drugs to prevent medication errors. The next step is to engage new suppliers to adopt and apply GS1 DataMatrix barcodes on their products," says Silva from CAISM.

As products are received by CAISM, GS1 barcodes are scanned to confirm receipt of the products in the hospital's inventory system.

About the Authors

Nice Maria Oliveira da Silva *is a Clinical Pharmacist at CAISM. She has more than 20 years of experience in healthcare. In 1996, she graduated with a degree in Pharmacy from Universidade Metodista de Piracicaba, UNIMEP, in Brazil. In 2010, Nice Maria was awarded a post-graduate degree with a Specialisation in Clinical Pharmacology from the Centro Universitário Hermínio Ometto de Araras, Uniararas. In 2016, she received her Master's degree in Health Sciences from the Department of Tocoginecology, Faculty of Medical Sciences, State University of Campinas, Unicamp.*

Paula F. Magalhaes de Souza *is Deputy Production Director at Cristália Produtos Químicos Farmacêuticos Ltda. She has more than 18 years of experience in the pharmaceutical Industry, in the departments of Quality and Industrial. Paula graduated as a pharmacist-biochemist from UNESP Araraquara and later completed her post-graduate degree in Industrial Management (INPG), Finance and Controllership (IPEP), and Management Development from Fundação Dom Cabral and an MBA in Project Management from FGV.*

About the Women's Health Hospital – CAISM UNICAMP

*Inaugurated in March 1986, the **Women's Health Hospital or CAISM** was consolidated for teaching, research and highly specialised assistance in supporting the health of women and newborns, as part of the Unified Health System. CAISM encompasses 42 municipalities and nearly 5 million people, not counting thousands of patients from other regions who seek treatment and care from the hospital each year. Conceived as a university hospital, the CAISM has established itself as a teaching hospital for students at varied levels, including technicians, undergraduate, postgraduate, residency, and specialised fields. The hospital receives students from the Faculty of Medical Sciences, Faculty of Nursing and Faculty of Pharmacy of UNICAMP, but also from many other public and private educational institutions throughout the metropolitan region of Campinas, including universities, colleges and technical schools.*

www.caism.unicamp.br

About Cristália Produtos Químicos Farmacêuticos Ltda.

Cristália *is a pioneer and leader in the hospital market in Biotechnology, Anesthetics and Narcoanalgesics, and medicines for pain. About 15 years ago, it developed research on new molecules and products. The company focuses on improving healthcare for Brazil's population through the innovation, development, production and distribution of quality pharmaceutical products. Today, Cristália has two plants that have already received from ANVISA the Certificate of Good Manufacturing Practices (CBPF) for biological pharmaceutical inputs. The Biotechnology Industrial Plant and the Anaerobic Bacteria Plant, installed in the Industrial Complex of Itapira (SP), are among the most modern in the world.*

www.cristalia.com.br

Hospital Israelita Albert Einstein continues its journey to full traceability of pharmaceuticals

Patient safety is the fundamental goal of Hospital Israelita Albert Einstein (HIAE). For the past 15 years, the hospital has implemented and used GS1 standards to enable the traceability of all medicines for improved patient care and safety. HIAE has partnered with its suppliers to ensure that all medicines at the single-dosage level are each assigned a unique identifier—specifically the GS1 Global Trade Item Number® (GTIN®), batch/lot number and expiration date, encoded in a GS1 DataMatrix barcode. With GS1 identification in place, the hospital can now scan the barcodes of medicines as they travel from receiving to patient bedsides and to HIAE's surgical centre, completing an end-to-end traceability system. Information captured with each barcode scan is downloaded into the hospital's inventory management system and its new electronic medical record (EMR) system. More than 240,000 single-dosage units each month are labelled at suppliers' manufacturing sites, saving HIAE more than 600 hours and R$13,620 in associated labour costs monthly.

By Nilson Gonçalves Malta

Commitment to patient care

Hospital Israelita Albert Einstein is an integrated healthcare system in São Paulo, Brazil with more than 13,000 employees, including over 1,200 physicians. In 1999, HIAE become the world's first hospital to receive Joint Commission International (JCI) accreditation. In 2018, HIAE became the first JCI-accredited hospital to receive the seventh consecutive re-accreditation certificate.

The hospital provides healthcare services that span the spectrum: promotion, prevention, diagnosis, treatment and rehabilitation. With a commitment to patient care, HIAE set out to develop an internal traceability system to ensure quality services and safety for all of its patients.

Pharmacy leads the way

"Our vision was to create an intra-hospital traceability system that would enable the visibility of individual doses of medicines throughout the hospital's receiving, distribution, dispensing and administration processes," says Nilson Gonçalves Malta, Hospital Automation Manager at HIAE.

At that time, traceability was not possible because the pharmaceutical drugs supplied by HIAE's manufacturers did not include the minimum identification requirements for such control. Even if suppliers did include barcodes on their drugs, they typically only identified the type of drug, and barcodes were applied only to secondary packaging.

To achieve traceability, it was imperative that the barcode include complete identification—not only the type of product, but also, batch/lot number and expiration date. Furthermore, for administration purposes, each dosage needed to be identified and labelled.

Relabelling in the pharmacy

To address this need, incoming medicines that were not properly barcoded or carried only a GTIN were re-identified and relabelled in-house by the hospital's pharmacy staff. An internal barcode was developed for this purpose, carrying the type of product and batch/lot number, as well as the barcoded information in a human readable format. The barcoded information matched the same unique combination in the hospital ERP system that informed about the expiration date.

For ampoules and vials, it was a cumbersome task due to their small sizes. Yet, the situation became more critical when dealing with drugs in solid dosage forms (e.g., tablets, capsules). In order to have the needed detailed identification information on each dosage, the pharmacy had to cut original blister packs and individually overwrap each unit. To facilitate this process, HIAE invested in a table-top machine for unit dose repackaging.

In 2005, at the beginning of the project, HIAE repackaged approximately 80,000 oral solids and relabelled about 250,000 ampoules or vials per month supporting its 460 beds, emergency care and two outpatient units. Today, more than 200,000 oral solids and 200,000 ampoules or vials are still relabelled per month, supporting 630 beds, emergency care and seven outpatient units.

Significant improvements in the identification and control of oral solids have been recently made with a complete automated solution called Swisslog PillPick®. The machine double-checks processes throughout each step of production, including a camera-based validation system, cutting blisters, overwrapping them and identifying every single-dose with a GS1 DataMatrix barcode, carrying the GTIN, batch/lot number, expiration date and serial number. Currently, more than 100,000 units per month are being identified this way.

"Relabelling introduces risk into the process since drugs could be incorrectly identified," advises Malta. "In addition, it requires a significant amount of time and resources."

To prevent errors, a post-labelling quality control step needed to be developed and added. This meant increased costs—primarily the high cost of labour. Finally, HIAE needed to pay particular attention to the quality of barcodes since a faded or "smudged" barcode could not be read when scanned, thus compromising the ability to capture data and ensure traceability.

> " Today, we require that all of our suppliers must codify their products at the dosage level with the GS1 DataMatrix barcode. Currently, about 70 products are received from suppliers with GS1 DataMatrix barcodes, representing about 240,000 single-dosage units each month."
>
> **Nilson Gonçalves Malta**, Hospital Automation Manager, Hospital Israelita Albert Einstein

Suppliers join in

With help from GS1 Brazil, HIAE identified a supplier—Hypofarma—that accepted the challenge to print a GS1 DataBar barcode on the label of each unit of electrolyte ampoules in its production line. This barcode could hold the needed, additional information of a batch/lot number and expiration date. The partnership demonstrated for HIAE the value of having a supplier assign and apply the barcodes at the source—in its production facilities.

In 2008, the GS1 DataMatrix barcode was introduced. The GS1 DataMatrix barcode is highly desirable for healthcare products since it can hold large amounts of data in a very small footprint—ideal for small bottles, individual dosage blisters and vials.

At that time, other suppliers—Baxter, Isofarma and Eurofarma—partnered with HIAE by uniquely identifying their medicines at the single-dose level with GS1 DataMatrix barcodes. Soon, other suppliers followed.

"Today, we require that all of our suppliers must codify their products at the dosage level with the GS1 DataMatrix barcode," says Malta. "Currently, about 70 products are received from suppliers with GS1 DataMatrix barcodes, representing about 240,000 single-dosage units each month."

Other products that don't receive barcodes at suppliers' locations are still relabelled. Yet, HIAE continues to relentlessly negotiate with new suppliers. Suppliers that find barcoding more difficult to comply with are those that produce in different facilities around the world.

With medicines labelled at suppliers' manufacturing sources, HIAE is saving more than 600 hours and R$13,620 in associated labour costs every month since its pharmacy no longer needs to relabel medicines. Furthermore, this minimises the risk of inaccuracies in the identification process.

> With medicines labelled at suppliers' manufacturing sources, HIAE is saving more than 600 hours and R$13,620 in associated labour costs every month since its pharmacy no longer needs to relabel medicines. Furthermore, this minimises the risk of inaccuracies in the identification process.

Lots of data in a small space

The transition to scanning GS1 DataMatrix barcodes had its own set of challenges for the hospital. "Some suppliers printed different information in the human readable format," says Malta, "Others printed barcodes so that our scanners could not 'read' them when scanned, like barcodes printed on black backgrounds. It has been a learning experience for us and our suppliers."

The hospital was also challenged about how to "best engage" with their suppliers—to encourage them and eventually require the application of barcodes.

"We also had to upgrade the barcode decoding logic in the hospital ERP system in order to

capture the correct information from each identifier's AI (application identifier)," recalls Malta. "Our barcode readers had to be reconfigured because of the AI structure in GS1 barcodes. Throughout the implementation, GS1 Brazil has been very helpful with its guidance."

Ampoules labelled with GS1 DataMatrix barcodes
The GS1 DataMatrix barcode is ideal for use in healthcare where a significant amount of information is needed in a small space.

End-to-end traceability for patient safety

Under the direction of the pharmacy, safer logistics processes, including an electronic ordering system, have been implemented with barcode scanning each step of the way. The hospital now scans medicines' barcodes at:

- **Receiving** – As medicines are received, GS1 DataMatrix barcodes are scanned to register the type of medicine, batch/lot number, expiration date and active ingredients in the hospital's inventory system.

- **Distribution** – As medicines move from the warehouse to the pharmacy, the GS1 DataMatrix barcodes are scanned to capture the movement of the medicines from one site to the other.

- **Dispensing** – When a dosage of medicine is scheduled for administration to a patient, the GS1 DataMatrix barcode is scanned as it is dispensed by the pharmacy or at the time of

its compounding inside the cleanroom within the IV Workflow software. Compounded medicines receive a label with a unique code generated by the EMR (identifies the patient, drug, form, dosage and route of administration) and a serial number for traceability purposes (refers to patient, drug, dose, route, expiration date, lot number, beyond use dating (BUD), and compounding technician and laminar airflow workbench (LAFW) where it has been prepared). The EMR code is printed in the DataMatrix barcode format for the administration step.

- **Administration** – After the caregiver logs into the EMR system, and as the dosage of medicine is administered to the patient, its GS1 DataMatrix barcode is scanned along with the patient wristband barcode, registering the type of medicine (drug, dosage and form). The capture of the batch/lot number and expiration date of the medication is under development.

    Drugs that do not carry a GS1 DataMatrix barcode applied by suppliers, carry an EMR code (in the DataMatrix barcode format) containing the internal product code and batch/lot number. This identification is applied in the relabelling processes previously discussed and the EMR is appropriately configured to identify drug, form and dosage. Pharmacy compounded medicines are also identified by a unique EMR code.

Taking traceability into the operating room

The next phase of the traceability project introduced the identification of surgical supplies with GS1 DataMatrix barcodes. As products are scanned for use in the OR, the information is captured in the hospital's inventory system as well as the EMR system.

Identification information about surgical supplies and products used for a specific procedure in the OR can now be captured for tracking back to the patient's electronic health record. This new capability has helped HIAE extend traceability to the patient level. The hospital can analyse and control materials used for each patient based on the lot information and expiration date.

Benefits centre on patients

The most important benefit is patient safety by enabling the traceability of a medication's use until its final step when it is administered.

Traceability System of Medicines at Hospital Israelita Albert Einstein

Receipt — Distribution — Compounding — Dispensation — Administration

From receipt to administration, pharmaceuticals are scanned each step of the way for end-to-end traceability.
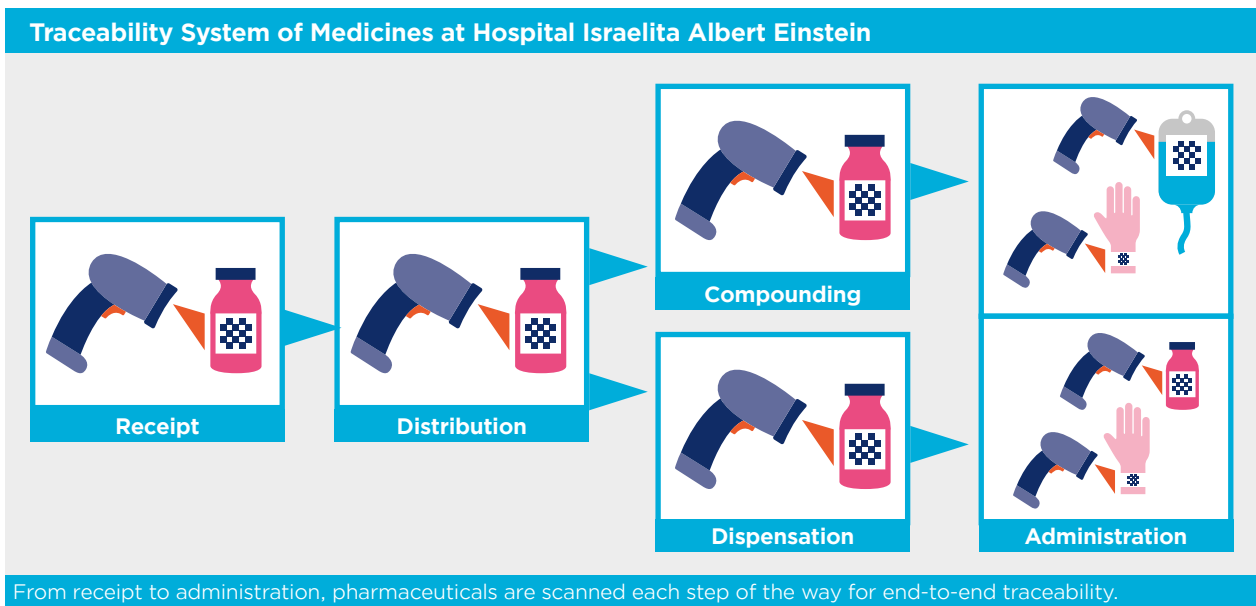
Positive impacts of traceability with GS1 barcode scanning includes:

✔ End-to-end traceability of medicines—inside and outside of the hospital—from suppliers' production sites to the hospital's patient bedsides and into the surgical centre

✔ Agility in the dispensing process, with up-to-date, online inventory status

✔ Verification of the medicine dispensed, as ordered

✔ Confirmation of dispensing drugs that have not expired nor have been recalled

✔ Ability to quickly locate recalled products and link to patients that they have been administered to or used on in a procedure

✔ Automated bedside check of medication being administered, ensuring control over 7 of 9 administration rights—right patient, drug, dose, time, route, form and documentation

✔ Essential capability for obtaining quality certifications

In the near future, HIAE plans to capture more detailed information about medicines, recording the product's serial number, when available. In the OR, tracking high-cost products is also planned by using GS1 EPC (Electronic Product Code)-enabled RFID (Radio Frequency Identification) technology.

About the Author

Nilson Gonçalves Malta is Hospital Automation Manager at Hospital Israelita Albert Einstein. For 18 years, he has led multiple automation projects in hospital pharmacy logistics and clinical processes. Nilson graduated as a Pharmacist-Biochemist with a post-graduate degree in Hospital and Healthcare Systems Administration. He is a member of the ANVISA (Brazilian Regulatory Agency for Drugs) committee for the National System of Drug Control. Nilson is a former member of the GS1 Healthcare Providers Advisory Council.

About the Hospital Israelita Albert Einstein

Hospital Israelita Albert Einstein opened its doors in 1971 as a nonprofit diagnostic and treatment centre, and today it has more than 5,000 employees, including more than 500 full-time physicians. HIAE is the world's first hospital to receive Joint Commission International (JCI) accreditation. The hospital's specialties include integrated cardiology, neurology, and oncology diagnosis and treatment, as well as organ transplantation, orthopedics, dermatology, gastroenterology, hematology, ophthalmology, plastic surgery, and urology. Einstein also has a Diagnostic and Preventive Medicine Center that offers numerous health screenings, scans and other tests. HIAE prides itself on personalised care for its patients, employing state-of-the-art protocols, procedures, and technologies.

www.einstein.br

Healthcare providers

Study of three international health systems showcases the benefits of supply chain transformation

The World Health Innovation Network (WIN) provides the first research of its kind by developing empirical case studies that quantify the operational and financial benefits of highly automated and integrated supply chain infrastructure in health systems, enabled by global standards adoption. Examining Alberta Health Services (AHS) in Canada, the National Health Service (NHS) in England, and Mercy in the US, the research uncovers their implementation strategies, outlines the emerging impact and identifies returns-on-investment as high as 7:1 from adopting supply chain processes to strengthen health system performance. Although, the case studies profile supply chain implementations in three different countries (characterised by unique leadership approaches, implementation strategies and system governance structures), all three reported significant outcomes.

By Dr. Anne Snowdon

The need for research

In 2016, the seminal research paper, *Visibility: The New Value Proposition for Health Systems*, proposed a new direction to improve patient safety and health system performance by transforming supply chain infrastructure to increase visibility and transparency through global supply chain standards adoption.

Following up that paper, empirical case studies documenting the evidence of the impact of supply chain infrastructure across three health systems have been produced. This type of evidence was identified as a critical gap in knowledge needed to inform governments and health system leaders of the value and opportunity to improve quality and safety of care for patients and strengthen health system performance, all enabled by the adoption of global standards.

These organisations were chosen because of their system-level approach to transforming supply chain infrastructure across the entire health system. AHS, NHS and Mercy are also considered international leaders in supply chain transformation.

The research

Each case offers a unique perspective regarding the need for supply chain transformation and the opportunity it offers health system safety and performance.

Each health system has a unique governance structure and leadership strategies that progressed in very different ways. AHS and the NHS are both publicly funded, while Mercy is a for-profit health system.

The case study data was derived from observations, public health system reports, financial data, online publications and key informant interviews. Findings highlight drivers of change, evidence of returns-on-investment, and the outcome and impact achieved through the transformation of supply chain.

Alberta Health Services

Alberta Health Services is Canada's first and largest province-wide, fully integrated health system. When Alberta's health regions were consolidated into one publicly funded health system in 2008, it provided a unique opportunity to accelerate supply chain integration and transparency.

AHS' approach to introducing supply chain transparency focused on four key areas:

1. **Implementation of ERP (Enterprise Resource Management Programme) infrastructure:** By implementing new procurement software province-wide, AHS standardised all e-commerce processes across the province. This enabled streamlining of procurement processes to ensure clinical programmes had the products they needed, when and where they needed them.

2. **Price harmonisation:** In consolidating Alberta's previous health authorities, AHS gained visibility to multiple contracts with different price points for the same item, allowing them to standardise pricing and gain economies of scale to purchase products at the lowest price possible.

3. **Province-wide item master and data infrastructure:** The AHS team adopted global standards to identify all products with unique item numbers in an item master file to create an accurate item master, including product data with 100,000 items.

4. **Centralised warehouse strategy:** Alberta leaders created a provincial warehouse system to efficiently stock and distribute supplies to all sites across the province. By centralising, AHS gained greater visibility of products, reduced duplication and reduced waste due to surplus or expired items.

Key wins for AHS include:

✓ 7:1 return-on-investment in supply chain efficiency and inventory cost savings

✓ One-time savings of $80 million from the consolidation of procurement contracts and standardisation of pricing

National Health Service (NHS) of England

The NHS is a nationally governed health system under the leadership of the UK's Secretary of State for Health and Social Care.

Two crises influenced the NHS to transform supply chain processes: a public inquiry into a high number of patient deaths at the Mid Staffordshire NHS Trust from 2005-2008 and the recall of breast implants in 2012, which demonstrated NHS' inability to identify the 30,000 women who had received the defective implants.

These safety events informed the NHS' strategy to reduce variation and strengthen safety, a programme called Scan4Safety, which supported participating hospitals to adopt both GS1 and PEPPOL standards.

The Scan4Safety programmeme goals are defined as "patient, product, place and process." Adoption of GS1 and PEPPOL standards enabled NHS trusts to track and trace people, products, places and care processes to improve efficiency of health services and patient safety. This encompasses:

- Patient—improving safety, improving care

- Product—everything recorded, everything accounted for

- Place—everything trackable, everything traceable

- Process—simplifying processes, releasing time to care for clinicians

Key wins for the NHS include:

✓ Anticipated £1.5 billion in inventory savings when Scan4Safety is implemented across all 148 trusts

✓ 4:1 return-on-investment in inventory savings alone. This figure is expected to be higher once clinician time savings and patient safety outcomes are counted.

✓ Average savings of £2.4 million per participating hospital trust realised from operational efficiencies

✓ Average savings of the equivalent of 16 full-time staff per trust gained from releasing clinician time from managing supply chain processes back to patient care

✓ Patient safety improvements with 93 percent of implants now being accurately tracked

Read more about the Scan4Safety programmeme on . Case studies about two NHS trusts— University Hospitals of Derby and Burton NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust —can also be found on and , respectively.

Mercy

Mercy, the fifth largest Catholic health system in the US, viewed supply chain as a strategic asset for health systems to improve operational, clinical and financial performance.

Mercy's objectives for supply chain transparency focused on three goals:

1. **High-value care delivered by clinical programmes:** Supply chain transparency enabled by GS1 global standards has allowed products to be tracked and traced from manufacturer to individual patient at the point of care, documenting care procedures and clinicians linked to patient outcomes. Automated inventory management systems track products to reduce the risk of using expired or recalled products in surgical procedures.

2. **Sustainable change in operational performance:** Point-of-care scanning has substantially reduced clinican workload burden due to efficiency of scanning products and uploading product data into a patient's electronic health record (EHR), overcoming the time-intensive burden of manual documentation.

3. **Strengthened financial outcomes across the system:** Three key areas provide the greatest financial savings.

   – Asset inventory management: Dynamic inventory management in high-cost programmes accurately tracks product use and identifies the best outcome for patients at the lowest cost.

   – Inventory reduction: Inventory waste has been minimised by improving product forecasting based on greater visibility of product use and expected patient volumes.

   – Charge capture: Automated capture of product use due to point-of-care scanning achieves greater accuracy in case-costing, creating transparency of product costs per case and labour costs per case.

Key wins for Mercy include:

✓ Reduction of "never events" by 70 percent in participating hospitals as a result of implementing standards-enabled, point-of-care scanning in perioperative programmes

✓ 29 percent reduction in labour costs since implementing point-of-care scanning in perioperative programmes

✓ $81 million growth in revenue over a four-year period since implementing tracking and tracing in perioperative programmes at just two of its 45 hospitals

✓ Identification of $2.4 million in unrecognised inventory assets

✓ Optimisation of charge capture by $13 million in just one year after implementation

Read the Mercy case study on .

Key findings across the case studies

The role of executive and government leadership: All three cases identified the need for both executive leadership and supply chain champions to drive implementation. In Alberta and the NHS, large-scale change was driven by senior levels of government. At Mercy, it came from the strong mandate of a CEO who believed in the significant value of supply chain transformation.

Cost savings: Significant economic impact of supply chain transformation was demonstrated in all three systems. Significant cost savings generated support and momentum for implementation across the health systems.

Clinical time: Each organisation reported that significant labour cost savings were achieved by releasing clinician time from managing supply chain processes back to patient care.

Integration: Integrating supply chain expertise into clinical programmes was identified as one of the key conditions for success. Integrating supply chain data and technology into clinical data and processes of care advanced efficiency in care delivery, strengthened safety and quality outcomes for patients, and improved clinician efficiency and effectiveness.

Conclusion

In all three cases, there was a very strong leadership mandate to transform supply chain infrastructure to advance safety, quality and financial sustainability. Although the three health systems implemented supply chain infrastructure to achieve different objectives, each health system demonstrated significant financial cost savings, improved patient safety and strengthened efficiency, allowing more time for clinicians to spend on patient care.

About the Author

Dr. Anne Snowdon is a professor and Academic Chair of the World Health Innovation Network (WIN), and Scientific Director and CEO of SCAN Health, a Networks of Centres of Excellence International Knowledge Translation Platform located at the University of Windsor's Odette School of Business. Dr. Snowdon works to build collaborative partnerships around the globe to advance innovation and scalability of innovation across health systems to strengthen performance, economic value and sustainability.

About World Health Innovation Network

The World Health Innovation Network (WIN) is based at the Odette School of Business at the University of Windsor, Ontario, Canada under the leadership of world renowned researcher, Dr. Anne Snowdon. WIN brokers partnerships between key stakeholders to source, embed and scale innovations in health systems. WIN develops the evidence of impact and scalability across health systems and disseminates this information to accelerate health system transformation, drive economic growth and improve patient outcomes.

www.worldhealthinnovationnetwork.com

Healthcare providers

LM-Dental moving to GS1 standards for dental product traceability with EPC/RFID

LM-Dental, a leading manufacturer of dental products based in Finland, is implementing GS1 standards across its entire product portfolio, starting with dental hand instruments. Drivers for these efforts include the US Food and Drug Administration (FDA) Unique Device Identification (UDI) regulation. Since 2015, LM-Dental has applied EPC-enabled RFID (Radio Frequency Identification) technology and GS1 identifiers to its dental hand instruments. LM-Dental's customers (e.g., hospitals, universities and dental clinics) can now partner with them to track dental instruments with an automated traceability system—the LM-Dental Tracking System™ (DTS), using GS1 standards. Instruments are tracked from the time they are dispensed through to utilisation, processing, sterilisation and return to storage.

The Universtity of Copenhagen's School of Oral Health Care is one such hospital that has leveraged LM-Dental's use of GS1 standards to make continuous improvements in its daily operations and long-term planning for increased patient safety. With GS1 standards, the school's staff has greater control over the infection control status and stock levels of all instruments, reducing inventory costs by approximately 10 percent.

By Valter Rönnholm and Bo Danielsen

The perspective of the hospital

On a late afternoon in autumn 2010, Bo Danielsen sat in his office at the University of Copenhagen where he had recently been appointed head of the School of Oral Health Care. He was reviewing the school's budget for the following year and felt a bit uneasy. The school and clinic were operating smoothly, the budget was balanced and he felt confident that the next year would run as well as the year before.

Yet, Danielsen wanted his staff to spend their time teaching students and focusing on patients — on value-added activities rather than spending time in the sterilisation room and creating inventory reports and budget estimates.

"I felt we needed information about the utilisation of instruments and their turnover in the clinics to make fact-based decisions about the required staff assigned to the sterilisation room and the need for new instruments," explains Danielsen.

The school didn't know exactly how much budget was needed for new mouth mirrors, curettes and other dental hand instruments that would eventually need to be replaced during the next year. In past years, Danielsen and his team had estimated the needed renewal of instruments based on intuition rather than data.

To estimate the number of extra instruments, several factors needed to be considered. First, all instruments were not always in the right place at the right time. At any given time, a number of instruments would be in the autoclave, some in other phases of the reprocessing cycle and some would need to be replaced. Secondly, the demand for instruments varied from day-to-day depending on the number of treatments scheduled and on the type of clinical procedures. Finally, the capacity of the reprocessing section varied. Resourcing the sterilisation room and developing contingent plans (e.g., when members of staff were sick) was difficult when the needed capacity was not known.

Danielsen also realised that misplaced instruments represented a wasteful, hidden cost. At times, staff and students had to go from one operating room to the other to get an instrument—not because there weren't enough instruments but because the instruments were not in the right places, at the right time.

It might have been easy to disregard the time spent on this trivial task, yet every footstep meant additional cost, a frustrated staff and longer wait times for patients. It also meant that capital invested in the facilities and dental delivery unit was not being used wisely, and student time was spent on something other than treating patients and learning. In summary, the cost per patient and cost per student were inflated due to time wasted and inefficient processes.

"We didn't know exactly 'how big' the impact of these inefficiencies had on costs and how much more could be done with the same resources, if processes were optimised," says Danielsen. "Previous brainstorming sessions had yielded ideas about how the wireless tracking of instruments could change both how we developed the budget and how we ran our daily operations at the clinic. In the spring of 2015, we decided to take action."

From vision to reality

By collaborating with LM-Dental, part of the largest privately owned dental conglomerate, Planmeca, Danielsen's vision was soon to become a reality.

"The development of DTS started in 2011 when a strategic decision was made to develop further the LM-Dental hand instrument offering with a new handle design and to include

intelligence in the instrumentation. The target to add intelligence into instruments initiated an in-depth analysis of latest technologies to enable data migration and storage related to the use of an individual instrument. After research and tests LM-Dental found UHF EPC/RFID as the optimal technology for the purpose. "We soon realised that in order to be complete, this system needed to read and track not only our own instruments but also all moving valuable items and materials in the clinic," explains Timo Helenius, CEO of LM-Dental.

The R&D team at LM-Dental was aware that the organisation needed to meet the requirements of the US FDA's UDI legislation and chose GS1 as its issuing agency. The UHF RFID technology, using GS1 EPC/RFID standards proved to be most suitable for wireless tracking of instruments and materials in dental environments. LM-Dental was also in the process of planning an organisation-wide UDI implementation

After listening to customers, LM-Dental worked to ensure that the first stage of the LM-Dental UDI project focused on dental hand instruments as part of the LM-Dental portfolio. This meant that LM-Dental moved ahead of regulatory requirements to provide unique identification and EPC/RFID marking.

Now, every LM-Dental instrument is available with the option of being uniquely identified with a Global Trade Item Number® (GTIN®) and serial number, encoded in a tiny EPC/RFID

Instruments are uniquely identified with a GS1 Global Trade Item Number and serial number—identification data that is encoded as a so-called Serialised Global Trade Item Number (SGTIN) – in an EPC/RFID tag and can be read via wireless ultra high frequency (UHF) readers.

tag that can be wirelessly read in an instant without slowing down daily routines at the clinic. Likewise, aspirating syringes, dental turbines and micromotor handpieces are equipped with a tiny, autoclavable EPC/RFID tag.

The University of Copenhagen School of Oral Health Care is equipped with an LM-Dental wireless RFID-reader at the point of delivery and additional readers are placed, for example, next to the autoclave in the reprocessing room and in storage rooms that serve different parts of the clinic.

Benefits for all stakeholders

While LM-Dental was driven to both develop a wireless tracking system and meet the regulatory requirements by using GS1 standards and UHF-RFID, the identifiers and data carriers continue to provide value within LM-Dental's own business processes. The company recognises that its efforts and UDIs are not only beneficial for customers, but also for its organisation, particularly as the implementation of GS1 standards for the full product portfolio continues to progress.

Certainly, for hospitals such as the one at the University of Copenhagen, the benefits are clear. When Danielsen sits down at his computer, he logs into the cloud-based server that receives all the information from readers that scan and collect information from the EPC/RFID tags on instruments across the clinic.

"On my screen, I can see where each instrument is located and whether it is ready for clinical use or [is] contaminated and awaiting reprocessing," says Danielsen. "The complete history of the specific instrument is also documented, including information about when it was autoclaved and by whom."

> " On my screen, I can see where each instrument is located and whether it is ready for clinical use or [is] contaminated and awaiting reprocessing. The complete history of the specific instrument is also documented, including information about when it was autoclaved and by whom."

Bo Danielsen, Head of the School of Oral Health Care, University of Copenhagen

Gaining visibility, safety and facilitating education in the hospital

Today, thousands of instrument-specific events are logged each month. Dental Chairside Assistants, Malene Nielsen and Nanna Sørensen, find the new GS1 standards-based traceability system easy and fast to use. Anyone from the Danielsen team can view data from the perspective of his/her role and responsibility.

"When budgeting, we can get a statistical report to see, for example, what percentage of turbines has been used and autoclaved more than 250 times and, therefore, may need to be replaced during the following year," advises Danielsen.

Also, the person responsible for the clinic's logistics can run a report in the afternoon to review current inventories of ready-to-use instruments; and, based on inventory levels, decide which instruments need to be delivered to different storage rooms or operatories before the end of the day, for use the following morning. With the daily monitoring of stock levels, it is possible to ensure the right amount is available at every operatory and that stockpiles are not collected unnecessarily.

Another benefit: Teachers can ensure that students return all instruments given to them. Likewise, the instruments a student has or hasn't used in a clinical simulation exercise can be tracked in order for teachers to give timely feedback, if a vital step was not taken and perhaps misunderstood.

Infection control and patient safety are top priorities in Denmark. "While there may be room for human error, you should strive to create a system that makes it easy for those mistakes to surface and be dealt with in a constructive manner," says Danielsen.

With the traceability system, a layer of automatic safety checks is added without any administrative burden on the maintenance and clinical staff. When an instrument's GS1 identifier in the EPC/RFID tag is read, its status is automatically checked. An alert is given if the instrument isn't appropriate for clinical use, for example, if the sterile shelf life has expired. Likewise, a maintenance reminder can be set to make sure that curettes are sharpened and handpieces are lubricated, as planned.

Vision to reality to tangible benefits

"With the new traceability system, we have the needed data to improve our daily operations, support education, improve long-term planning and budgeting, and obtain big data that can be used for analysis and research purposes," concludes Danielsen.

Specific benefits realised by the School of Oral Health Care include:

✓ Several hours per week are saved by each staff member as they no longer have to search for misplaced instruments.

✓ Just-in-time processes for instrument maintenance have reduced inventory costs by approximately 10 percent.

✓ Visibility of utilisation count and maintenance reminders reduce the time needed for manual checking of instruments by more than 100 hours per year, for the 250,000 instruments sterilised per year. This is the equivalent of three person-weeks.

> " With the new traceability system, we have the needed data to improve our daily operations, support education, improve long-term planning and budgeting, and obtain big data that can be used for analysis and research purposes."

Bo Danielsen, Head of the School of Oral Health Care, University of Copenhagen

Lessons learned

The collaboration between LM-Dental and the Universtity of Copenhagen has led to a highly successful implementation of GS1 standards to meet both the FDA UDI requirements while delivering significant benefits for the School of Oral Health Care.

Throughout the process, much has been learned by LM-Dental that will help to streamline future implementations and feed into the company's project to implement GS1 standards for the remaining products.

Experience has also shown that marking UDI information in human-readable format can be challenging at times, depending upon the substrate used to produce surgical instruments. Therefore, the testing of different direct marking mechanisms is very important.

Overall, LM-Dental advises that understanding the need of customers should be a primary focus, given that clinics will need to make investments if they are to support traceability of products within their facilities.

Having open discussions to understand the current logistics flows within the clinic as well as the overall plans of the clinic and how the implementation of RFID technology for specific applications could fit into their longer term goals is key, particularly given the current overall industry trend for use of barcoding for UDI. When needing item-level traceability of LM-Dental instruments, the time-saving benefit of the multi-reading capability of UHF RFID has a significant impact on the daily manual handling times.

10%

Just-in-time processes for instrument maintenance have reduced inventory costs by approximately 10%.

About the Authors

Bo Danielsen *has extensive experience in clinical and educational administration as well as dentistry and particularly oral hygiene and periodontology. He is the head of the School of Oral Health Care at the University of Copenhagen in Denmark and the president of the Danish Society of Periodontology as well as the Danish Association for Dental Health Without Borders. He has a degree in dentistry from the University of Århus in Denmark, a MBA from South Bank University, England, and a MIL from it-Vest, Denmark.*

Valter Rönnholm *holds a M.Sc. in Communications Engineering from the Aalto University School of Electrical Engineering. He has extensive experience in product development, product management, sales and marketing, ranging from industrial and consumer electronics to medical devices. He is currently Business Development Manager at LM-Dental.*

About the Organisations

The School of Oral Health Care at the University of Copenhagen *is the largest school in Denmark, educating dental chairside assistants and dental hygienists. The school is co-located with the dental school in the Panum Institute, housing Denmark's largest dental clinic with 230 dental units. More than 400 people related to School of Oral Health Care attend the Panum Institute daily. Furthermore, between 100 and 300 patients are treated in the clinics every day. The School of Oral Health Care closely collaborates with other similar institutions in Denmark, as well as abroad.*

https://skt.ku.dk

LM-Dental, *founded in 1973, develops, produces and markets high-tech dental hand instruments and its tracking system together with ultrasonic devices, orthodontic appliances and more. Ergonomics and usability have been the guiding lights of the company's product development since the company was established. All LM-Dental products are produced in Finland and Sweden, combining high-tech production technology with handmade craftsmanship to produce top-quality products with optimal functionality. LM-Dental is a part of the Finnish medical corporation, Planmeca Group.*

www.lm-dental.com

FDA UDI	GS1 STANDARDS
FDA UDI Unique Device Identification	**GS1 Standards** Product Identification
Labeller One who applies or modifies the label with intent to put device into commercial distribution	**Brand Owner**
DI FDA Device Identifier (DI)	**GTIN** GS1 Global Trade Item Number® (GTIN®)
Dynamic Data (PI) FDA Production Identifier (PI) (if applicable)	**Dynamic Data (AI)** GS1 Application Identifier (AI) • Batch/Lot Number: AI(10) • Production Date: AI(11) • Expiration Date: AI(17) • Serial Number: AI(21)
DI + PI = FDA UDI	**GS1 GTIN** or **GTIN + AI = UDI**

UDI
....
• **DI** (Static Data)
• **PI** (Dynamic Data)

Unique Device Identification

GUDID
....
Static Data Elements
• **DI** = Primary Access Key

Global Unique Device Identification Database

AIDC
....
Machine Readable Data Carrier
• Linear Barcode
• GSI Data Matrix
• RFID

Automatic Identification and Data Capture
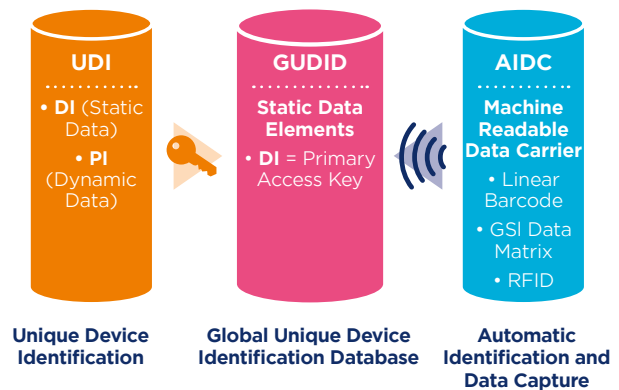
Supporting UDI regulations

GS1 is not responsible for and does not verify LM-Dental's compliance with the US Food and Drug Administration's UDI requirements.

LM-Dental is responsible for assessing the UDI requirements from other markets and regions to ensure its implementation complies with both the UDI requirements and GS1 standards.

Healthcare providers

Traceability of medical devices in the Gottsegen György Hungarian Institute of Cardiology

The Gottsegen György Hungarian Institute of Cardiology has always been a pioneer in the introduction and adoption of new surgical techniques and modern devices. So, when the institute learned about GS1 standards, it wanted to become the first to deploy and use this technology in its inventory management processes and financial systems. The institute has found that GS1 standards offer significant opportunities for the identification of medical devices with the ultimate goal to improve patient safety. Going forward, the institute intends to adapt existing applications in other parts of its hospital operations and systems.

By Professor Peter Andreka MD,

István Nagy and Balázs Sommer

Modern medicine

The Gottsegen György Hungarian Institute of Cardiology (GOKI) was founded in 1977. Today, the institute performs complex cardiovascular examination, non-invasive[1] and invasive[2] therapies for the entire spectrum of cardiovascular diseases for the pediatric and adult populations in the field of interventional cardiology, electrophysiology, cardiac surgery and heart transplants. Other activities include the prevention of cardiovascular diseases and the monitoring of cardiac conditions.

To provide therapeutic and preventive treatments in inpatient and outpatient care and effective cardiology rehabilitation, the institute uses modern forms of therapies that target the best

possible physical, mental and social outcomes for patients. In 2000, the new Pediatric Cardiac Centre was built and opened, further shaping GOKI as a foremost medical institution.

Optimised inventory

For diagnostic interventions and cardiac surgeries performed, high cost and specialised devices are used at GOKI. Since few surgeries can be planned in advance, a wide range of devices and instruments must to be kept in stock and readily available.

The institute had a critical need for accurate warehouse record-keeping to help optimise warehouse inventories, using standardised and up-to-date technologies.

In short, GOKI needed a highly efficient solution—a warehouse that would maintain a steady supply of inventory with nearly instantaneous replenishment of devices as they were consumed.

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1   *The given organs and the heart are examined without intruding the body, with the use of externally applied instruments, such as ultrasound procedures.*

2   *Medical procedures during which the body is intruded by means of incision or pricking.*

> " We realised that the volume of manual data entry activities could be potentially reduced if products had GS1 barcodes. Since not all of our products carried barcodes by manufacturers, this method made our delivery processes and the registration of the products' use more complicated."

István Nagy, IT Leader, Gottsegen György Hungarian Institute of Cardiology

For more than a decade, GOKI had been using various types of barcodes for product identification, yet, the hospital was unable to convince its manufacturers and suppliers to apply standardised barcodes on their products at manufacturing sources. As a result, the institute independently labelled the high-value medical devices with internally produced GS1 EAN-13 barcodes.

Products that were labelled with non-GS1 barcodes were managed by the financial system and could also be identified and selected from the existing master inventory system. However, for products identified with the GS1 EAN-13 barcodes and picked using a barcode scanner, data had to be entered manually when preparing financial documents since it was not integrated with the financial system. By using this manual process, there were numerous points where errors could be made. Also, the process itself demanded a significant amount of time.

"We realised that the volume of manual data entry activities could be potentially reduced if products had GS1 barcodes," says István Nagy, IT Leader at GOKI. "Since not all of our products carried barcodes by manufacturers, this method made our delivery processes and the registration of the products' use more complicated."

Suppliers advised the institute that they would start replacing their old product barcodes with the standard GS1 barcodes. With the deployment the new linear GS1-128 and 2D GS1 DataMatrix barcodes, the institute faced a significant challenge since its current product identification system was now unable to select the manufacturers' products from the master inventory system.

Development challenges

GOKI decided that product identification via GS1 barcodes needed to be used with the opening of the consignment warehouse. To do this, the following issues needed to be resolved:

- Barcodes based on various standards (and handled by the institute in its financial system) were being gradually replaced by manufacturers with GS1 barcodes. As a result, the institute had to manually enter data concurrently, and in different formats.

- The new GS1 barcodes needed to be assessed to determine how they might be implemented as part of the existing financial system in order to minimise manual data entries.

- It was problematic for the institute when trying to interpret linear and 2D barcodes that appeared in various formats; the human-readable data on 2D barcodes was not always included.

- It took time for GOKI to become acquainted with application identifiers (AIs), group separators and the data sets they marked.

- An additional challenge involved the technological data that determined the structure of GS1 barcodes (e.g., data of fixed and variable lengths).

- The appropriate separation and storage of data in appropriate locations needed to be determined, as well as their alignment with the data that was stored in the current system.

- The separation of the same product in varied collective packaging proved to be a similarly difficult task, because the barcodes differed based on each individual manufacturer. Alignment of the individual and various collective packaging units was an issue that had not been defined at the institute.

"For the proper specification of the development, we called on the experts of GS1 Hungary," says Nagy. "They assisted and supported us with the familiarisation and interpretation of GS1 standards, and then during the implementation and deployment phase. We truly appreciated their help."

At the same time, software needed to be designed together with the developers of the financial system. GOKI wanted to ensure that the new processes and screens would not be confusing for users during their daily work routines.

Major issues, decisions and tasks during the development ranged from familiarisation and interpretation of GS1 standards to transformation of the IT system for automated data entries to deciding what types of barcode scanners should be used. Testing was done each step of the way to correct any errors and complete the developments.

Another major challenge was that all development, transformation and introduction activities had to be completed with a live, operating system in place. There was no time to stop normal operations.

Technical and implementation-related questions during the development were handled by GS1 Hungary experts and developers of the internal system.

New warehouse processes based on GS1 standards

In 2017, the new warehouse opened with the following processes in place:

1. Receipt at the consignment warehouse

Now, when incoming products are received by the institute's warehouse, the products' GS1 barcodes are simply scanned for the automated registration of each product's complementary data in the inventory management system. After this, only the quantity received must be manually entered before the accounting documents are completed and closed. During the receipt process, the new system is now able to handle both linear and 2D barcodes that may be applied on various package levels of the same product.

2. Release from the consignment warehouse to the consignment field warehouse (to the surgical theatre)

Materials are released from the consignment warehouse into the warehouse of the surgical theatre with GS1 barcodes. The names of the sending and receiving warehouses must be entered before the accounting document is closed.

3. Release from the consignment warehouse for direct use

Products may be released for direct consumption (e.g., gas-cooled ablation, contrast agent injection), yet, at this point, are not associated with a specific patient and cannot be registered into the patient's electronic health record (EHR). When the accounting document is opened, the names of the consigning warehouse and the department of use must be entered, followed by the scanning the products' barcodes to be released. At the time of closing the accounting document, the system generates two additional accounting documents to record the product in the material registration and invoicing system, as well as the central warehousing system. A preliminary accounting record is automatically produced to assign the value of the product consumed from the budget of the appropriate department.

4. Registration of use with a specific patient

In the surgical material registration module of the financial system, only information about the patient needs to be selected, and then the barcodes of products used during the surgical intervention are scanned. One after another, products consumed by several patients can be scanned and registered; to close the process the associated accounting documents are generated. As a result, additional accounting documents are produced for the appropriate suppliers and serve as the basis of invoicing and stock replenishment. A preliminary accounting record is automatically produced to assign the value of the product consumed from the budget of the appropriate department.

Benefits of the new system

With the deployment of GS1 barcodes, the quality of the registered data has significantly improved and work processes have accelerated. Additional benefits include:

✔ All product data registered with the use of GS1 barcodes is entered in the appropriate fields of the software with no data loss, for both receipt and consumption. In turn, the institute now has increased visibility of its inventory levels, leading to increased availability of products for procedures.

✓ The workload of employees in charge of data registration has been reduced by 30–40 percent. Employees can now perform additional warehousing activities based on their additional, available time.

✓ Wireless barcode scanners can be used during the implementation for more streamlined processes.

✓ Users receive requested materials and devices quicker, which is very important for them.

✓ Online data registration is now available (unique identifier, serial number, lot number, reference number).

✓ A solution has been identified for the multi-level management of GS1 Global Trade Item Numbers (GTINs) on packages. (This will be part of a future software upgrade to the financial system.)

✓ Based on the development efforts at the institute, the software module has become available and ready for introduction by other healthcare institutions.

Next steps

Since its subsystems contain huge amounts of data, today's hospital IT operations must focus on efforts to implement interoperability and integration of these systems. Since this is an immense challenge to standardise the data, the decision to undertake such a project should be based on the consensus of all parties involved.

In addition, financial and technical resources are necessary for the integration of very large volumes of data generated by diagnostic devices and methods into systems, and the unambiguous assignment to specific patients.

In addition to integrating systems within a single institution, healthcare professionals need to consider the full-scale integration and connection of entire healthcare systems—something that can only be accomplished with global standards.

And with the spread of web-based solutions, GS1 standards can enable maximum mobility, making patient data available at bedsides, thus improving the efficient delivery of patient care.

GOKI advises that the new solution — scanning products' GS1 barcodes for automated registration of the associated product data in the inventory management system — has been significantly beneficial for both patient care and the back-end logistics processes.

With the use of GS1 standards and barcodes, the institute has benefitted in the following ways:

✓ Improvements of the quality of healthcare services

✓ Introduction of a uniform patient identification system

✓ Increased safety when administering medicine

✓ Safer practice when identifying patients before performing examinations and diagnostic procedures

✓ Real-time registration and quantitative record-keeping of devices (trays) used in surgeries and procedures

✓ Accurate tracking of implants and high-value devices (trays) used in surgeries and interventions, both for clinical and financial purposes

GOKI advises that the new solution can potentially serve as an example for Hungary's hospitals and may assist with the professional preparation for European Union (EU) and national grant applications for the fulfilment and implementation of the new EU product identification requirements (UDI or Unique Device Identification).

30-40%

Reduction in workload of employees in charge of data registration—available time that can now be used to perform additional warehousing activities

> **"** We trust that in the future both authorities and other healthcare institutions will be eager to share this good example after they have become familiarised with the details."

Professor Peter Andreka, MD, PhD, Director General of the Gottsegen György Hungarian Institute of Cardiology

Details about the new GS1 standards-based system were presented to professional stakeholders at the joint event of GOKI and GS1 Hungary in December 2017. "We trust that in the future both authorities and other healthcare institutions will be eager to share this good example after they have become familiarised with the details," says Professor Peter Andreka, Director General of the Gottsegen György Hungarian Institute of Cardiology.

About the Authors

Professor Peter Andreka graduated from the Semmelweis Medical School in 1993 and is Board certified in internal medicine, cardiology and anesthesiology, and intensive therapy. He completed his cardiology training in the United States. Professor Andreka's main interest is interventional cardiology and he is among the few international proctors for CoreValve/EvolutR transcatheter valve implantation. As a visiting professor at the University of Aberdeen, he became Chief of the Department of Adult Cardiology in 2006. Besides his clinical duties, Professor Andreka is also responsible for teaching and research activities. He has introduced interventional cardiology procedures in Hungary, including intracoronary stem cell transplantation, transcatheter valve implantation, left atrial appendage closure, assist device therapy and more. He has been the General Director of Gottsegen Hungarian Institute of Cardiology since December 2017.

István Nagy graduated from the Kandó Kálmán College of Electrical Engineering as an electrical engineer, and then earned a degree on Specialised Engineering of Computer Science. He also has degrees as an IT Security Auditor and GDPR Manager. From 1997 to 1999, István worked as the Project Manager of the World Bank's Hospital IT Program Office at the National Korányi Institute for TB and Pulmonology. Since 1999, he has been the Head of the IT Department at the Gottsegen György Hungarian Institute of Cardiology. He took part in the creation of

the set of standards for electronic data exchange (MSZ22800). In relation to sectoral healthcare developments, he also had a key role in the implementation of the Electronic Healthcare Service Space (EESZT). He is the Vice-Chair of the Division of Biomedicine of the Neumann János Society of Computer Science. He has been active for 15 years now as a member of the editorial board of the periodical titled Interdisciplinary Hungarian Medicine (IME). Association of Economic Managers of Health Institutions (EGVE) – member of the management.

Balázs Sommer has been working as the warehouse manager at the Material Management Department of the Gottsegen György Hungarian Institute of Cardiology since 2003. He is responsible for the operation of the central and consignment warehouses of large-value cardiac surgery materials. In recent years, Balázs has participated in the implementation of numerous development projects, such as the establishment and startup of the consignment warehouse with the involvement of 15–20 contracted suppliers and the compilation of a centralised product catalogue for public procurement initiated by the maintainer of the institute. He has created his own stock-taking and evaluation process in cooperation with suppliers, which resulted on outstanding precision and traceability in inventory management in a country-wide comparison.

In 2015, Balázs was awarded as an excellent employee of the institute in recognition of his contribution to the cost-efficient operations. Thereafter, he joined the project launched for the integration of the barcode-based, record-keeping system relying on GS1 standards in the economic operations of the institute.

About Gottsegen György Hungarian Institute of Cardiology

Founded in 1997, the **Gottsegen György Hungarian Institute of Cardiology** is owned by the Hungarian State and supervised by the Ministry in charge of healthcare affairs, currently the Ministry of Human Capacities. Its operating costs are provided by the National Health Insurance Fund on the basis of the performance funding report. The institute makes available its intellectual and tangible infrastructure for private use by domestic and foreign patients, undertakes contract-based research activities for foreign organisations, and performs other medical professional services. The institute is particularly focused on the accurate assessment of the conditions of every patient and the determination of the requirements towards the accomplishment of the desired goals.

www.kardio.hu

Healthcare providers

Tokai University Hospital achieves traceability and increased efficiencies in operating theatres

Tokai University Hospital implemented a new management system by using GS1 standards in its operating theatres. The system records detailed information about medical products used for surgical operations—the product's Global Trade Item Number® (GTIN®), lot number and other valuable data—all by scanning source-provided GS1-128 barcodes. By capturing information about which medical products are used on what patients, the system has helped the hospital significantly improve medical safety and increase responsiveness for recalls. In addition, the hospital has reduced costs associated with data recording and enhanced the accuracy of reimbursement claims.

By Dr. Makoto Sawada and Mie Narusawa

TOKAI UNIVERSITY

Ensuring traceability

Located near Tokyo, Tokai University Hospital has 804 beds and 21 operating rooms in which approximately 12,000 operations are performed each year.

In 2015, the hospital installed a new management system for the surgical department, in conjunction with replacing the electronic medical record (EMR) system. Until then, medical products used for surgical operations had been manually recorded with "pen and paper" by doctors or nurses. As a result, the records were sometimes ambiguous or even incomplete. Furthermore, if a product was ever recalled, it took a significant amount of time to identify which medical products were used on what patients.

"For patient safety, the sterilisation and quality management of medical products are crucial, so we decided to implement a new system to record the use history of medical products," says Mie Narusawa, Head Nurse of the Surgical Department, Tokai University Hospital.

"It is extremely important for us to keep accurate information of the name, serial or lot number of individual medical products. We found that the GS1-128 barcode could capture all the data we needed. In Japan, most medical products already have GS1-128 barcodes on their packages. By using GS1-128 barcodes, we do not need to use our hospital's in-house, proprietary barcodes on the products."

> " It is extremely important for us to keep accurate information of the name, serial or lot number of individual medical products. We found that the GS1-128 barcode could capture all the data we needed."

Mie Narusawa, Head Nurse of the Surgical Department, Tokai University Hospital

Adoption of GS1-128 barcodes for accurate use history

The operating theatre management system didn't originally support GS1 barcodes. Thus, before the implementation, the hospital needed to expand the data processing capabilities of both the management system and the EMR system to be able to import data from GS1-128 barcode.

The process to record the use history of medical products is as follows:

- During a surgical operation, nurses store empty packages of medical products used for the operation in a plastic bag.

- Then, nurses scan GS1-128 barcodes on those packages when they are available during an operation.

- By scanning barcodes, the management system imports data from GS1-128 barcode and automatically saves the GTIN, the lot or serial number and the expiration date.

- The management system automatically sends the data to the EMR system.

Scanning GS1-128 barcode on a medical product

Data is captured from scanning the GS1-128 barcode and recorded in the operating theatre management system.
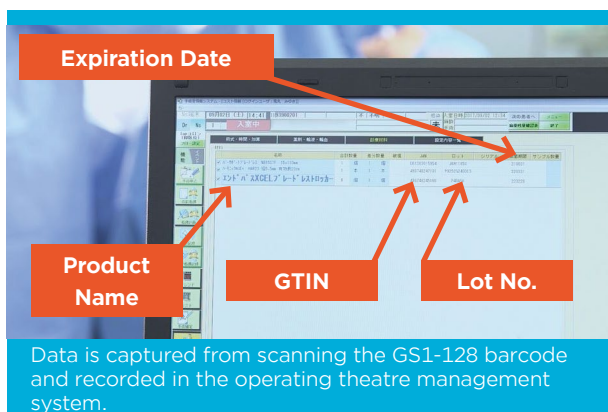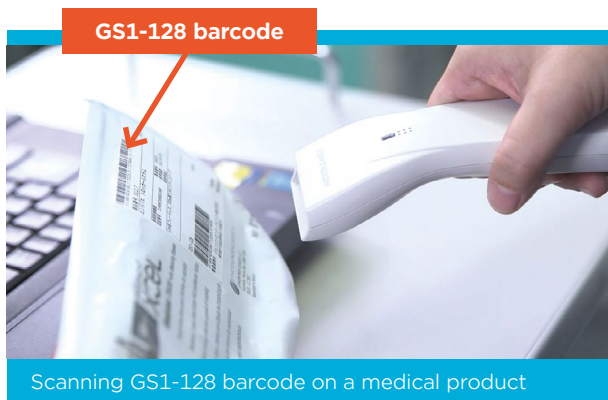
"There are some medical products that don't have a barcode on their primary packages. However, we did not think that less than 100 percent barcode availability should prevent us from implementing the system. We were sure that the system using GS1-128 barcodes would provide benefits in terms of safety and efficiency," says Dr. Makoto Sawada, Research Associate of the Department of Anesthesiology, who led the implementation of the new system.

Ensuring a smooth transition

Dr. Sawada points out that it is important to find suitable ways to manage a new system smoothly.

"For medical products without a barcode on their primary packages or for extremely small products such as brain surgery clips, we created a barcode sheet by copying barcodes on their secondary packages," continues Dr. Sawada. "For a while after the implementation of the management system, scanning errors sometimes occurred due to products being not registered in the master data. To resolve this, we set a collection box in each operating room to temporarily store packages that caused scanning errors and registered those products data after surgeries."

"At first, there were dozens of medical products each day not registered in the master data. However, one month later, the number of non-registered items decreased to only several per week, and today we only have a few per month."

> " At first, there were dozens of medical products each day not registered in the master data. However, one month later, the number of non-registered items decreased to only several per week, and today we only have a few per month."
>
> **Dr. Makoto Sawada**, Research Associate of the Department of Anesthesiology, Tokai University Hospital

96%

To date, in Tokai University Hospital, the number of medical products registered to the master data is about 55,000 items inclusive of non-reimbursable. This number covers about 96% of reimbursable materials used in the operating theatres.

For medical products without a barcode on their primary packages or for extremely small products such as brain surgery clips, the hospital created a barcode sheet by copying barcodes on their secondary packages.

Benefits of the new system

The new system has enabled the Tokai University Hospital to record which medical materials are used with which patient during an operation as well as check the expiration date of materials—making it highly beneficial in terms of patient safety.

Before the implementation of the new traceability system, the use history of medical materials needed to be handwritten and manually input into a system. Thanks to the new system, the hospital has been able to optimise the work process and can precisely calculate costs spent for an operation by accessing accurate data imported from GS1-128 barcode. In fact, the hospital advises that, based on the ease of scanning barcodes, the new system has opened up job opportunities for workers with disabilities—an unexpected and positive benefit.

"An accurate reimbursement claim requires the accurate identification of medical products actually used," explains Dr. Sawada. "Before the implementation of the system, we had often received inquiries about the used materials from the division that is in charge of reimbursement claims. Since running the system, we have received significantly fewer inquiries."

Comparison of work flow before and after the implementation of the system

Before the implementation of the system

During or after an operation, nurses count the number of medical products used for the operation and fill out a cost bill form.
In addition, they peel off product labels, which include information such as product name, lot number, and expiration date, from their packages, and put them onto a recording form.

Workers of operational theatre scan the two forms using a image scanner to record into EMR system as medical history.

The cost bill form is sent to the division which is in charge of reimbursment claims. Workers there enter the information on the form into the reimbursement system manually to calculate the cost of the operation.

After the implementation of the system

During an operation, nurses scan GS1-128 barcodes of medical products. The product name, GTIN and lot number are automatically recorded into the system.

Data is automatically forwarded to the EMR system.

Data is automatically forwarded to the reimbursement claim system

Total number of cost billing from anesthesia division and number of inquiries from the division that is in charge of reimbursement
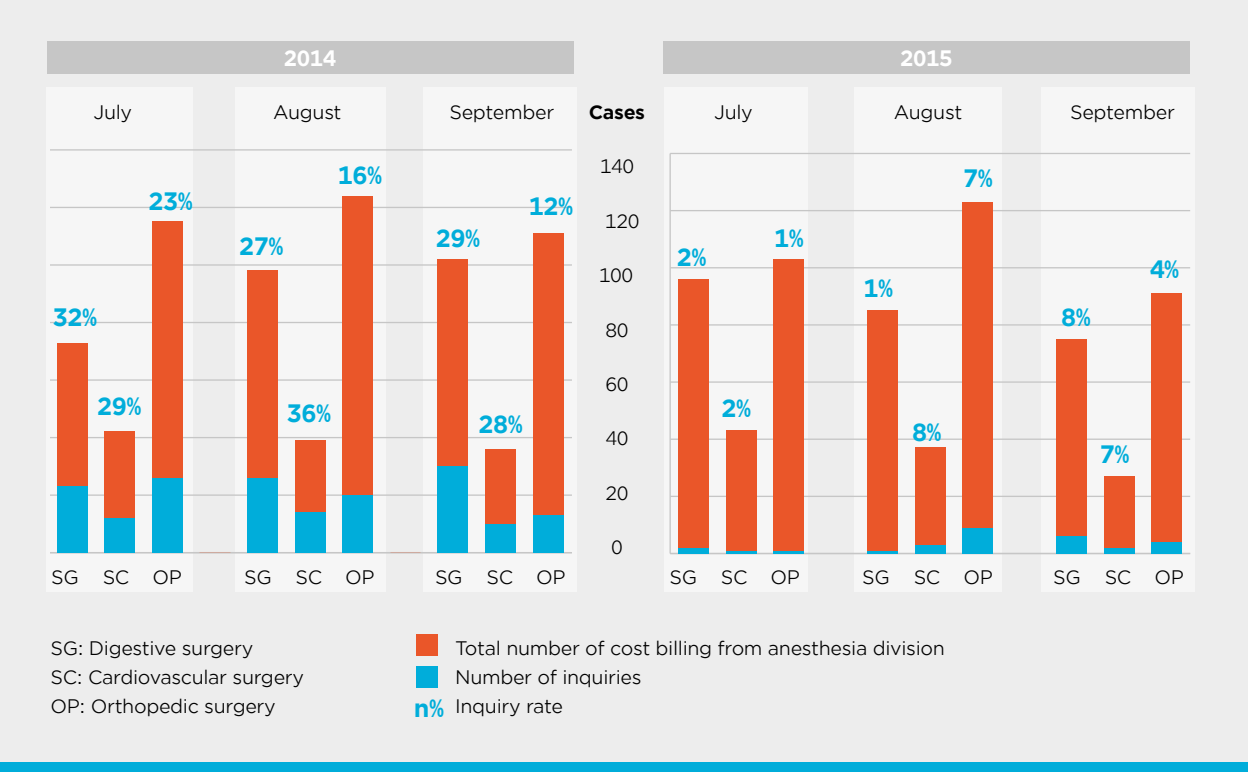
SG: Digestive surgery
SC: Cardiovascular surgery
OP: Orthopedic surgery

■ Total number of cost billing from anesthesia division
■ Number of inquiries
n% Inquiry rate

"An accurate reimbursement claim requires the accurate identification of medical products actually used. Before the implementation of the system, we had often received inquiries about the used materials from the division that is in charge of reimbursement claims. Since running the system, we have received significantly fewer inquiries."

Dr. Makoto Sawada, Research Associate of the Department of Anesthesiology, Tokai University Hospital

By scanning GS1-128 barcodes, the hospital is able to capture the accurate medical products used in operations, thus capturing the actual and accurate cost. This has resulted in an 81.7% reduction in inquiries from the division in charge of reimbursements.

Expanding the use of GS1 standards

In order to utilise GS1-128 barcodes in its operating theatres, Tokai University Hospital needed some technological and operational support.

However, Dr. Sawada emphasises "In the field of retail, barcodes have already been utilised worldwide, and the effectiveness of barcodes has been proven. While there are still not many medical institutions using GS1-128 barcodes, many hospital systems still support non-GS1 barcode formats like patient wristband barcodes."

"I believe that technological issues are likely to be resolved simply by supporting the GS1 standards format, and the true difficulty actually lies in the fact that the system operation methods have not been well established because there are few examples of the introduction of GS1 barcodes," continues Dr. Sawada. "Similarly, in the area of medical information, I believe GS1 standards will provide significant benefits as a fundamental technology, though there are still few examples."

To date, Tokai University Hospital is using GS1-128 barcodes to manage medical products only in its operating theatres—the first such implementation of GS1 standards in the hospital. However, since the traceability system has a very good reputation with multiple benefits, the hospital is considering expanding it to inpatient and outpatient wards in the future.

Also, while surgery costs (as an indicator of current hospital management) are only calculated from reimbursable medical products, large costs are also spent on medical products that cannot be reimbursed. Such non-reimbursable medical products have already been registered to the hospital's master data. The hospital is considering calculating the complete and accurate surgery costs associated with all products used in an operation, as an indicator of hospital profitability.

About the Authors

Makoto Sawada, MD is a Research Associate in the Department of Anesthesiology, Tokai University Hospital. In addition to being an excellent anesthesiologist, Dr. Sawada is familiar with IT systems in hospitals and has led the implementation of GS1 standards in the hospital. Collaborating with GS1 Japan, he is continuously promoting safe and efficient healthcare management with GS1 standards.

Since 2015, **Mie Narusawa** has been the Head Nurse of the Surgical department, Tokai University Hospital. In 2004, Mie graduated from the School of Health Science of Tokai University. She is leading the implementation of GS1 standards in operating rooms to ensure traceability and efficient management.

About Tokai University Hospital

Tokai University Hospital was established in Isehara City, Kanagawa Prefecture, in 1975. The hospital provides opportunities for education and training for various medical professionals, including students and interns from the School of Medicine or the School of Health Science, as well as advanced medical care. The hospital also plays a central role in regional healthcare as the medical institution operating Kanagawa prefectural doctor helicopters, which constitute the wide-area emergency transport system.

www.u-tokai.ac.jp

Healthcare providers

Derby Teaching Hospitals save £2.8 million by using GS1 standards in operating theatres

University Hospitals of Derby and Burton NHS Foundation Trust (DTH) provides both acute hospital and community-based health services, serving a population of over 600,000 people in and around Southern Derbyshire. The trust runs two hospitals: the Royal Derby Hospital, which is a busy acute teaching hospital and London Road is the trust's community hospital. DTH has implemented GS1 standards throughout their operating theatres by scanning GS1 barcodes for full traceability of caregivers, equipment, products and patients as procedures and overall care are performed. Theatre processes are now much more efficient, saving time and costs as well as improving patient safety. The product recall process is also much more precise and efficient; a recall once took up to 50 hours on average per patient and now only takes 30 minutes per patient.

By James Mayne

Optimising without compromise

Derby Teaching Hospitals realised they needed to make a change in their operating theatres. The acute hospital, Royal Derby, had been built more than 10 years ago with 35 theatres that were now operating at maximum capacity. Rather than build more, the hospitals needed a solution that would optimise their existing theatres' efficiency and use—without compromising patient safety.

As with many trusts, DTH was also challenged with efficiently and effectively managing product safety recalls. They used a manual, paper-based process that was time-consuming for clinicians and inadequate for patient safety. The hospitals also wanted a solution that would not only work in their theatres but could eventually work in their wards and clinics.

" By scanning barcodes each step of the way, Derby hospitals are confident that these new processes are safer for our patients. In addition, our inventory management, product catalogue and financial systems have all been integrated so that data captured from scanning barcodes can be used across all hospitals—such as automating the creation of orders to suppliers triggered by the actual usage of products and supplies."

James Mayne, eProcurement and Inventory Manager and Scan4Safety Programme Manager, University Hospitals of Derby and Burton NHS Foundation Trust

Scanning barcodes at each step

In response, Derby Teaching Hospitals implemented and are now using GS1 identifiers encoded in barcodes to track and trace every person, product, piece of equipment and location that is part of an operating procedure. They have implemented scanning barcodes across all of their theatres as well as in endoscopy and cardiac catheter labs.

Basically, everything and everyone involved in a procedure is now identified with a GS1 identifier encoded in a barcode that is scanned and can be traced back to the related patient. Clinicians scan barcodes that identify the patient and the times during which the procedure starts and progresses—from administering the anaesthetic through to recovery, and then at the time when the patient is out of recovery. Location barcodes are scanned as well as barcodes that identify who is present and what job they are performing, the type of anaesthesia used and any procedure that is performed on the patient, especially when a medical device is implanted.

"By scanning barcodes each step of the way, Derby hospitals are confident that these new processes are safer for our patients," says James Mayne, eProcurement and Inventory Manager at DTH and Scan4Safety Programme Manager. "In addition, our inventory management, product catalogue and financial systems have all been integrated so that data captured from scanning barcodes can be used across all hospitals—such as automating the creation of orders to suppliers triggered by the actual usage of products and supplies."

As a result, Derby Teaching Hospitals are saving valuable clinical time that was once spent ordering stock and, at the same time, has reduced inventory waste and costs.

The hospitals have also achieved complete and accurate procedure cost calculations since equipment and implants are recorded based on each patient and procedure, and linked to the associated costs, staff and time information.

Analysing patient outcomes

By scanning GS1 barcodes, Derby Teaching Hospitals now have access to large amounts of data. Since information about all of their theatre procedures is recorded, this major database can be used to identify and analyse patient outcomes and differences in clinical treatments.

The hospitals also use barcodes to record co-morbidities. In particular, there has been a major improvement in endoscopy practices based on the ability to track patient outcomes.

Increased access to data has had huge implications for performance management in Derby hospitals. Having accurate costs and times linked with each procedure highlights any variations between a group of clinicians performing the same procedure. And because scanning barcodes improves the accuracy of data captured, the data is undisputed, enabling clinician-to-clinician discussions about where procedural efficiencies can be made.

> " Before GS1 standards, our recall process took on average 50 hours per patient to trace the affected products and/or medical devices used. Now, it takes 30 minutes at most—a dramatic savings in time and improvement in patient safety."

James Mayne, eProcurement and Inventory Manager and Scan4Safety Programme Manager, University Hospitals of Derby and Burton NHS Foundation Trust

150,000+

theatre episodes have been recorded by scanning GS1 barcodes, giving DTH an expansive database to identify patient outcomes and variances in clinical treatments and outcomes.

Realising benefits at multiple levels

By using GS1 identifiers and barcodes, the hospitals have experienced improvements in their clinical processes with associated financial implications, to include:

✔ DTH now have full traceability in their theatres. When a recall is needed, they can identify all patients that may have been impacted and if any of the recalled products are still in inventory. "Before GS1 standards, our recall process took on average 50 hours per patient to trace the affected products and/or medical devices used," says Mayne. "Now, it takes 30 minutes at most—a dramatic savings in time and improvement in patient safety."

✔ The hospitals have increased the recording accuracy of their OPCS codes—codes used to classify procedures that are encoded in GS1 barcodes—and are now capturing all data and costs at the point of care. This improvement has enabled DTH to earn more than £1 million in additional revenue per year from commissioners.

✔ Complete and accurate procedure costs are now captured by patient due to the recording of scanned data from barcodes on all implants, equipment and products.

✔ DTH have recorded more than 150,000 theatre episodes, giving them an expansive database to identify patient outcomes and variances in clinical treatments and outcomes.

✔ Efficiencies in the hospitals' processes are expected to reach £2.8 million in savings during the hospitals' 2017 - 2018 fiscal year—and that's just from the implementation of standards in theatres, endoscopy and cardio catheterisation labs.

Enhancing the patient experience

Based on the positive impact of GS1 standards in theatres, DTH are expanding their use into other areas. Every location in the hospitals, even stairwells, is now uniquely coded with a GS1 identifier called the Global Location Number (GLN).

The standards-based approach in theatres is now being implemented in wards, bringing the same level of detail and efficiency to the total care experience for patients. In wards, they use Apple iPads, combined with their existing system to track the staff and tasks they are performing, their locations and the devices being used. At the touch of a button, a clinician can track the patient pathway from the point of entering the hospital for an elective procedure and through the course of the treatment, all with back-up detail.

The hospitals' vision: GS1 standards integrated in everything they do as an organisation since the impact so far has been significant for patient safety, outcomes and the total patient experience.

About the Author

James Mayne is the eProcurement and Inventory Manager at University Hospitals of Derby and Burton NHS Foundation Trust and the Scan4Safety Programme Manager. He is responsible for leading the DTHFT Scan4Safety programme that enables the capture of patient-level data at point of care along with the opportunity to positively impact never events and hospital adverse events, while delivering significant financial benefits. James's responsibilities include eProcurement, GS1 standards adoptions, UDI, GDSN and Scan4Safety.

About DTH

University Hospitals of Derby and Burton NHS Foundation Trust provide both acute hospital and community- based health services, serving a population of over 600,000 people in and around Southern Derbyshire. The trust runs two hospitals: Royal Derby Hospital, which incorporates the Derbyshire Children's Hospital and is a busy acute teaching hospital, and London Road, which is the trust's community hospital. Community services are based in health centres and GP practices across Southern Derbyshire provide care to patients in their own homes.

www.derbyhospitals.nhs.uk

Leeds Teaching Hospitals takes huge savings in time and spends it on patient care

Leeds Teaching Hospitals NHS Trust (LTHT) is one of the largest in England with more than 2,000 beds across eight hospitals. The two main hospitals are the Leeds General Infirmary and St James' University Hospital with over 17,000 staff, 1.1 million out-patient appointments annually and delivering regional specialist care for up 5.4 million people. Based on the need for greater efficiencies, improved patient safety and lower costs, LTHT decided to focus on standardising the way it captured data. As a result, LTHT implemented Scan4Safety, a programme designed to leverage GS1 standards and barcodes to track patients, products and locations. The benefits for both LTHT and its patients have been immense. From improvements in inventory to more time with patients, Leeds hospitals are taking an incredible journey as they scan for safety.

By Stuart MacMillan

The Leeds Way

The future of healthcare is about building seamless integrated services, supported by specialist providers that are there when people need them. In order to deliver this, LTHT healthcare professionals have developed and committed to a common set of values. Called "The Leeds Way," it encompasses five goals: to always be patient-centred, fair, collaborative, accountable and empowered.

By delivering on these goals, Leeds Teaching Hospitals are creating a platform to build a strong portfolio of specialist care services at a national and regional level and provide seamless integrated care to local patients.

GS1 standards and Scan4Safety

Leeds Teaching Hospitals joined England's National Health Service Scan4Safety programme as the largest of six demonstrator sites, all charged with introducing GS1 standards to initially increase supply chain efficiency, improve patient safety and significantly reduce costs.

The trusts were tasked with implementing Global Location Numbers (GLNs) to identify each of their locations, Global Trade Item Numbers (GTINs) to identify each of the hospital's products and Global Service Relation Numbers (GSRNs) to identify patients. Encoded in GS1 barcodes, these GS1 identifiers enabled the hospitals to streamline inventory management, purchase-to-pay and product recall processes.

"GS1 identifiers helped to lay the initial, needed foundation, yet, we immediately recognised additional opportunities for using GS1 standards," says Stuart MacMillan, lead of the Scan4Safety Programme at Leeds Teaching Hospitals NHS Trust. "We took the initial requirements and expanded upon them. Our vision was to completely disrupt the healthcare industry through the utilisation of standards and interoperability."

The trust's recent successful audit based on the Department of Health and Social Care (DHSC) criteria is testament to the journey under way.

Taking on the task

How would LTHT bring about one of the largest business change programmes in one of the largest trusts in England? And how would it do this while improving patient care, cutting costs and having no negative impact on the service provided?

This was certainly a formidable task.

"Our initial focus and motivation centred on the benefits that could be realised through improved supply chain efficiencies," explains MacMillan. "We also needed to include the broader vision of the trust."

Additional questions and goals addressed include:

- How could LTHT ensure it was using the most accurate product data throughout its processes?

- How could the hospitals systematically track products from the supplier through to the patient?

- What about reducing clinical time spent on procurement practices?

- What other patient safety initiatives could be improved through data captured via GS1 barcodes?

Increased supply chain efficiencies

LTHT had been working with GHX, a GS1 UK Industry Partner, to implement an inventory management solution that could capture not only product data, but also patient identification data that could be used to link each product administered or used to the patient.

The trust decided to leverage this existing solution, rolling out mobile barcode scanners that worked with the inventory management solution in their operating theatres. Clinical staff could now scan the patient's GSRN encoded in the barcode on their wristband, the theatre's GLN that identified its location, and the barcodes on products issued at the point of care.

Patient wristband scan

Throughout 2017, the trust was able to track all Class III implantable medical devices by batch-level information, using the GTINs encoded in GS1 DataMatrix barcodes. "Using GS1 standards, we not only reduced inventory on hand by more than £1.5 million," says MacMillan. "Our clinical staff had more time to care for patients. We also realised improved efficiencies in our theatres since products were now readily available when needed."

Using GS1 standards in the supply chain has allowed Leeds hospitals to automate their order and receipt processes and helped reduce online requisitions to 11 percent of total orders. In turn, this has released valuable staff time and reduced the cost of ordering, while also saving approximately £75,000 per year based on increased productivity through the use of automated quoting systems.

Real-time patient tracking

To achieve full traceability throughout its hospitals, the trust needed to deploy GLNs encoded in barcode labels to 22,303 locations. The initial rollout prioritised clinical areas with the intent to tackle clinical areas first—the most logistically complex—and, at the same time, encourage clinical staff to engage with the programme and consider different ways of working.

Room / door GLN

"Implementing Scan4Safety with GS1 standards has paid dividends for our hospitals," says MacMillan. "Combining GLNs with the development of a mobile application that links directly to the patient's electronic health record, we were able to explore real-time patient tracking."

In fact, the trust has delivered a successful prototype that allows nursing staff to scan a patient's barcode on the wristband and either open the record or scan the location, down to the bed level.

The electronic whiteboard on each ward is then updated with this information, showing the exact location of the patient.

"Scan4Safety has made a big difference to us as a team, by knowing at a glance where the patient is in our system," explains Gillian East, Senior Sister with Leeds Teaching Hospitals. "When patients arrive on the ward for their surgery they are 'scanned' from then on. One look at the electronic board enables us to see if the patient has gone to another department (for pre-theatre procedures), and at what time, as well as what time they actually went to theatre, or how long they have been out of theatre and in the recovery area. Previously we would not have known which department the patient had gone to and how long they would be and would have had to go into the theatres to get other information.

> **"** Implementing Scan4Safety with GS1 standards has paid dividends for our hospitals. Combining GLNs with the development of a mobile application that links directly to the patient's electronic health record, we were able to explore real-time patient tracking."

Stuart MacMillan, Lead for the Scan4Safety Programme at Leeds Teaching Hospitals NHS Trust

The times and locations provided are very useful for the staff to know and are really helpful when speaking to waiting relatives. It is time-saving to have it all in one place."

"I believe we are the first trust in the NHS to implement this solution," adds MacMillan. "This has led to a host of benefits: reduced calls from the patient's family; improved information that can be shared with them (which leads to their increase satisfaction); clinical time saved when locating patients, and improved management and efficiency of our theatres and beds."

Mobile application

Much faster product recalls

Once the trust had implemented the GLNs, labelling all of its locations, and the theatre staff were scanning barcodes on products and patients, the focus moved to improvements in product recalls.

Previously, any information about used implants was captured, handwritten in a book. Now, with standards, the trust can electronically store this information with a simple barcode scan. A product recall that once could took days, now only takes minutes, with an estimated savings of over £80,000 annually based on saving nurses' time. Patients are safer, too. With implantable products recorded electronically, if a recall is needed, the patient can be more quickly identified and brought back into the trust with urgency.

Improved data management

To support these use cases, product management has been key. The trust has worked directly with suppliers and other trusts to lead the largest work of its kind in the NHS, producing a singular, transparent source of product information for all products purchased by the trust. The catalogue

now holds over 130,000 GTINs and has integrated this data through all points in the demand systems.

Now, the trust can scan products efficiently at the point of care and automate the process of re-ordering products, all because of GTINs on suppliers' packages.

Significant benefits for LTHT and its patients include:

✓ Reduced inventory across the trust to 21 days.

✓ Reduced inventory across theatres, wards and pharmacy by more than £1.5 million.

✓ Saved more than £80,000 annually based on saving nurses' time through more efficient product recalls.

✓ Saved approximately £75,000 annually on implementing automated quoting systems.

✓ Several rooms were cleared of stock for re-utilisation.

✓ Improved reliability and increased visibility of the trust's supply chain.

✓ Minimised stock wastage.

✓ Improved accuracy in patient-level costing.

✓ Freed up clinical staff's time to spend caring for patients.

Taking the journey

"It's been an interesting journey so far, which has brought us some huge patient and financial benefits," reflects MacMillan. "Yet, there is so much more that can be achieved."

As a pioneer in the use of GS1 standards across the NHS, LTHT is keen to take these fundamental building blocks of identifying each patient (GSRN), place (GLN) and product (GTIN) to expand the use of real-time, point-of-care data capture.

MacMillan envisions a world where GS1 barcodes can be used to accurately capture the "who, what, where, when and why" of every patient interaction.

Why couldn't a trust use barcodes to map the patient to not just the products used, but the procedure of care delivered, the co-morbidities they suffer from, the medical and surgical

equipment used, and the staff who delivered the care," says MacMillan. "All while knowing exactly where the patient is on their journey. That level of data capture would allow clinical variance to be fully addressed, improving the patient journey and reducing the cost of the NHS."

Leeds Teaching Hospitals is taking an exciting journey indeed.

Read more about Leeds Teaching Hospitals on page 50.

About the Author

Stuart MacMillan is the Lead for the Scan4Safety Programme at Leeds Teaching Hospitals NHS Trust and a huge advocate of standards in healthcare. He has 10 years of experience in the NHS and has recently led the trust through a successful implementation of GS1 standards, bringing about improved patient safety and substantial financial savings.

About Leeds Teaching Hospitals NHS Trust

Leeds Teaching Hospitals NHS Trust is one of the largest teaching hospitals in Europe, a regional and national centre for specialist treatment, a world renowned biomedical research facility, a leading clinical trials research unit, and the local hospital for the Leeds community. With a £1 billion budget, the trust provides local and specialist services for a population of 770,000 and regional specialist care for up to 5.4 million people, maintaining an international reputation for excellence in specialist care, research and medical training.

www.leedsth.nhs.uk

About GHX

Global Healthcare Exchange, LLC (GHX) is a healthcare business and data automation company, empowering healthcare organisations to enable better patient care and maximise industry savings using its world-class cloud-based supply chain technology platform. GHX brings together healthcare providers, manufacturers and distributors in North America, and Europe, who rely on smart, secure healthcare-focused technology and comprehensive data to automate business processes and make more informed, timely and fact-based decisions. Solutions span procurement and accounts payable automation, contract and inventory management, vendor credentialing and management, business intelligence, payment management and other supply chain-related tools and services.

www.ghx.com

Leeds Teaching Hospitals deploy Zebra printers and GS1 standards for positive patient identification

Leeds Teaching Hospitals NHS Trust (LTHT) wanted to adopt barcode technology to use with its patient identification systems to improve patient safety and to comply with GS1 standards as part of the NHS Scan4Safety programme. As part of the implementation, LTHT explored and assessed various technologies, ultimately selecting Zebra Technologies (Zebra) as the most appropriate technology and implementation partner. Results seen have been comprehensive, including cost savings related to both the hardware and ongoing purchase of wristbands, as well as an improved patient experience from the use of more comfortable Z-Band UltraSoft wristbands. The overall percentage of ongoing calls received by LTHT about wristband printer issues has been monitored and has decreased since the deployment of the Zebra solution.

By Vicki Dodsworth, Mark Songhurst and Wayne Miller

About Scan4Safety and LTHT

The Scan4Safety programme was launched in 2016 and is currently being piloted at six demonstrator sites across the UK. These hospitals are using GS1 standards to trace NHS patients and their treatments, manage medical supplies and monitor the effectiveness of equipment. This is enabling staff to quickly and easily track each patient through his/her hospital journey and to enhance the quality of care they can provide. The hospitals are also reducing unnecessary waste and more effectively managing medical stocks. Early results from the six demonstrator sites show that Scan4Safety has the potential to save lives.

Furthermore, it can save up to £1 billion for the NHS over seven years. Zebra has a varying range of solutions deployed in every one of these six demonstrator sites to assist with the implementation of GS1 standards.

One of the demonstrator sites is Leeds Teaching Hospitals NHS Trust, one of the largest trusts in the UK and one of the largest teaching hospitals in Europe. LTHT provides world-class care to the population of Leeds and surrounding areas. It is also the provider of the largest number of regional and national specialist commissioned services in the UK. The trust has approximately 2,000 beds across eight hospitals. The two main hospitals are the Leeds General Infirmary and St James' University Hospital with over 17,000 staff, delivering regional specialist care for up 5.4 million people.

The positive patient identification challenge

The Department of Health and Social Care (formerly called the Department of Health) has mandated that every service and product procured by an NHS acute trust in England must be GS1 compliant by 2019. GS1 has established standards for identifying, capturing and sharing information, about products, assets, services, people and locations. The goal is to achieve improved patient safety, regulatory compliance and operational efficiencies.

With this in mind, LTHT decided to trial solutions and hardware for positive patient identification (PPID), selecting Zebra Technologies' HC100 printer and Z-Band Ultrasoft Wristbands as the solution to enable the needed positive patient identification throughout the trust.

Programmes were created to take feeds from the LTHT Patient Administration System (PAS) and Accident and Emergency System to reformat patients' wristbands to comply with GS1 standards. Today, this ensures the wristbands are printed with the patient's NHS number, hospital number, name, date of birth and two barcodes— one GS1 linear barcode and a 2D GS1 DataMatrix barcode—for GS1 compliance.

Results: PPID for all patients

The GS1 DataMatrix barcode printed on the patient wristband is scanned at various points of care in the hospital, for example, upon entering an operating theatre or the radiology department. The information encoded in the barcode and captured with each scan allows for the accurate tracking of the patient throughout the journey of care. The use of this data also helps caregivers verify that the right patient is receiving the right treatment and the right procedures.

Following the successful implementation of the new solution, LTHT collaborated with its integration partner, Dakota Healthcare, to enable neonatal and infant wristbands to be

GS1 compliant. The solution incorporated the provision of the wristband printer hardware along with a customised programme to take a feed from the trust's PAS and reformat the data into a compliant wristband layout to meet Information Standards Board (ISB) standards.

As Zebra's Premier Solution Partner in healthcare, Dakota worked closely with the trust and Zebra to provide a fully compliant solution with the trust's iPM PAS System and include a 2D GS1 DataMatrix barcode for ease of scanning to successfully verify patient identification.

Similarly, LTHT has created links with its accident and emergency systems to enable wristbands to be printed for all patients entering the hospitals. The result of this effort is that all patients entering LTHT requiring a wristband will be given a GS1-compliant wristband, enabling PPID, regardless of the route of their admissions.

> " The key to the success of Scan4Safety has been the interaction with our suppliers and technology providers. Working with the market, we have been able to achieve change in a very limited timeline."
>
> **Mark Songhurst**, Information Analyst, Leeds Teaching Hospitals NHS Trust

In addition, feedback from users (staff and patients) about the PPID process and technologies has been very positive. This includes the ease of using the wristband printers, comfort of the wristbands, and readability and resistance of the printed data to hand sanitisers.

LTHT is compliant with the Scan4Safety programme with regard to PPID. The trust now produces over 250,000 barcoded wristbands every year, helping to ensure the safety of every patient within its facility.

Read more about Leeds Teaching Hospitals on .

About the Authors

Vicki Dodsworth qualified as a Registered Nurse in 1992 from Leeds Western Health Authority, specialising in Cardio Thoracic Nursing, also gaining experience in Cardiology, Coronary Care and Cardiovascular Research. Following this Vicki spent 10 years working for a Medical Device manufacturer as a Clinical Advisor / Product Specialist with a particular focus on Intravenous Therapy products. Vicki returned to Leeds in 2010 in the role of Lead Clinical Procurement Specialist within the Supplies and Procurement Department. Today, Vicki is responsible for reviewing the range of medical and surgical supplies and equipment in use and identifying, sampling, trialling and evaluating new and alternative products to ensure and support best practice and value for money, which does not compromise patient care or clinical outcomes and supports patient safety.

Mark Songhurst has been working in the NHS for 18 years, most recently on helping successfully deliver the Scan4Safety programme in the organisation. Having worked for the last 13 years in the Internal Audit department, he has an understanding of governance and process that is being used to enhance the work undertaken at Leeds. Mark is also an NHS Future-Focused Finance Value Maker and a School of Health and Care Radicals Change Agent. He has a real passion for working with people and understanding how people collaborate across the NHS to make changes that will have a lasting impact on the service provided to patients. His infectious willingness to accept change and try something new is helping drive the Scan4Safety programme forward at Leeds.

Wayne Miller is the lead for Healthcare solutions for Zebra Technologies and works to directly improve patient care, supporting partners and end users by delivering the latest mobile, cloud and IoT solutions that assist hospitals and healthcare organisations to deliver efficiencies and improve patient care and outcomes. Wayne has worked for Zebra Technologies for 18 years and has a true passion for healthcare, technology and innovation.

About Leeds Teaching Hospitals NHS Trust

Leeds Teaching Hospitals NHS Trust is one of the largest teaching hospitals in Europe, a regional and national centre for specialist treatment, a world renowned biomedical research facility, a leading clinical trials research unit, and the local hospital for the Leeds community. With a budget in excess of £1 billion , the Trust provides local and specialist services for a population of 770,000 and regional specialist care for up to 5.4 million people, maintaining an international reputation for excellence in specialist care, research and medical training.

www.leedsth.nhs.uk

About Zebra Technologies

Zebra healthcare technology solutions connect medical providers to patient records, caregivers to colleagues and patients to practitioners for better care. Zebra offers a full suite of technologies designed specifically for the unique needs of the healthcare industry, including wristband and label printers, scanners, mobile computers and software that provides visibility and creates efficiencies throughout the care environment. Zebra is a leader in patient identity, mobility and real-time locating and tracking.

www.zebra.com

CentraState lays foundation for safer future

For a small community hospital, CentraState Healthcare System (CentraState) is faced with the same compliance issues and business imperatives as any larger healthcare system: patient safety and cost containment. Clinical supply chain and information system professionals joined together to develop processes for using GS1 standards to automatically and accurately identify products in its operating room (OR), while recording them in patient records required by the Centers for Medicare & Medicaid (CMS) and Office of National Coordinator (ONC). The ability to uniquely identify products used throughout the healthcare supply chain will not only enable CentraState to satisfy regulatory requirements, but also help the hospital increase patient safety, improve staff productivity, achieve precise and inclusive capture of costs, and continue to build community trust.

By Kim Kelly, Beth Finan,
Kevin Giles and Jane Girling

The burden of small, the advantage of independence

As an independent medical centre, CentraState combines the best of two worlds. It maintains a community hospital atmosphere, yet it offers the technology and professionalism typically found at larger healthcare systems. CentraState's independence gives it the agility to move forward swiftly, because it is without a vast hierarchy and the red tape that goes with it.

This is typified by the CentraState's current drive to embed supply chain efficiencies inside the hospital setting through the adoption of GS1 standards. Using barcodes and standards-based automation, CentraState aims to improve patient outcomes and safety, remain in compliance with various initiatives and regulations, and keep careful track of costs involved in providing superior patient care.

The best prescription for effectively tackling this project can be summed up in one word: collaboration.

CentraState's clinical administrator has joined with supply chain and technology colleagues to introduce efficiencies that will benefit all stakeholders—from patients to caregivers to employees. The team is leveraging the Global Trade Item Number® (GTIN®) that uniquely identifies each product supplied by medical device manufacturers. In fact, the GTIN is an essential component of the global supply chain, allowing for automated digital communication with the simple scan of a barcode.

"Without visibility and transparency, it's become more and more complicated to understand our cost for procedures—what's a winner and what's a loser," says Beth Finan, Perioperative Business Administrator at CentraState. "Surgical supplies such as implants and tissues are driving particularly high costs, and we need intelligence and solid knowledge around these supplies."

L to R: Beth Finan, Kim Kelly, Jane Girling, Nancy Miller, OR Billing Assistant, Kevin Giles and Lisa Floyd, Team Leader Surgical Services are members of the CentraState cross-functional team for implementing GS1 standards.

As the person responsible for OR management, Finan recognised the many manual processes being used were extremely labour-intensive for both supply chain and administrative support staff. The adoption of the GTIN as the central standard at CentraState provided the motivation to collaborate system-wide for better, more holistic solutions.

> Without visibility and transparency, it's become more and more complicated to understand our cost for procedures—what's a winner and what's a loser. Surgical supplies such as implants and tissues are driving particularly high costs, and we need intelligence and solid knowledge around these supplies."

Beth Finan, Perioperative Business Administrator, CentraState Healthcare System

Three heads better than one

Kevin Giles, IS Management Team Leader for CentraState, came to the hospital just two years ago and immediately recognised that manual processes and data input was fraught with potential problems. "I knew multiple points of failure could arise within our system [with manual processes], so the IT department was on board right away to modernise and automate the system."

"Reading GTINs embedded in barcodes [barcode scanning] obviously eliminates problems, improving accuracy tremendously," Finan says. "And productivity will significantly improve because people won't be spending time validating what was used, what was purchased or searching out invoices to match with supplies."

> I knew multiple points of failure could arise within our system [with manual processes], so the IT department was on board right away to modernise and automate the system."

Kevin Giles, IS Management Team Leader, CentraState Healthcare System

Jane Girling, Assistant Vice President for Corporate Materials Management, the department that handles supply logistics, supply chain contracting and purchasing for CentraState, had long supported the idea of barcode scanning, but knew it had to be based on a solid system of standards. As the liaison with the CFO, Girling and her team are instrumental in helping to facilitate a one-to-one relationship of item-to-charge. "Once GS1 standards were presented, I joined and provided our support to the effort," Girling says.

As the largest internal client for the supply chain team, the OR was the phase one focus of CentraState's efforts to match GTINs to actual OR products in inventory. Specifically, implantables were the focus because of their limited number and relative high cost. The catheterisation lab's GTINs, with its finite number of consumable products—about 800—were created and mapped during phase two. The third phase will involve operating room consumables and phase four will be the orthopedic implants, non-sterile and non-single units, those with non-sterile packaging.

"Points of failure largely had been the way we were getting our GTIN information and what the vendor was providing to us," Girling says. "In some cases, a manufacturer had not provided the same GTIN as the one on the actual package. Or they hadn't implemented the UDI requirement appropriately or we had older inventory."

"You don't know what you don't know," Finan adds. "If somebody charged for the wrong item and it was an item in the master database, the likelihood is that we would never know."

Scanning for significant time savings in the OR
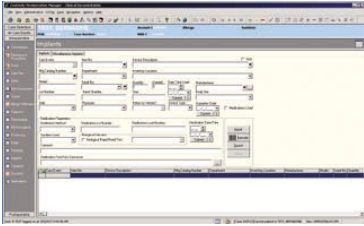
1. Click on "Search" button.
2. Type in value to search.
3. Click "Search Now" button.
4. Scroll through list of items that meet search criteria.
5. Select item from the list.
6. Enter Serial Number.
7. Enter Lot Number.
8. Enter Expiration Date.

Average time to complete: 72 seconds.
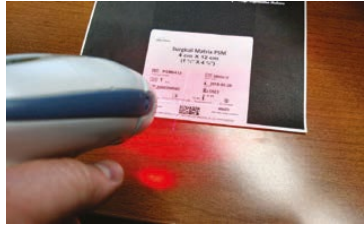
1. Scan barcode.
2. Enter patient-specific information.

Average time to complete: 24 seconds.

> By scanning a product's GTIN encoded in the barcode, CentraState saves substantial time in its OR—approximately 67% or one minute per product—savings that adds up with approximately 7,000 operations a year.

To overcome some of the choke points, the team did a physical inventory to find identical matches and segregate problem items. CentraState's back office systems—the one for supply chain, the one for compliance with electronic medical records (EMR), the health information management system and the clinical system for patient care—would all need to access synchronised information based on the GTIN.

Fortunately, one of the systems allowed them to record multiple identifiers for a single item, and in the case of items without a GTIN, let what information they had to be input until a perfect match could be verified. The team called upon its vendors for tissue, pacemakers and surgical meshes, asking them to provide their GTINs for their low units of measure, populating the correct GTINs manually. (Working directly with some manufacturers is ongoing, as is educational efforts with the clinical staff, showing them what to look for.)

Today, when an OR nurse scans an item from the product categories completed that does not appear automatically in the system, she holds the packaging aside until the GTIN can be found. The IS team has written a script that updates any linked back office systems, in particular the master data system used by the hospital, so no information is lost. Interfaces are also now being developed to automate the input of UDI information into relevant systems.

> " Points of failure largely had been the way we were getting our GTIN information and what the vendor was providing to us. In some cases, a manufacturer had not provided the same GTIN as the one on the actual package. Or they hadn't implemented the UDI requirement appropriately or we had older inventory."

Jane Girling, Assistant Vice President of Corporate Materials Management, CentraState Healthcare System

Moving from process to practice

"This is an industry issue and it's not something that we can always work out directly with manufacturers. GTIN placement is inconsistent and causes confusion: where it is placed on a package, or if a single item comes in a box, inside of which is a peel pouch (that gets opened in an OR) that shows a different number," Finan says. "The independence given to manufacturers is challenging to us, the end-users. These are now coming to light as more of us get involved."

Despite the hurdles, CentraState now has nearly 80 percent of all phase one items loaded into its Clinical System, assuring that barcode scanning of implantables in the OR will match a product—and product charge—in inventory. The move from process to practice took only about six months. Remaining product identification issues may be worked out upstream as more vendors get up to speed on UDI adoption.

" **Reading GTINs embedded in barcodes [barcode scanning] obviously eliminates problems,** improving accuracy tremendously. And productivity will significantly improve because people won't be spending time validating what was used, what was purchased or searching out invoices to match with supplies."

Beth Finan, Perioperative Business Administrator, CentraState Healthcare System

Scannable implantables

Hardware was analysed by Giles' team. Scanners utilised in operating room environments must be able to be properly sanitised by cleaning products and protocols already in use. In addition to the native programmes that can parse barcodes, the scanners needed to be programmable, since CentraState created nearly 50 rules for identifying different types of barcodes.

CentraState has been recognised for its efforts, nominated by the American Hospital for the *Most Wired Innovator* award and named one of four finalists for an innovator award by HealthTrust Group Purchasing.

The accolades helped underscore for the leadership team the project's return-on-investment, but the project team knew the time-savings element—the minutes when eyes are on the patient rather than processes—would be most persuasive. They produced a 60-second video that vividly demonstrates what the system improvements deliver to patients and to the hospital.

"I report to the Vice President of Clinical Services and her primary focus is always patient safety," Finan says. "The fact that this process is impactful on patient safety gives us a lot of support from leadership."

Knowing that the initiative would do double duty in complying with CMS and ONC requirements for "meaningful use" raised the level of support among the hospital administrators and Board. "This is a big deal and it enables us to pass the UDI information to our EHRs," Girling says.

From a practical standpoint, having accurate costs captured for every item used, particularly in the OR where the most expensive products are expended, is important for any not-for-profit institution like CentraState. Accuracy is equally key to avoiding audits from multiple payer entities. And having accurate chargebacks on a patient's bill is vital in building trust, especially for a community hospital.

" **This was a terrific demonstration of collaboration between the clinical staff, the systems administrator,** materials management and the IT team. The results improved work flow and much improved product tracking and charge capture. This effort clearly demonstrates the value in the multidisciplinary approach to project management. The team did outstanding work."

Kim Kelly, Vice President of Clinical Services, CentraState Healthcare System

Factors of success

"I attribute our success to the quality of people that we had on the project," Giles says of the many who contributed to the project.

"Just knowing the benefit from the end result is very motivating. It's easy for the end-user to see that this is something that is going to be valuable to them, so they support us," says Finan.

"This was a terrific demonstration of collaboration between the clinical staff, the systems administrator, materials management and the IT team," says Kim Kelly, Vice President of Clinical Services. "The results improved work flow and much improved product tracking and charge capture. This effort clearly demonstrates the value in the multidisciplinary approach to project management. The team did outstanding work."

"The work that GS1 Healthcare US is doing is great, because they have workgroups on the provider's side and on the manufacturer's side and they're bringing us together," Girling says. "It gives both groups an appreciation for what's happening in the real world."

The CentraState team agrees that a project like this takes time and patience. "I think anyone in the hospital sector understands that there is no small change in a hospital. The ramifications of downstream systems and affects are huge," Giles says.

And collaboration between supply chains and clinical is absolutely essential. "CentraState demonstrates that a small system without a large supply chain and staff support can still have an enormous impact on outcomes. I think that our example can help guide some of the larger systems with greater resources," Girling says.

> **"** CentraState demonstrates that a small system without a large supply chain and staff support can still have an enormous impact on outcomes. I think that our example can help guide some of the larger systems with greater resources."

Jane Girling, Assistant Vice President of Corporate Materials Management, CentraState Healthcare System

Scanning for significant time savings

About the Authors

Kim Kelly, is Vice President Clinical Services with responsibility for operational oversight and strategic planning and development for clinical service areas. She oversees two assistant vice presidents, nine directors and managers, and more than 400 employees in an organization with a $35 million dollar operating budget and $7 million dollar capital budget. Accomplishments include the selection and implementation of a clinical documentation system for peri-operative service areas; implementation of a robotic surgery program; accreditation as a Bariatric Center of Excellence; expansion and relocation of Outpatient Infusion from 6 to 12 bays; and ACR accreditation and re-accreditation in ultrasound, CT Scan, Nuclear Medicine and Women's Imaging (BICOE).

Beth Finan is currently the Perioperative Business Manager at the CentraState Healthcare System responsible for overseeing ancillary, financial and IT functions within Perioperative Services departments. Additionally, she collaborates and takes a lead role on implementation teams for project initiatives. Beth has an extensive background in Accounting and Information Systems practices. She has a strong aptitude for process redesign and efficiency analysis.

Kevin Giles, IS Management Team Leader, brings a different viewpoint to the healthcare IT space with more than 25 years of progressive IT experience, across several verticals. With vast knowledge of how other sectors use technology, he has made it a goal to see new and more efficient IT processes brought to both CentraState's backend and clinical systems. Kevin oversees all of backend applications and systems at CentraState with several analysts and software developers reporting to him. He holds a BS in Computer Science from Rutgers University and an MS in Computer Science from Fairleigh Dickinson University, both in New Jersey, US.

Jane Girling, Assistant Vice President of Supply Chain Management, is a professional health care supply chain executive with over 40 years of progressive experience in the delivery of contemporary, best practice sourcing, procurement, and supply chain services. At CentraState, she created and now directs all aspects of the enterprise-wide supply chain, including an acute care hospital, nursing home, assisted living facilities, retirement community, ambulatory centres and community practice sites. Jane is a Supply Chain Knowledge Leader and was selected as one of only 10 supply chain executives nationwide to serve on the Cardinal Health Customer Advisory Council. She is currently a member of the GS1 Healthcare Provider Advisory Council on implementation of the GS1 standard for UDI. Jane and her team were a finalist in both the American Hospital Association Most Wired Innovator Award 2017 and Health Trust GPO Innovator Award 2017.

About CentraState

CentraState Healthcare System is a nonprofit community health organisation consisting of an acute-care hospital, an ambulatory campus, three senior living communities, a family medicine residency program, and a charitable foundation. CentraState's mission is to enhance the health and well-being of its community through the compassionate delivery of quality healthcare.

www.centrastate.com

Mercy advises that collaboration is the best medicine

GS1 standards are providing the Mercy healthcare system with the needed foundation for automating its operations. And, as its cross-functional team demonstrates, collaboration is the mortar that is enabling its steady digital transformation to address challenges from compliance to care to cost containment. As a result, Mercy has increased its operational efficiency and productivity while continuing to focus on improved patient safety and outcomes. Case in point: Charge capture in its highest cost area—surgery—has improved by 28-30 percent. This has resulted in more than a $340 charge capture per procedure and the documentation of tens of millions of charges not previously captured.

By Betty Jo Rocchio and Matthew Mentel

Care, cost containment and compliance

For more than a decade, the healthcare industry has endeavoured to meet the challenges of improving patient care with an expanded focus on outcomes, cost containment and the ever-growing demand of regulatory compliance. As specialised care has, in many instances, become much more customised—treatments tailored to a single patient's genome rather than to a widespread disease—the need for increased efficiencies has become more urgent than ever before.

While healthcare providers continue to focus on the delivery of improved patient outcomes and safety, they are also making significant changes to streamline processes while striving to comply with emerging regulations.

To this end, healthcare providers and suppliers alike are partnering with GS1 US as well as one another to champion industry initiatives and help government agencies to formulate regulations. The connection between voluntary initiatives and government regulations is increasingly evident as compliance moves from suppliers to healthcare providers. (See sidebar on page 61.)

For hospitals that are now on the frontlines of compliance and improving long-held processes in the interest of visibility, safety and efficiency, new relationships within their own institutions are being forged. This is especially evident at Mercy, the fifth largest Catholic healthcare system in the United States.

> " For collaboration to be successful, there must be a partnership between all aspects of operations, including clinical, supply chain, finance, revenue and other relevant functions."

Matthew Mentel, Executive Director for Business Transformation and Integration, Mercy

Change requires collaboration

"For collaboration to be successful, there must be a partnership between all aspects of operations, including clinical, supply chain, finance, revenue and other relevant functions," says Matthew Mentel, Executive Director for Business Transformation and Integration at Mercy.

Mentel leads a centre of excellence team that focuses on driving improvements throughout Mercy's operations. "Our team concentrates on finding new and better ways of helping our staff and clinicians work—improving processes that will deliver better outcomes to what our coworkers do on a daily basis," continues Mentel. "Our focus is to improve patient care and the clinical experience."

Mentel's clinical colleague and collaborator agrees. "Before I came to Mercy, my vision of the supply chain organisation was that they simply assisted us in what we needed in the operating room (OR), so that we could take care of patients," says Betty Jo Rocchio, Chief Nursing Optimization Officer. "I didn't appreciate the complexity of the supply chain nor did I view it as a strategy. Processes like inventory management were somewhat foreign to me."

" We're working to optimise our inventory, ensuring that the products we are bringing into the OR are managed by our supply chain colleagues and that the cost per case and the charges are accurately captured and documented. This is huge for us because it's how we both measure ourselves financially and, most importantly, document how we cared for the patient."

Betty Jo Rocchio, Chief Nursing Optimization Officer, Mercy

System preferences

The collaboration between Rocchio's perioperative team and Mentel's team began in earnest when Rocchio was trying to find efficiencies to optimise Mercy's preference cards, the "recipe card" of the operating room that provides a set of instructions for the supplies and equipment required for every case or surgical procedure.

At the centre of compliance

The 2013 Drug Supply Chain Security Act (DSCSA) mandated adopting lot-level standards among all supply chain partners, manufacturers and distributors. The DSCSA is now moving toward item-level serialisation, which can be accessed by healthcare providers for patient safety in the next two years.

In 2013, the US Food and Drug Administration (FDA) established the Unique Device Identification regulation to "adequately identify medical devices through their distribution and use." When fully implemented by the 2020 deadline, the label on most devices will include a unique device identifier (UDI) in human- and machine-readable forms, ultimately readable by the caregiving community.

Healthcare providers have been at the forefront of the transition to Electronic Health Records (EHRs) as part of a mandate within the American Recovery and Reinvestment Act enacted in 2009. An important part of the EHR regulation provides criteria for doctors and other caregivers to be certified for "meaningful use." The Meaningful Use Stage 3 requirements make it a requirement to capture UDI on implantable devices, beginning in 2018.

Throughout the evolution of these programmes and regulations, GS1 standards have provided the needed foundation for enabling compliance by pharmaceutical and medical device manufacturers, supply chain participants including distributors, warehouses and shippers, and by healthcare providers—all with a focus on better patient outcomes and safety.

GS1 standards in OR workflow

1 A surgical case is scheduled and matched with a preference card.

2 Preference card items are picked and scanned, including products required, those that may be needed, and those that are supplementary.

3 Case cart enters the OR and product required and scanned are used during the procedure. Products that are needed and add-on products may be used, requiring a barcode scan before use.

4 Upon procedure completion, the case cart contents are verified via two-way confirmation.

5 Unused products are scanned and returned to inventory.

6 Consumed products are replenished as directed.

Each surgeon may have a unique set of requirements spelled out for the procedures performed. Mercy's 259 operating rooms within its 45 healthcare facilities in Missouri, Oklahoma and Arkansas, are governed by preference cards for its thousands of cases.

"What I have come to learn is that preference cards really represent inventory management, not merely items on a list that we use in surgery," Rocchio says. "I turned to Matt's centre of excellence team to examine the problem to see if there was any technology that could assist us in 'cleaning up' the preference cards."

As the two teams began to tackle the preference card process, both recognised the value of taking a holistic approach. "Each of our functions had a different approach to the problem," Mentel says. "The challenge became, how do we do something that allows all points of view to come together for an integrated solution."

"We expanded our scope and looked at enhancing our operational work flows, both clinical and supply chain. That was key," Rocchio says.

The work of Mentel's and Rocchio's teams dovetailed with the concurrent need to adopt processes surrounding UDI that were moving from healthcare manufacturers' production lines into healthcare providers' operations such as the OR.

In addition to leveraging the benefits of UDI in their systems, the inventory management aspects

of the improvements are not inconsequential. Mercy's ORs hold the dual distinction of being among the highest cost centres as well as the highest revenue-generating centre for the non-profit system.

"We're working to optimise our inventory, ensuring that the products we are bringing into the OR are managed by our supply chain colleagues and that the cost per case and the charges are accurately captured and documented," Rocchio says. "This is huge for us because it's how we both measure ourselves financially and, most importantly, document how we care for the patient."

No one remains naïve to the increases in healthcare costs. Institutions that can efficiently deliver superior care while they control their costs will best serve their communities. And because surgical care is the most expensive, its cost-of-care makes it among the most obvious areas for improvement.

Surgical precision

"Perioperative services represent from 40-50 percent of any hospital's revenue stream. It's essentially a business within a business," explains Rocchio. "You have to deliver quality care to be successful in that business, but once you hit the quality care mark, you need to look at the cost of that care. And the very most

successful organisations today and in the future are going to be delivering that same or higher quality for less cost."

Being able to identify the exact products that an OR is using in every single case helps establish the cost and reduce risk to the patient. "GS1 standards and barcodes allow us to consume a product, capture it in a highly technological system, identify any product expiry or recall and understand our true cost of care," Rocchio says. "Mercy wants to know the cost of delivering that care so we can tie it to a quality outcome for comparative effectiveness."

A new product may have clinical advantages, but it may be a device never seen before in the OR. A surgeon about to perform a complex procedure with an instrument or product never seen before can affect an unknown outcome. "That's a lot of variability to work through," Rocchio says. "There is a lot to consider—a contracting strategy, an item management approach and a preference card process."

> "An accurate barcode that can be quickly and simply scanned by caregivers, so they can focus their complete attention on the patient and not try to interpret what was said by someone who manufactured that product three cycles ago. These are the things that are important."

Matthew Mentel, Executive Director for Business Transformation and Integration, Mercy

A unique product identifier like the GS1 Global Trade Item Number® (GTIN®) helps the system track the product's origin, its attributes, including expiration date, and once consumed, its cost and contribution to patient well-being 30, 60 or 90 days post-surgery. Post-market surveillance of the patient is impossible if data is not linked. And data can be linked with help from barcodes based on GS1 standards.

"Product identification becomes so important in this instance. The reality is that on the clinical side, it's not about cost. It's about 'how do I make sure I reduce risk and provide the best possible care to the patient?' Using barcodes based on standards allows us to deliver healthcare consistently and into the future," says Rocchio.

"An accurate barcode that can be quickly and simply scanned by caregivers, so they can focus their complete attention on the patient and not try to interpret what was said by someone who manufactured that product three cycles ago," Mentel adds. "These are the things that are important."

A full circle

But the true measure of its success is the widespread collaboration Mercy has achieved. Hospital representatives proudly tell the story of the surgeon who asked to use a product before it was scanned. The circulating nurse stopped the surgery and said, "Doctor, please recognise we're scanning a product to make sure it's been properly identified, to see if it's been recalled or expired before you put it in that patient's body. Do you want to go around that process?" He said: "I do not. Scan the product. I can wait."

There are still obstacles to seamless operations, in both senses of the word, some of which are occurring upstream. Manufacturers may not be applying the proper barcodes to products or are applying multiple barcodes that can be a source of confusion in the OR. Some suppliers are using a single GTIN for several similar, but not identical, products. These issues associated with the implementation of standards and barcodes are being corrected throughout the healthcare supply chain and will eventually impact providers like Mercy.

Rocchio has high praises for the changes being realised by the use of GS1 standards in product identification. She urges the improvement of the preference cards themselves—the roadmap to any surgical procedure, some of which may not have changed in years.

"Charges are taken from the preference card. Now we have a system for keeping preference cards cleaned up. We have a system for scanning products. And the back half of the system checks us to make sure what we brought into the room is consumed and charged or it shows up to be put back in inventory. It goes full circle to make sure we've obtained charge capture," Rocchio says.

Rocchio believes this ultimately leads to improved clinical user satisfaction. She also stresses: "I'm not making any more money by optimising charge capture, but what I am doing is being able to provide the true cost of care in every single procedure."

" *Charges are taken from the preference card. Now we have a system for keeping preference cards cleaned up. We have a system for scanning products. And the back half of the system checks us to make sure what we brought into the room is consumed and charged or it shows up to be put back in inventory. It goes full circle to make sure we've obtained charge capture."*

Betty Jo Rocchio, *Chief Nursing Optimization Officer, Mercy*

Bottom-line benefits

Both Mentel and Rocchio stress how standards are helping in the important area of inventory management – not expending labour to pull unneeded product that then has to be returned to inventory.

"It may seem a low priority, but the amount of time spent on a redundant activity increases your risk of inaccuracy. And obviously optimally managed inventory is huge for everybody. You must have complete visibility to what you have if you want to optimise it," Mentel says.

The partnership between business operations and clinical operations is clearly one of the keys to Mercy's ongoing success in adopting GS1 standards throughout the system, not just as a means of compliance, but leveraging standards to make vast system improvements. More than just generating data, barcodes accelerate pre-op and post-op processes because information is instantly available and inventory replenishment is vastly improved.

"We've already noticed a 28-30 percent improvement in the identification of supply charges being captured per [surgical] case. These are products that we thought we were capturing that we weren't. We have much better visibility into our cost per case now," Mentel says.

The charge capture improvements equal more than $340 in additional charge capture per surgical case. With over 250 operating rooms doing multiple procedures every day of the year, the cost capture improvement equates to tens of millions of dollars now documented by Mercy.

"You can't have this unless you have unique product identification. It's the barcodes that facilitate this capture and reduces the burden on operations," Mentel concludes.

Rocchio adds: "Healthcare systems cannot afford to ignore GS1 standards for UDI and so much more. It's going to be the foundation of our business, our future."

Impact of GS1 standards in OR operations

Realising unrecognised inventory assets	Improving inventory utilisation	Optimising charge capture	Improving preference card accuracy
$2.4M	**$4.7M**	**$13M**	**$459K**
Automating replenishment	Reducing cycle counts	Improving clinical user satisfaction	Optimally managing owned vs. consigned inventory
$4.SK	**$167K**		

CLINICALLY LED	OPERATIONALLY DRIVEN

"" We've already noticed a 28-30 percent improvement in the identification of supply charges being captured per [surgical] case. These are products that we thought we were capturing that we weren't. We have much better visibility into our cost per case now."

Matthew Mentel, Executive Director for Business Transformation and Integration, Mercy

About the Authors

Betty Jo Rocchio, Chief Nursing Optimization Officer, has oversight and leadership accountability for 45 plus clinical and procedural areas across four states within Mercy. She manages the quality, service and financial initiatives for Perioperative Services, Cath and EP Labs, and GI Labs. This includes a $2.8 billion revenue stream and $550 million cost structure.

Betty Jo has more than 26 years of experience in healthcare, including 20 years in various leadership positions in Perioperative Services and Procedural Areas. These include Chief Nurse Anesthetist, VP Nursing and CNO, System Director of Surgical Services, and now Vice President of Perioperative and Procedural Areas. At Mercy, Betty Jo is focused on developing the Triple Aim strategy for her areas and advancing the three key operating paths—clinical, operational and financial—to help successfully position Mercy for the next phase in healthcare.

Matthew Mentel, Executive Director for Business Transformation and Integration, is responsible for identifying, designing and implementing creative solutions as well as leveraging current technology to drive efficiency and expense reduction throughout Mercy. He oversees several key initiatives that seek to optimise the use of tools, technology, process improvement and metrics across the entire care continuum, driving more predictive and outcome-based decisions that help improve and enrich the Mercy experience for caregivers and patients.

Matthew has more than 25 years of experience in healthcare, including 17 years in supply chain and information technology. His career includes service to a variety of other healthcare providers, including ROi (Resource Optimisation & Innovation), SSM Healthcare System, BJC Healthcare and St. Louis University Hospital, as well as a healthcare consulting/accounting firm.

About Mercy

Mercy was founded by the Sisters of Mercy in 1986, but its heritage goes back more than 185 years. It began with an Irish woman named Catherine McAuley, who wanted to help the poor women and children of Dublin. Though Catherine had a modest upbringing, she received an unexpected inheritance that allowed her to fulfil her dreams. In 1827, she opened the first House of Mercy in Dublin, intending to teach skills to poor women and educate children. Many volunteers came to help. A few years later, Catherine founded the Sisters of Mercy, the first religious order not bound to the rules of the cloister, whose Sisters were free to walk among the poor and visit them in their homes. By the time Catherine died in 1841, there were convents in Ireland and England, and in 1843, the Sisters of Mercy came to the United States. In 1871, they traveled to St. Louis and from there throughout the Midwest, beginning what would, today be known as Mercy.

www.mercy.net

Suppliers and GPOs

Suppliers and GPOs

Device identification for traceability in the IVD-reagent supply chain

Dian Diagnostics Group Co., Ltd. (DIAN) is a China-based in-vitro diagnostics (IVD) company that primarily offers medical diagnostic outsourcing services. In China's IVD-reagent supply chains, there was no consolidated material coding standard. This caused a series of problems, such as information inconsistency between upstream and downstream enterprises, the lack of traceability in supply chain processes, human-input information that was prone to errors, and high costs with low efficiencies.

To address these issues, DIAN and the Zhejiang Institute of Standardization implemented an IVD-reagent solution based on GS1 standards. They labelled each IVD-reagent individual unit with a GS1 Global Trade Item Number® (GTIN®) and key attributes encoded in a GS1 DataMatrix barcode. They also linked upstream and downstream enterprise information to the GS1 identifiers, as well as upgraded healthcare providers' supply processing distribution (SPD) systems for compatibility with the GS1 standards.

DIAN has improved overall operating efficiency, reduced logistics information errors and maintained the traceability of IVD-reagents. GS1 standards have also eliminated the labourious work of applying non-standard proprietary codes in hospitals. Since DIAN is manually labelling the IVD-reagents, it is continuing its work to ensure that the labelling is eventually completed by IVD-reagent manufacturers.

By Zhenggang Wei, Lei Fang, Xiu Wang, Zhiqiang Zhao and Jin Shi

Background

IVD-reagents—clinical test kits, quality control materials, calibration materials and more—are used for biological sample tests in the process of disease prevention, disease diagnosis, prognostic evaluation, health evaluation and genetic disease prediction. Initially, IVD-reagent logistics information often relied on handwritten notes and manual investigation, which was not efficient and error prone. Moreover, due to the lack of unique identification, when an issue occurred, DIAN could only estimate which IVD-reagent caused the issue by using the IVD-reagent's lot or batch number, thus, creating traceability errors in quality control.

With the emergence of automatic scanning information technologies, GS1 identifiers and barcodes are now applied to IVD-reagent secondary packages within the supply chain. In the US and Europe, major IVD-reagent manufacturers have already adopted GS1 standards for the unique identification of their products (e.g., Roche, Thermo Fisher, Sysmex, BioMérieux, and others). Yet, some manufacturers are applying GS1 barcodes only at the IVD-reagent's secondary level of packaging, which limits the granularity of tracing individual items.

In China, there is no consolidated material code regulation nor Chinese Unique Device Identification (UDI) regulation to necessitate the application of GS1 barcodes in the IVD-reagent supply chain, as yet. Different jurisdictions and supply chain participants are using their own way of material coding.

DIAN's third-party, independent clinical laboratories (ICL) provide diagnosis services to clients, and DIAN is the largest IVD reagent agency in China market. IVD-reagents are widely used in DIAN's core businesses, such as ICL tests, logistics processing in the supply chain, and precision medicine centre test projects.

The lack of a consolidated coding standard in IVD-reagent supply chain causes a series of problems. For example, the company must use a significant amount of labour to manually check and even generate logistics information in its processes. This manual work is very inefficient, error prone and can provide ambiguous information. Achieving traceability across the entire supply chain is also not possible. All of these problems significantly increase the company's operating costs and negatively impact quality control and customer satisfaction levels. With business becoming increasingly sophisticated coupled with growing volumes of products, the lack of a consolidated coding standard has impacted DIAN's growth.

To improve traceability, transparency, efficiency, information accuracy and data exchange in the IVD-reagent distribution process, DIAN and Zhejiang Institute of Standardization designed and implemented a GS1 standards-based IVD-reagent identification solution. The solution, used in DIAN's core business, also helps the company monitor adverse events and recall defective products, while eventually enhancing service quality and customer satisfaction.

Identify and label the minimum IVD-reagent unit pack with GS1 barcodes

When an IVD-reagent enters DIAN's warehouse, the warehouse operator labels the minimum unit pack with a unique GS1 GTIN, batch/lot number and expiration data, encoded in a GS1 DataMatrix barcode. This barcode is the key when DIAN traces the unit within the warehouse and in the supply chain. The IVD-reagent GS1 barcode structure is shown in Figure 1.

The IVD-reagent GS1 barcode structure

Required		Optional			
AI*	GTIN	AI	Batch/lot number	AI	Expiration date
01	N14	10	X20	17	N6

Figure 1: Each unit pack of IVD-reagent is labelled with this information encoded in a GS1 DataMatrix barcode.

Link upstream and downstream enterprise information to the GS1 barcode

When an IVD-reagent is delivered from storage, an operator scans the barcode, reviews the item, and binds the ODO (Outbound Delivery Order, including customer name, outbound date and order number) with the barcode in the system. Thus, DIAN links the upstream and downstream enterprise information with the GS1 barcode, and IVD-reagent traceability is established.

Upgrade hospitals' supply processing distribution (SPD) system to be compatible with the GS1 barcode

DIAN has shared the IVD-reagent GS1 identification structure and rules with hospital SPD software vendors that have upgraded their SPD software to be compatible with GS1 standards.

Hospitals can now utilise the same GS1 standards-based barcodes. When an IVD-reagent unit enters the hospital's storage area, hospital staff use a handheld wireless scanner to scan the GS1 barcode to collect the product information (shown in Figure 2).

Figure 2: The hospital staff scans the GS1 barcode to collect product information.

Since GS1 identifiers and barcodes are used to maintain traceability and are scalable, hospital staff can add more information based on use, such as stock inbound date, distributor's information, department information, and more. Since the end of Q1 2018, DIAN has deployed this solution to more than 60 hospitals.

Benefits

DIAN's GS1 standards solution improves the IVD-reagent supply chain by:

✓ **Ensuring the accuracy of IVD-reagent logistics information.** The data is collected by scanning the GS1 barcode instead of using manual input. Human-generated errors in this process have been dramatically reduced.

✓ **Improving the traceability in the IVD-reagent supply chain.** The IVD-reagent is labelled with a GS1 barcode at the single-use or unit-level of packaging. The upstream supplier information and downstream ODO (Outbound Delivery Order, including customer name, outbound date, order number) information is accessible via the identification information within this barcode, so all parties in the supply chain can easily query this information. When a quality issue occurs, DIAN can precisely locate the defective product and tell which IVD-reagent batch/lot the issue originated from. Parties in the entire supply chain can respond much quicker and with increased agility, and any logistics-induced medical negligence can be proactively managed.

✓ **Reducing the workload of labelling barcodes in hospitals.** Since the hospital SPD systems are compatible with GS1 standards, hospital staff can continue using GS1 barcodes in their work. When an IVD-reagent enters the hospital's warehouse, hospital staff only needs to use a handheld wireless scanner to scan GS1 barcodes, rather than printout a proprietary barcode and apply the label to the IVD-reagent again. As a result, hospital staff workload has been significantly reduced.

Conclusions

In summary, DIAN's GS1 standards solution increases access to accurate and complete logistics information in the IVD-reagent supply chain across participating entities, improves IVD-reagent product traceability and reduces hospital workload.

However, it should be noted that DIAN, as a distributor of IVD-reagents for its business trading segment, must still manually label a significant amount of IVD-reagents with GS1 barcodes when they are received into DIAN's warehouses for the following reasons:

- Manufacturers do not use identification barcodes.

- Identifiers and barcodes used by manufacturers are proprietary.

- Identifiers and barcodes do not provide enough information.

The resulting manual work is error prone. In addition, DIAN's GS1 barcodes can only trace back to DIAN's immediate upstream suppliers, and downstream traceability is compromised if the company's system is not compatible with GS1 standards.

Given this, a one-for-all material identification solution should begin with the IVD-reagent manufacturers. When a GS1 identifier is assigned and barcode applied on an IVD-reagent in production, before entering into circulation, true end-to-end traceability across the entire supply chain is possible. All entities that have participated in the process are able to trace every single IVD-reagent's status—whenever and wherever it may be, including manufacturers, suppliers, distributors, healthcare institutions, hospitals and even individual patients. Regulators can digitalise their monitoring systems to automate the supervisory process via the GS1 standard as well. The overall business scenario is illustrated in Figure 3.

Using GS1 standards in IVD-reagent distribution is gaining momentum. With ongoing adoption by key stakeholders, the overall IVD industry's distribution costs could be reduced while the service quality, security and customer satisfaction levels could increase.
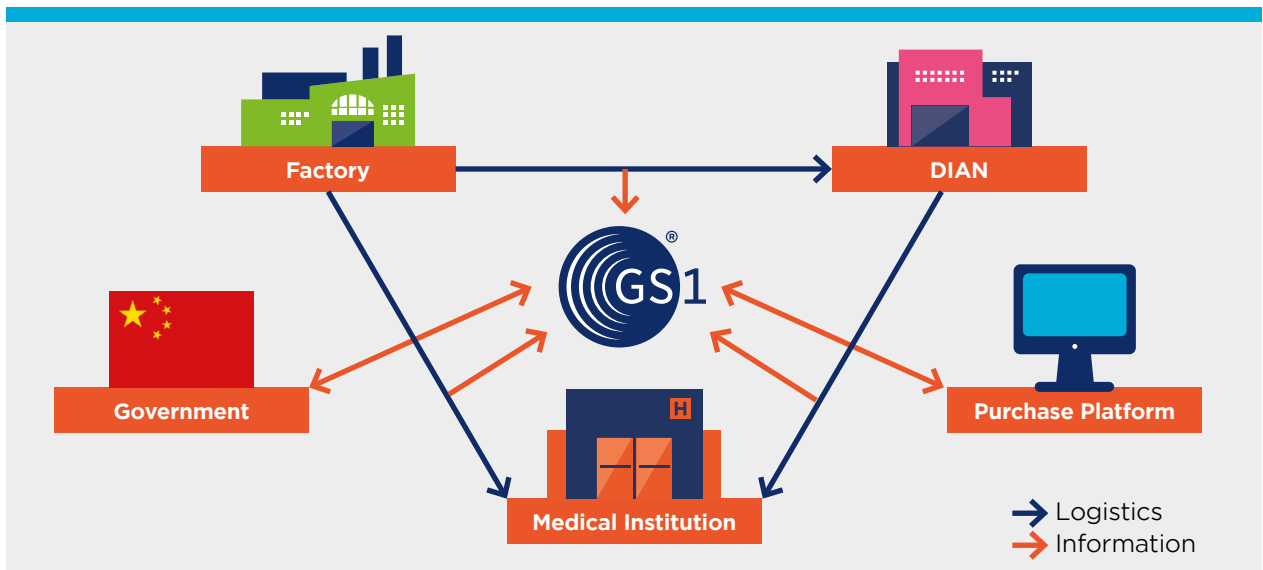
Figure 3: The overall business scenario when GS1 barcodes are applied to the entire IVD-reagent supply chain.

About the Authors

Zhenggang Wei (David Wei) is the Vice President and Chief Information Officer (CIO) at DIAN. He has 20 years of consultancy and IT services practice in strategy, planning and digital technologies.

Lei Fang is the Warehouse Management System Project Manager. He has 10 years of experience in business analysis and IT solutions in the supply chain and logistics.

Xiu Wang is IT PMO at DIAN. She is experienced in IT project management assistance and coordination.

Zhiqiang Zhao is Chairman of Zhejiang Logistics Information Technology Standardization Technical Committee . He is engaged in the research and promotion of coding management, policy and automatic identification technology, especially in the field of coding internationalization and supply chain management.

Jin Shi is Member of Zhejiang Logistics Information Technology Standardization Technical Committee. He is engaged in the research and promotion of coding and automatic identification technology, especially in the field of pharmaceutical product coding and supply chain logistics management.

About the Companies

Dian Diagnostics Group Co., Ltd., formerly Zhejiang Dian Diagnostics Co. Ltd., a listed company in China Shenzhen Stock Exchange, is a China-based in-vitro diagnostics company principally engaged in the provision of medical diagnosis outsourcing service. The company operates through two main segments: service industry segment and business trading segment. The service Industry segment is primarily involved in the fields, including diagnosis services, diagnostic equipment distribution, cold chain logistics and physical health examinations, among others.

www.dazd.cn

Zhejiang Logistics Information Technology Standardization Technical Committee provides the services of promoting, managing and supervising automatic identification technology in the entire Zhejiang province. In recent years, its prominent achievements have been accomplished in standardization of logistics information, electronic commerce and Smart Cities.

GAM launches E_GEN, a platform for exchanging product and supply information

Today's French health institutions are challenged by new regulations that require new capabilities to track and trace all healthcare products. More than ever, doctors and pharmacists need reliable and complete trade item data for increased knowledge about the products they use on patients. In 2016, Groupement d'Achat Mutualiste (GAM), a French group purchasing organisation (GPO), launched the deployment of the E_GEN platform to automate the exchange of inventory data between its members and their suppliers. Connected to the Global Data Synchronisation Network® (GDSN®), the platform receives up-to-date product and order tracking information (order status, shipping advice and more) to ensure better data quality and greater patient safety.

By Stéphane Ancel

Automating the flow of information

Healthcare professionals need complete and accurate data about healthcare products to enable highly efficient processes such as order-to-cash, inventory management and the dispensing of 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 a decade, French hospitals have been aware of this need and have attempted multiple times to synchronise product information with their suppliers and their points of care. Yet, the automated flow of information is not yet a widespread reality in France's healthcare sector.

Some suppliers have offered the possibility of turning manual purchase orders into electronic ones, but have not gone further to automate the entire order-to-cash process. In addition, deployed solutions have used proprietary protocols that impede interconnectivity between actors. In 2018, FAX technology for sending and receiving healthcare product orders is used in most situations.

However, regulations (e.g., European Union's Falsified Medicines Directive and Unique Device Identification, and the French Code of Public Procurement) are evolving and aim to automate product information and exchange formats. This represents a major opportunity to deploy an electronic catalogue, which can be an essential tool for market access.

GAM, as a facilitator of relationships between healthcare institutions and their suppliers, wants to harmonise product data and its exchange formats.

The GPO's strategy is to rely on new tools to facilitate the automation of information flow and by using regulatory requirements as a driver for logistics optimisation.

The need for global standards

Created in 2012, GAM consolidates the purchases of healthcare and medico-social organisations associated with health insurance companies. GAM's objective is to provide solutions to its members to reduce operating costs while improving the quality of care for patients and residents. The GPO selects a small panel of suppliers per procurement segment based on competitive bidding. In return for an identified volume of purchases, the selected suppliers apply specific commercial conditions (e.g., prices, terms for delivery) for the duration of the contract on the selection of their products.

In 2016, GAM launched a project to digitalise product information and all the data related to healthcare supplies. The specifications of the planned project was to build a solution based on existing international standards in order to be the least restrictive and facilitate a lower-cost deployment for all stakeholders.

With this goal in mind, GAM chose to implement GS1 standards to identify products and to share product information through the GDSN, to enable the interoperability of systems between actors.

GAM teams contributed to the development of a pharmaceutical drug and medical device data model in the working groups led by GS1 France. This step was essential to facilitate the deployment of the product sheets by facilitating consensus with all the players, including institutions, purchasing groups and manufacturers.

To save time, the project managers relied on logistics processes that had proven their worth in other sectors such as mass-market supply chains. The strategy aimed to adapt these processes to the unique need of the healthcare sector.

Introducing the E_GEN platform

GAM chose @GP—an IT provider that is active in agribusiness and DIY sectors—to provide an interoperable platform that complied with GS1 standards. @GP developed a customised platform and GAM branded it E_GEN.

GAM is the first GPO in France to initiate a platform that enables the full digitalisation of supply chain data flow between suppliers and healthcare providers. E_GEN is a platform for order tracking information and a database for
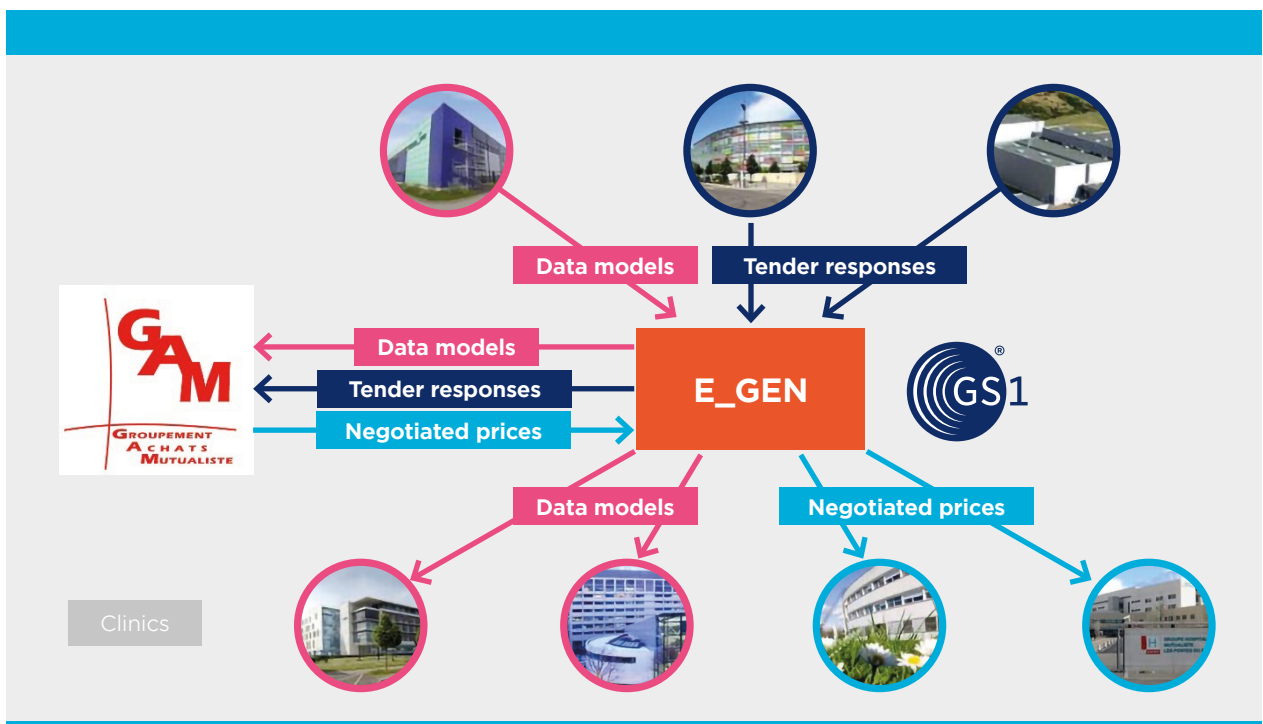
product information exchange. The platform receives suppliers' data models and tender responses, and sends consolidated information to healthcare providers.

Two steps were launched in parallel to create the database E_GEN: a first step to perform integration tests of suppliers' data models to the E_GEN database; a second step to develop interfaces with the healthcare providers' IT systems to provide them with consolidated information through E_GEN.

Once the suppliers' electronic catalogues are accessible to healthcare providers, a second phase will be launched on the platform for electronically distributing electronic data for order tracking, including orders, despatch advices, delivery notes and invoices.

GAM wanted to ensure perfectly synchronised data between all suppliers and healthcare providers before advancing to the next phase. This will make the content of the data exchanges reliable and enable the automated integration of orders and delivery notices, electronic invoicing in EDI and other processes all along the supply chain.

Expected benefits of the E_GEN platform include:

✔ Improved quality of existing product data in the ERP systems of healthcare providers (identifiers, data model contents and negotiated purchase prices)

✔ Faster and streamlined transactions based on reducing the "red tape" burden along with the automation of information

✔ Improved patient safety by adding traceability product data from suppliers into healthcare providers' IT systems

But that's just a start and more than ever in healthcare: "It is the function that creates the organ."

About the Author

*Since 2012, **Stéphane Ancel** has been leading GAM, a group purchasing organisation (GPO), for 100 private hospitals in France. He started his career as a CEO of Polyclinique du Parc, care provider in the city of Dole, France. From 2001 to 2008, he was in charge of investments and services at Helpevia, a private French GPO. He then managed the purchasing department of GHMF, a group of 85 care providers from 2008 to 2012.*

About GAM

Groupement d'Achat Mutualiste (GAM) *is a public group purchasing organisation that manages an annual volume of purchases of €70 million on behalf of 50 health establishments and 400 medico-social structures. It supports high performance for all actors, thanks to mutualisation and professionalisation of purchasing and logistical activities. The goal of GAM is to generate savings for institutions and member services through the levers of price, commercial conditions and specific commitments made by suppliers. GAM acts on behalf of health facilities and services (medicine, surgery, obstetrics, follow-up care and rehabilitation, home care and medico-social (early childhood, disability and elderly).*

www.gam-mut.fr

Automating inventory management with GS1 EDI standards

When a fellow healthcare professional remarked about the German healthcare system on Facebook, the University Medical Centre Hamburg-Eppendorf (UKE) decided it was time to take action. The medical centre considered the situation as a good opportunity to finally address issues that had grown over time: increasing costs, time pressures and regulatory compliance requirements. UKE issued an invitation to tender for a vendor-managed inventory (VMI) solution with the goal of "stock optimisation with readily available supply." With a VMI, a supplier would assume responsibility for the medical centre's inventory. Johnson & Johnson Medical GmbH proposed taking "the bull by the horns," no longer accepting half measures, no more Excel lists and no more manual entry.

By Rüdiger Forster

Stock replenishment based on consumption

"Maintaining documentation required for invoicing gets in the way of my work and takes up time that I used to have for my patients," said an operating theatre nurse with over 20 years of experience. The nurse also mentioned cost pressures and personnel shortages—challenges that would not be easily solved.

Yet, the University Medical Centre Hamburg-Eppendorf decided to take a closer look at areas for potential improvements—processes that impacted patients such as logistics and medical device inventory management. The hospital and one of its major suppliers, Johnson & Johnson, set out to tackle the significant challenges in the inventory management processes and simply abolish list-making.

The strategy included a fully automated process cycle that would calculate on a daily basis which medical devices had been removed from the storeroom. It also provided information about

which of these were "shelf warmers" and which were "fast sellers" or frequently used. With this approach, Johnson & Johnson Medical GmbH was awarded the contract to implement a VMI software solution with Electronic Data Interchange (EDI) based on GS1 standards.

Today, the EDI-based solution is fully operating. It is different from other inventory management systems in that it reports what stock has been actually consumed—versus what products have simply been removed from stock.

Data about stock consumed is accumulated, evaluated and then translated into an optimised order. This allows Johnson & Johnson to deliver precisely the needed quantity for replenishment, at exactly the time needed.

"To do this, only an automated system could master this complex task," advises Christina Otto, Project Manager, with the Logistics department, University Medical Centre Hamburg-Eppendorf. "The 'human factor' could mean responding too late or even incorrectly."

While the road to implementation wasn't always smooth, the team developed a common strategy and built a partnership based on trust.

Master data and GS1 standards as the foundation

To enable digital communication between the manufacturer and hospital, data needed to be exchanged directly between their systems. This was implemented with help from a Trinovis subsidiary, GSG Gesellschaft für Standardprozesse im Gesundheitswesen (GSG).

When the hospital staff scans the GS1 barcode on a product's package, the consumption of the product is automatically recorded in the inventory management system. By scanning barcodes, the hospital staff has been able to save 90 percent of the time once required when entering the information manually. As soon the product's inventory level starts to drop, the system notifies the inventory management system to calculate a new level of stock and it automatically places a new order.

As mentioned earlier, GSG was instrumental in establishing the foundation for this process by providing the EDI infrastructure. "As a supplier, we played a key role by increasing the quality of our master data to 100 percent complete and accurate, as the basis for introducing an EDI ordering process," explains Rüdiger Forster, Customer Connectivity & Project Manager with Johnson & Johnson Medical GmbH. "We are also applying GS1 unique device identifiers encoded in barcodes on 100 percent of our medical device products for ease of scanning."

> " As a supplier, we played a key role by increasing the quality of our master data to 100 percent complete and accurate, as the basis for introducing an EDI ordering process."
>
> **Rüdiger Forster**, Customer Connectivity & Project Manager, Johnson & Johnson Medical GmbH

Positive across the board

The benefits for UKE have been positive across the board.

Stock levels have been reduced by streamlining the mix of products to levels that are actually needed, while achieving just-in-time delivery. As a result, the medical centre now benefits from higher stock availability, the ability to plan, a reduction in inventory levels and an electronic process that includes a history of products consumed.

In addition, the foundation for meeting regulatory requirements has also been established. Compliance with the German Ordinance on the Dispensing of Medical Devices (MPAV) and the new EU Medical Device Regulation (MDR), including the use of the Unique Device Identifier (UDI), is now achievable with time- and labour-saving processes based on accurate master data and electronic documentation procedures.

In turn, Johnson & Johnson Medical GmbH has benefitted from a reliable revenue stream as a result of long-term contracts with the medical centre. Having optimised available inventory levels and the ability to respond quickly in the event that a product is changed has led to the improved identification of discrepancies and fewer errors overall.

Trust is elementary

A triple-win situation has been achieved since time savings for caregivers translates into more time dedicated to patients. "With all the conflicting priorities that hospitals must deal with today, achieving this goal highlights the importance of upstream and downstream processes in the hospital's daily operations," says Forster. "This is where changes need to be made."

What are the key contributors of a successful implementation? Johnson & Johnson Medical GmbH advises that putting patients and their best interests first, followed by closely collaborating with the hospital are key contributors. These two strategies not only guarantee a successful implementation of a comprehensive VMI, but also enable a supplier to fulfil the mutual goals that it has with the hospital. This flagship project for the UKE is an ideal example of a supplier-hospital partnership in action.

By the numbers

Based on the new inventory management processes enabled by GS1 EDI standards, the University Medical Centre Hamburg-Eppendorf and Johnson & Johnson Medical GmbH are experiencing the following benefits:

✓ **75 percent fewer errors in the EDI process**, thanks to verified and continually updated master data that can be reliably mapped to hospital-specific data

✓ **40 to 60 percent less work involved in the ordering process** based on the automated consolidation of consumption notifications

✓ **75 percent fewer errors in the EDI process** due to bad master data

✓ **40 percent reduction in inventory levels**

✓ **44 percent fewer deliveries**

About the Author

Rüdiger Forster works as Customer Connectivity & Project Manager for Johnson & Johnson Medical GmbH with a focus on Customer Service, Supply Chain & Logistics. He has created a successful EDI business based on GS1 standards to optimise order-to-cash and delivery processes as his strong contribution in diverse customer projects over the last four years, thus improving the customer experience in end-to-end processes.

About Johnson & Johnson Medical GmbH

*Founded in 1956, **Johnson & Johnson Medical GmbH** is based in Norderstedt, Germany and operates as a subsidiary of Advanced Sterilization Products Services Inc. It manufactures and markets medical products and solutions for wound closure, general surgery, gynecology, minimally invasive procedures, and for metabolic surgery. The company offers needle and mesh production, braiding, finished goods production, sterilization, and research and development.*

www.jnj.de

About the University Medical Centre Hamburg -Eppendorf

The University Medical Centre Hamburg-Eppendorf (UKE) is one of Europe's most modern hospitals. It has over 1,700 beds, and every year its 10,000 staff treats approximately 95,000 inpatients and some 335,000 outpatients. Specialists in different disciplines collaborate, maintaining close links between medicine, research and teaching. Many specialist fields are available in the diagnosis and treatment of highly complex diseases in the areas of oncology, transplants, cardiac diseases, neurosurgery, systemic diseases in childhood, urology and many others.

www.uke.de

Mediplus leverages the GS1 Global Data Synchronisation Network for master data communication

Mediplus was established in UK in 1986. The company's focus is R&D, and the manufacturing and marketing of innovative medical devices. Mediplus needed to publish its medical devices' unique device identifiers (UDIs) to the US Food and Drug Administration's (FDA) Global UDI Database (GUDID), but wanted a scalable solution to meet the company's other demands on its product data. Mediplus decided to leverage the GS1 Global Data Synchronisation Network® (GDSN®) to communicate its product master data to trading partners, and selected LANSA's SyncManager multi-domain MDM platform, as its integration solution. Mediplus now spends less time managing product data and learning different rules and formats. The solution's audit features also provide Mediplus with full data governance.

By Emma Gray and Dominique Thomas

Business need

Mediplus develops, manufactures and markets innovative medical devices that meet the needs of patients and clinicians worldwide. Mediplus sells direct to end-users in the UK and to more than 40 countries globally through a network of select distributors.

With a growing customer base, both domestic and worldwide, greater demand was placed on Mediplus to provide product data to its clients. The requests included marketing content, logistics data, regulatory information and more. Each customer required different data to be provided in different formats, using different mechanisms. Maintaining a single version of the truth for product data was becoming impossible.

When the US FDA mandated that medical devices had to be registered with UDIs in a public database, a decision was made to investigate and adopt a LANSA Product information Management (PIM) System to meet these needs as spreadsheets had become ineffective.

It was important to Mediplus that the system it adopted would scale to meet both existing requirements and future demands from the market, like the UK's National Health Service (NHS) eProcurement.

A change for the business

After evaluating different approaches to product data management and UDI compliance, Mediplus selected the GS1 GDSN to support the company's master data management strategy with LANSA's PIM System as its data management and integration tool.
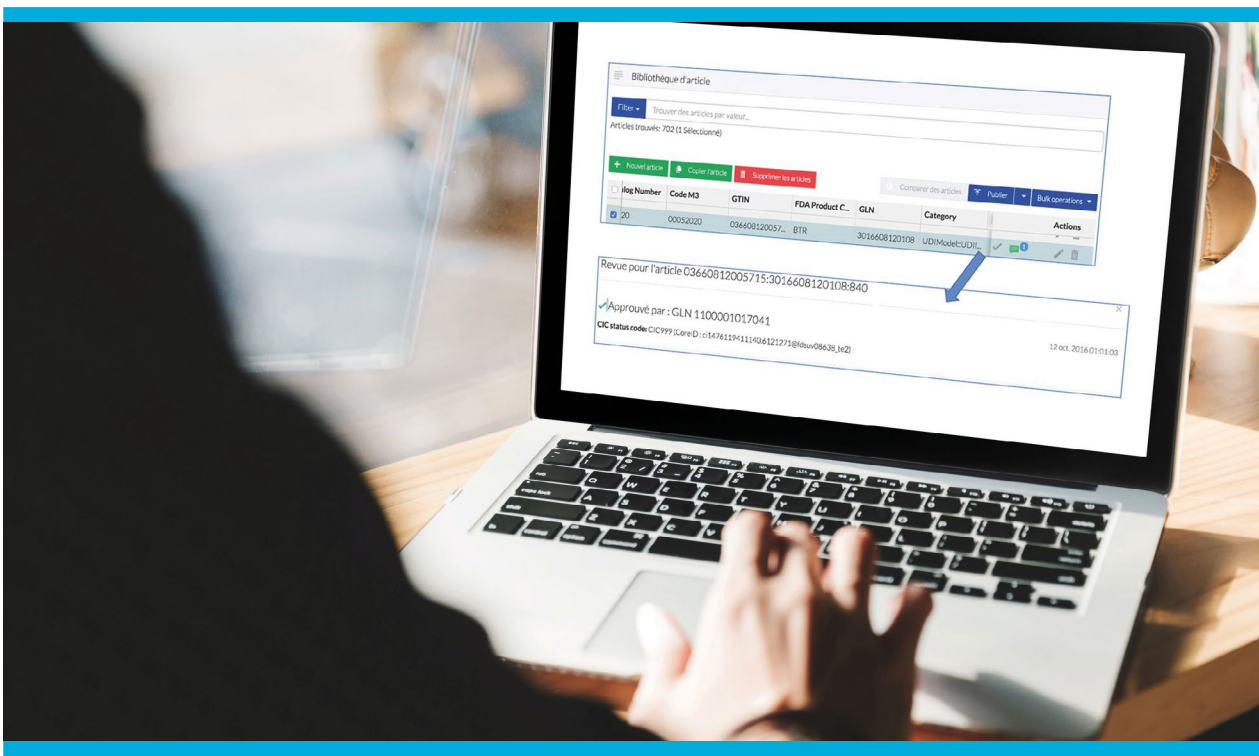
" Having a single PIM system to manage all our product data means we now have more time to invest in developing innovative products for market. Our organisation will be able to keep pace with developments relating to product data requirements in the market, and at the same time be sure that our own operations can rely on complete, accurate master data."

Emma Gray, Managing Director, Mediplus

Implementing data synchronisation meant moving from the current system of spreadsheets used by the team at Mediplus to store master data.

By implementing a PIM to manage the organisation's master data, Mediplus has now created a "single version of the truth" for master data, eliminating the need to manage multiple data sets. All data is now in one place and easily accessible and manageable by the Mediplus team.

Likewise, Mediplus has started to realise benefits simply from taking a standards-compliant approach. There is now a clear set of formats and definitions that they can rely on to structure the organisation's master data for intended recipients—whether GDSN recipients, the US FDA's GUDID or NHS trusts.

Having visibility of data changes and ownership has been a significant benefit for Mediplus. The process of implementing GDSN has led to the clarification of responsibility for the maintenance of data elements, and this clear ownership has meant even more focus on the quality and completeness of the data. All of the staff within the organisation who are responsible for master data maintenance are now even more empowered to own the data, thus safeguarding its integrity.

Already providing data

Mediplus is already using its new processes and infrastructure to prepare its product data for NHS eProcurement, using the newly extended validation rules that were added during 2017.

As additional requirements for product master data emerge, due to an ever-increasing industry reliance on accurate and complete data, Mediplus is confident that they have put in place the business processes and technologies to support future requirements in the market, negating the need for investments in additional infrastructure and systems.

> **"** We have now tamed the complexity; all of our product data is validated, enriched and organised in one central place."

Emma Gray, Managing Director, Mediplus

About the Authors

Emma Gray is Managing Director of Mediplus, taking over the helm in May 2009 after 14 years within the Company. Prior to this she was Commercial Director, responsible for all commercial, financial and regulatory aspects of the business.

Emma is a qualified accountant. Having worked in practice, she moved into industry and worked for a number of years as part of the finance team within Hertz and brings this global experience to Mediplus.

Emma is a fellow of the Association of Chartered Certified Accountants and a member of the Association of Accounting Technicians

Dominique Thomas is the General Manager for LANSA's PIM business. He has over 20 years of experience as an operational director in providing support to executive teams, having developed a hands-on approach with entrepreneurial spirit, high levels of credibility and influencing skills. In 2013, Dominique brought the LANSA Data Sync Direct solution to Europe. In 2015, he developed the strategy and the sales of the leading-edge, cloud-based PIM/MDM solution, SyncManager. At the same time, he has grown LANSA's partners' ecosystem, starting with a closer collaboration with the GS1 Global Office and local GS1 Member Organisations.

About Mediplus

Since its creation in 1986, **Mediplus**'s name has become synonymous with quality and reliability in the field of single-use medical and surgical products.Continuous technological and market research, implementation of the latest technology at all levels, dedication to customer satisfaction, and high quality and reliability standards are all key factors in Mediplus's growth.

www.mediplus.co.uk

About LANSA

LANSA is a leading provider of business process integration and data synchronisation software. LANSA's product suite spans the entire supply chain process with solutions for GDSN participation, Product Information Management and data quality. LANSA is a solution provider for many GS1 Member Organisations worldwide and a leading 1WorldSync solution provider. LANSA is working with market category leaders including Kroger, P&G, Mars, Nestlé, Teleflex, J&J, Abbott Laboratories. Established in 1987, LANSA supports thousands of companies around the world with its products and services.

www.syncmanager.com

SyncManager is Software-as-a-Service (SaaS) operated on a subscription-based model, which provides instant connectivity to the GDSN via the 1WorldSync Data Pool.

Suppliers and GPOs

Teleflex harnesses strong partnerships for patient safety

Teleflex needed to implement a data management solution to comply with the US Food and Drug Administration's (FDA) Unique Device Identification (UDI) regulation. The company created a cross-functional team, including GS1 Solution Providers, 1WorldSync and LANSA. A multi-phased project was launched that identified and integrated device data from diverse systems across the company and included processes to assign and validate each device's Global Trade Item Number® (GTIN®) and attributes on their way to the FDA's Global UDI Database (GUDID). Teleflex also achieved full Global Data Synchronisation Network® (GDSN®) operability for trusted data-sharing with trading partners. Now, Teleflex can provide accurate, complete and validated product data to regulatory bodies and trading partners alike, including healthcare providers.

By Mark Hoyle

Teleflex®

" Our commitment to patient safety and the importance of UDI in achieving this goal is something we hold in the highest regard. When we deliver our products to customers, we are also delivering patient safety in the form of UDI, enabling accuracy, efficiency and traceability. That's not just a regulatory box to check or a supply chain process to complete—it's a real and positive impact for real people."

Mark Hoyle, Technical Director, UDI Compliance, Teleflex

Understanding what it takes

Teleflex is a global provider of medical technologies designed to improve the health and quality of life for patients. The company's diverse portfolio of medical devices spans the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care.

When the US Food and Drug Administration finalised its ruling for a unique device identification system, Teleflex commenced working to comply with all designated deadlines.

"Even before the UDI regulation, Teleflex had primarily used GS1 standards," says Mark Hoyle, Technical Director for UDI Compliance at Teleflex. "We were expanding the use of GS1 standards within our product lines exclusively. Given the UDI ruling, we accelerated our plans."

Originally Hoyle joined Teleflex to oversee international packaging, drawing on his background in qualification, validation and automation. Transitioning to UDI compliance for Teleflex was a natural undertaking in view of his prior experience in this arena.

"There's close alignment between packaging and product identification," Hoyle says. "The automated processes of device assembly married with packaging and labelling for primary, secondary or tertiary packaging levels involves all aspects of electronic data management and physical application in a validated manner."

Hoyle also had prior experience with GS1 as the Co-Chair of its GS1 Healthcare initative. "Working with GS1 and other members of the healthcare sector, we collaborated with the FDA and helped shape GS1 Healthcare GTIN Allocation Rules, leading to the eventual UDI regulation," says Hoyle. "So I came to Teleflex with a solid understanding of 'what it would take' to successfully implement a UDI strategy, with an additional goal of meeting customer expectations in data publication."

> " I felt strongly that Teleflex should be positioned to fulfil future regulatory needs around the globe. At the same time, I wanted to plan for the key requirements of our customers that were using or planning to use the GDSN to exchange information with us throughout the supply chain."

Mark Hoyle, Technical Director, UDI Compliance, Teleflex

According to Hoyle

Hoyle wanted to adopt a forward-looking strategy that would go beyond the immediate UDI requirements. "I felt strongly that Teleflex should be positioned to fulfil future regulatory needs around the globe," advises Hoyle. "At the same time, I wanted to plan for the key requirements of our customers that were using or planning to use the GDSN to exchange information with us throughout the supply chain."

Following a rigorous analysis and comparison of options, Teleflex chose to work with 1WorldSync as its GS1-certified data pool provider, and LANSA's Product Management Information (PIM)

system for business process integration and data synchronisation software.

"Healthcare as a sector is on a steep learning curve when it comes to automating its UDI processes in a standards-based way," explains Hoyle. "We needed to build a team with the necessary skillsets to help us develop a strong foundation. LANSA brought a wealth of experience in creating data management solutions and a willingness to partner with us."

> " Healthcare as a sector is on a steep learning curve when it comes to automating its UDI processes in a standards-based way. We needed to build a team with the necessary skillsets to help us develop a strong foundation."

Mark Hoyle, Technical Director, UDI Compliance, Teleflex

"Our goal was to build a single point of truth for the FDA's GUDID that could consume information from our enterprise resource planning (ERP) and product lifecycle management (PLM) tools," continues Hoyle. "1WorldSync offered a singular solution that we can leverage with all future regulatory demands, in addition to the FDA. With one global solution, there's less opportunity for misinterpretation. Harmonisation is more easily controlled, and divergence based on the target market is better managed. It's a clean solution."

United team for united effort

The Teleflex team was comprised of a central core UDI team with expertise in project management, regulatory issues and IT. The team was supported by the labelling group to manage the intricacies of artwork design that would allow packaging real estate to accommodate the GS1 standards-based barcode symbologies.

"1WorldSync supported project management efforts that furthered interactions between LANSA's technical development and the overall processes being delivered," says Hoyle. "LANSA was a critical member of our team in helping to design and implement the process requirements for product data input and validation, as well as making needed modifications as they arose."

An extended team of Teleflex professionals—including IT data analysis and data management support—joined with business unit team members, research and development, engineering, regulatory and quality assurance managers to coordinate a successful implementation.

"I was extremely keen to ensure that we didn't see this merely as a customer/supplier relationship, nor as a hard start/stop initiative," says Hoyle. "We established a strong partnership between LANSA, 1WorldSync and Teleflex because we were developing an embryonic technology, and we needed to be mindful of the platform expansions and the exponential growth that is already emerging."

> **"** I was extremely keen to ensure that we didn't see this merely as a customer/supplier relationship, nor as a hard start/stop initiative. We established a strong partnership between LANSA, 1WorldSync and Teleflex because we were developing an embryonic technology, and we needed to be mindful of the platform expansions and the exponential growth that is already emerging."

Mark Hoyle, Technical Director, UDI Compliance, Teleflex

Assess, assign, validate

As the first major step in the implementation process, the team conducted an assessment of the current situation—identifying where data resided in the various Teleflex organisations. While this may seem straightforward, Hoyle explains the challenging nature of the activity. "For more than 70 years, Teleflex has grown tremendously through acquisions, which equates to the existence of many different business systems and integration points throughout the company."

The second major work effort focused on creating the product data—the GTIN and attributes for each device—along with interfaces for input. "Our task focused on integrating all of the different systems in a centralised way to assign GTINs based on the different global company prefixes that we manage," says Hoyle. "The goal was to provide a complete, accurate and consistent way of presenting data attributes that would conform to UDI regulatory requirements and GDSN requirements."

LANSA became the single point of GTIN assignment, building the structure and hierarchies that followed GS1 Healthcare Allocation Rules. "At the same time, LANSA built customised rules that would uniformly manage the provision of correct information for new product creation and build," says Hoyle. "This would ensure accurate and automated GTIN assignment in our systems."
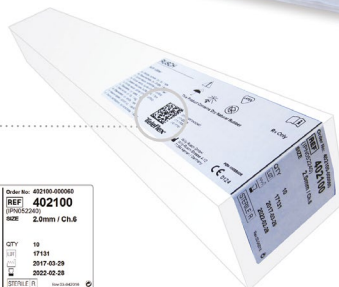
For every level of packaging, Teleflex leverages GS1 standards-based information encoded in GS1 DataMatrix barcodes.

The third step in the implementation process was to systematically validate data. Device GTINs and attributes were staged and automatically checked through loading and registration via the 1WorldSync data pool with publication to the GUDID, confirming the data at each step based on validations applied by LANSA, 1WorldSync and the FDA. "Based on these stages of validation, we achieved high confidence surrounding the format of data compliance on submission to the GUDID," explains Hoyle.

> **"** Making considered decisions upfront by understanding the present and future vision is critical; you will reap many benefits downstream. These benefits will be realised through accuracy and efficiency along the supply chain, ultimately leading to improved patient care."

Mark Hoyle, Technical Director, UDI Compliance, Teleflex

People, partners, processes

Hoyle attributes the success of the UDI project at Teleflex to people in the organisations that worked side-by-side to develop an industry-changing solution. "We have an excellent technical team at LANSA and a great project management function with 1WorldSync. Within Teleflex, people showed an understanding not just about the needs of the industry but the needs within the partnership, resulting in excellent collaboration."

With the UDI solution now in place, Teleflex has started the next phase of its journey, expanding its use of the LANSA team members as they are always looking for better ways and opportunities to automate business processes and improve the data that is being delivered.

"The second part of our success is the standards-based process itself," adds Hoyle. "We have a fully customisable PIM system in which we have information control, and the ability to configure it in such a way that allows it to fit other needs of our organisation and business practices."

In addition to picking the right partners to work with, Hoyle would advise others to take time to develop the right strategy.

"Making considered decisions upfront by understanding the present and future vision is critical; you will reap many benefits downstream. These benefits will be realised through accuracy and efficiency along the supply chain, ultimately leading to improved patient care."

Using GS1-128 barcodes, Teleflex encodes valuable product information on each product package.

Win-win for patient safety and operations

Hoyle considers the company's investment in time, resources and money well worth the return in patient safety and other benefits.

"One of the difficulties for healthcare—or for any industry for that matter—is how to measure the return-on-investment when implementing standards and new processes," Hoyle says. "Yet, once you start moving down the implementation path, you can quickly identify the improvements to your internal operations: distribution control, speed and efficiency, through to order fulfilment. You start to recognise all of the operational benefits. Couple this with delivering patient safety objectives and it's a win-win. The benefits are all there."

Hoyle concludes, "Our commitment to patient safety and the importance of UDI in achieving this goal is something we hold in the highest regard. When we deliver our products to our customers, we are also delivering patient safety in the form of UDI, enabling accuracy, efficiency and traceability. That's not just a regulatory box to check or a supply chain process to complete — it's a real and positive impact for real people."

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Mark Hoyle, Technical Director, UDI Compliance, Teleflex

About the Author

Mark Hoyle has been working for major multinationals for 33 years, specifically pharmaceutical and medical device companies and currently holds the position of Technical Director for UDI implementation globally at Teleflex. He has co-chaired the GTIN Allocation Rules for Healthcare working group for GS1, producing the baseline on which to manage the standard for healthcare. Mark is one of the founding members and former co-chair of GS1 Global Healthcare and is still an active participant, shaping and modelling the healthcare objectives for product identification and data sharing between trading partners and regulators using the GDSN (Global Data Synchronisation Network).

Mark is fully committed to global harmonisation, striving to deliver and educate both internally for Teleflex and externally as necessary. He and his team have delivered a global and adaptable solution for UDI enabling growth and varied requirements to be fulfiled in this ever-changing world of UDI expansion and usability.

About Teleflex

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. Teleflex applies purpose driven innovation to identify unmet clinical needs to benefit patients and healthcare providers. The company's portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care.

www.teleflex.com

About LANSA

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www.datasyncdirect.com

About 1WorldSync

1WorldSync is the leading multi-enterprise product information network, helping more than 23,000 global brands and their trading partners in 60 countries to share authentic, trusted content with customers and consumers, empowering them to make intelligent choices and decisions concerning purchases, lifestyle and well-being. 1WorldSync's Product Information Cloud platform was designed for businesses to exchange enriched product data and digital content, creating a mission-critical foundation for connected commerce. 1WorldSync is jointly owned by the member organisations of GS1 Germany and GS1 US.

GS1 is the preeminent global organisation for the development of global standards, for identifying, capturing and sharing product information.

www.1worldsync.com

Government
initiatives

Government Initiatives

More than bar codes: Integrating Global Standards-based bar code technology into National Health Information Systems in Ethiopia and Pakistan to increase end-to-end supply chain visibility

Bar codes can help track and trace health products in the supply chain. But to do so efficiently, they should be based on global standards rather than a proprietary system, and the captured data should be integrated into national health information systems to achieve end-to-end data visibility.

The United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID) DELIVER PROJECT work together to strengthen public health commodity supply chains by standardizing bar coding under a single set of global standards. From 2015, UNFPA and USAID collaborated to pilot test how tracking and tracing of bar coded health products could be operationalized in the public health supply chains of Ethiopia and Pakistan and inform the ecosystem needed to begin full implementation. Pakistan had been using proprietary bar codes for inventory management of contraceptive supplies but transitioned to global standards-based bar codes during the pilot. The transition allowed Pakistan to leverage the original bar codes that were preprinted by global manufacturers as opposed to printing new bar codes at the central warehouse. However, barriers at lower service delivery levels prevented full realization of end-to-end data visibility. Key barriers at the district level were the lack of a digital inventory management system and absence of bar codes at the primary-level packaging level, such as single blister packs. The team in Ethiopia developed an open-sourced smartphone application that allowed the team to scan bar codes using the mobile phone's camera and to push the captured data to the country's data mart. Real-time tracking and tracing occurred from the central warehouse to the Addis Ababa distribution hub and to 2 health centers. These pilots demonstrated that standardized product identification and bar codes can significantly improve accuracy over manual stock counts while significantly streamlining the stock-taking process, resulting in efficiencies. The pilots also showed that bar coding technology by itself is not sufficient to ensure data visibility. Rather, by using global standards for identification and data capture of pharmaceuticals and medical devices, and integrating the data captured into national and global tracking systems, countries are able to lay the foundation for interoperability and ensure a harmonized language between global health stakeholders.

By Liuichi Hara, Ramy Guirguis,
Keith Hummel, Monica Villanueva

Introduction

Low-and middle-income countries often rely on inaccurate and labor-intensive processes to manage key health commodity supply chains.[1] However, recent innovations in supply chain technology have helped improve the efficiency of commodity acquisition, management, and delivery systems, thus reducing stockouts and ensuring health commodities, such as pharmaceuticals and medical devices, reach the end user.[1,2] The challenge has been finding a consistent, effective, and inclusive approach to increasing supply chain data visibility, as the availability of quality and timely data often varies greatly within developing countries.

Supply chain visibility is "the awareness of, and control over, specific information related to product orders and physical shipments, including transport and logistics activities, and the statuses of events and milestones that occur prior to and in-transit."[3] Data visibility requires a robust data collection system that is agile and incorporates and synchronizes the needs of various partners into a single multitiered responsive system that begins with the production of the health product (drug or device) and ends with it in the hands of the end user.[3]

Adopting global standards and using bar code technology can help countries to address accuracy, interoperability, and timeliness of data across supply chain levels; achieve end-to-end (E2E) data visibility; and directly help improve forecast and quantification as well as improve procurement and supply coordination among the donor agencies.

To that end, the United States Agency for International Development (USAID) DELIVER PROJECT and the United Nations Population Fund (UNFPA) worked with the governments of Ethiopia and Pakistan to design and test pilot studies to validate the conclusion that automatic

identification and data capture (AIDC) systems could be used to improve E2E supply chain visibility of health commodities.[1,2] AIDC is a method of identifying items, collecting data, and transmitting that data directly electronically—in these pilots, through bar codes.

Achieving end-to-end supply chain data visibility

AIDC is a key tool for improving product visibility in the global supply chain. While there are various approaches used to achieve AIDC, bar codes and radio frequency identification are the most commonly used.

Leveraging AIDC provides an organization the ability to track and trace tangible assets in real-time or near real-time. The International Organization for Standardization defines track and trace as a "means of identifying every individual material goods or lots or batch in order to know where it has been (track) and where it is (trace) in the supply chain".[4] Unique product identification linked with the item's batch number or serial number and expiration date are rapidly becoming a prerequisite to track and trace health care products to create an E2E supply chain.[5]

With an efficient track and trace system, an organization or a country can effectively address complex integrity issues, such as distribution of counterfeit pharmaceutical products and theft or diversions of shipments. This can only be achieved by improving the E2E supply chain data visibility. Using a bar coding system that complies with global standards is crucial to maintain an organization's supply chain integrity and to safeguard public health.

Using global standards

As part of their formative research, UNFPA and the USAID DELIVER PROJECT identified a clear need to raise awareness of existing global standards, such as bar codes, and the value of integrating their use into the health care sector. Global standards for identification, capture, and sharing are provided

1   USAID DELIVER PROJECT. Case Study. Barcoding: Modernizing Warehouses to Lighten the Workload. Washington, DC: USAID DELIVER PROJECT; 2012. http://1i4rh11vccjs3zhs5v8cwkn2.wpengine.netdna-cdn. com/wp-content/uploads/2016/05/Barcoding-Case-Study_ Pakistan.pdf. Accessed October 24, 2017.

2   USAID DELIVER PROJECT. Traceability in Ethiopia's Health Sector: Piloting GS1 Barcodes with Global Trade Item Number Serialization to Track Health Commodities from Supplier to Health Facility. Brief. Washington, DC: USAID DELIVER PROJECT; 2016.

3   Heaney B. Supply Chain Visibility: A Critical Strategy to Optimize Cost and Service. Waltham, MA, USA: Aberdeen Group; 2013. https://www.gs1.org/docs/visibility/Supply_ Chain_Visibility_Aberdeen_Report.pdf. Accessed October 24, 2017.

4   International Organization for Standardization (ISO). ISO 12931:2012(en): Performance Criteria for Authentication Solutions Used to Combat Counterfeiting of Material Goods. Geneva: ISO; 2012. https://www.iso.org/obp/ ui/#iso:std:iso:12931:ed-1:v1:en. Accessed October 15, 2016.
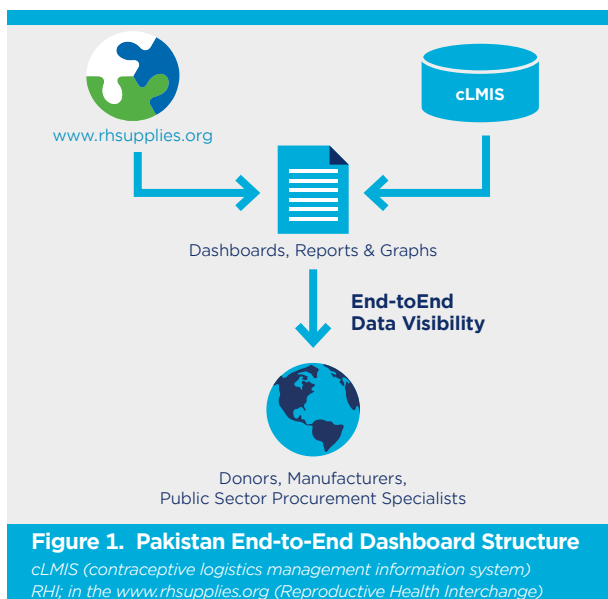
5   GS1. Healthcare GTIN Allocation Rules: GS1 Global Healthcare User Group. Issue 8, June 2013. Brussels, Belgium: GS1; 2013. https://www.gs1ca.org/pages/n/ sectors/hc/GS1_Healthcare_GTIN_Allocation_Rules.pdf. Accessed October 24, 2017.

by GS1, a "neutral, not-for-profit, international standards organization that develops global standards to improve the efficiency and visibility of supply chains across industries."[3]

Although bar codes have been used to improve inventory tracking in low-and middle-income countries, there is limited documentation of cases that have led to the adoption of bar code systems beyond the pilot phase or to realize their value across all the systems in the supply chain.[6] This may be explained by a lack of adoption of internationally accepted standards for AIDC among the key stakeholders—such as donors, pharmaceutical companies, logistics providers, regulatory agencies, and implementing partners— and resulted in each donor or provider developing a proprietary solution specific to a funded project.

However, there is growing acceptance among many donors, countries, and the private sector regarding the value of adopting a global standard for product identification and bar codes to improve supply chain efficiency. This is because GS1 global standards are product-agnostic and provide a framework to scale onto all products across the different health programs—such as childhood vaccines and HIV/AIDS—and build the foundation for interoperability. In effect, the use of global standards help to improve patient safety and reduce exposure to supply chain integrity issues.

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6   Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Promising Practices: Warehousing and Inventory Management. Arlington, VA: Management Sciences for Health; 2014. http://www.lifesavingcommodities. org/wp-content/uploads/2014/08/Copy-of-3_Warehousing-final.pdf. Accessed October 24, 2017.

Figure 1. Pakistan End-to-End Dashboard Structure
cLMIS (contraceptive logistics management information system)
RHI; in the www.rhsupplies.org (Reproductive Health Interchange)

The transition from proprietary tracking methods to global standards-based bar codes allowed Pakistan to leverage the original bar codes that were preprinted by global manufacturers, as opposed to printing new bar codes at the central warehouse.

Applying theory to practice: the journey

Pakistan and Ethiopia conducted proof of concepts for an E2E supply chain data visibility approach using bar codes with logistics information dashboards. The 2 cases are discussed individually in this section and their findings and lessons learned are compared in the following reflections section.

Pakistan

The USAID DELIVER PROJECT in Pakistan developed a web interface with global procurement information through the Reproductive Health Interchange (https://www.unfpaprocurement. org/rhi-home), and combined the interface with Pakistan's contraceptive logistics management information system, which tracks the distribution and stock status of family planning commodities across the entire country (Figure 1). This system informs federal and provincial procurement actions.

Pakistan was not new to the idea of using bar codes, as it already implemented use of proprietary bar codes for inventory management of contraceptive supplies in 2012.[1] However, the pilot conducted in 2015 emphasized the value of transitioning from proprietary tracking methods to bar codes based on global standards.

Healthcare Product	
Primary packging (one pill in one blister cell)	
Secondary packaging (two blisters in one box)	
Multi-pack (7 boxes) This is an example of another packaging level	
Case (8 multi-packs)	

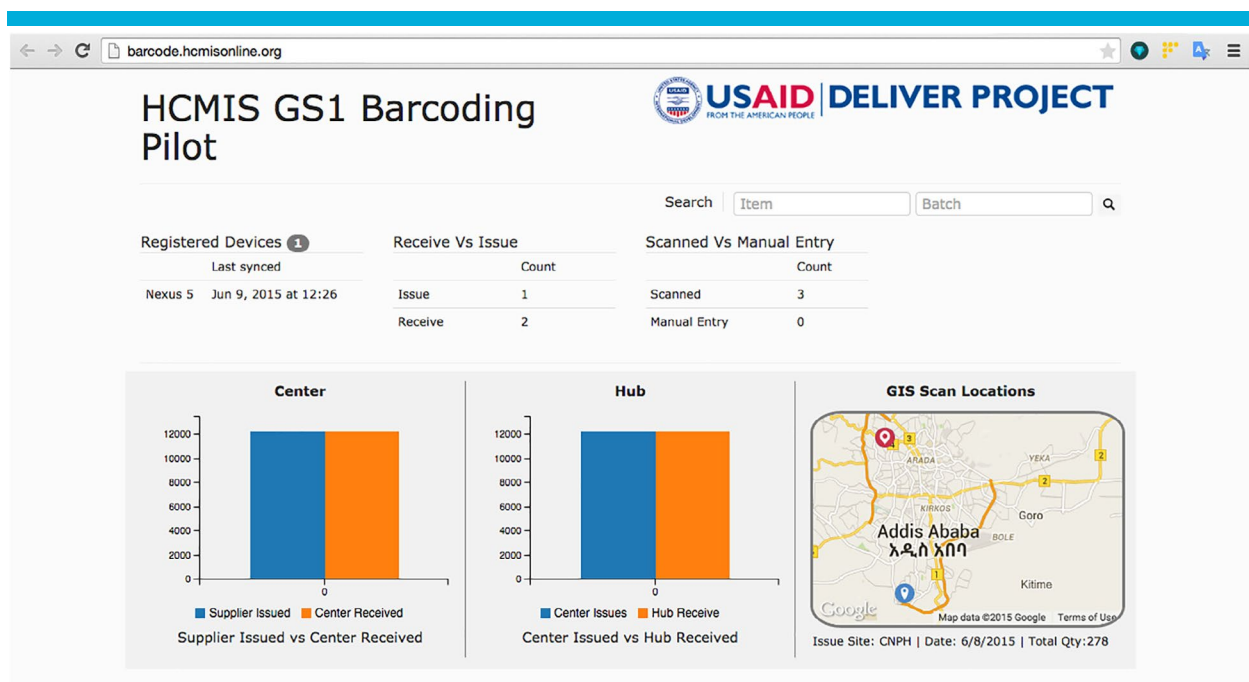**Figure 2. GS1 Package Hierarchy Examples**

Figure 3. Ethiopia End-to-End Dashboard Sample

The transition allowed the Pakistan team to leverage the original 2D DataMatrix bar codes preprinted by global manufacturers as opposed to printing new bar codes at the central warehouse. In order to read the original bar codes, the team invested in a new Windows mobile-based Motorola MC9200 handheld optical scanner, as the previous handheld scanner was limited to 1-dimensional linear bar codes only.

The Pakistan bar code pilot experience highlighted 2 key aspects for future work in E2E supply chain data visibility: (1) the lack of an inventory management information system at the district level posed a challenge to consolidating the captured bar code data; and (2) products arriving into the districts were primary-level packaging— for example, single blister packs— that lacked bar codes (Figure 2). Therefore, extending information system installation and applying bar codes at the primary package will be required if tracking and tracing is to be extended down to the district level.

Ethiopia

Similarly, the USAID DELIVER PROJECT in Ethiopia followed the approach of developing a web interface with the project's "My Commodities" system and the Reproductive Health Interchange to merge the global procurement information with the national warehouse management software (called the Health Commodity Management Information System). My Commodities provides registered users with shipment information of health supplies, contraceptives, condoms, personal protective equipment for avian influenza control, antimalarials, and other commodities.

The Ethiopia pilot demonstrated the immediate benefits that could be achieved by using globally standardized bar codes and integrating data systems; namely, by reducing manual steps for recording inbound and outbound goods and reducing the chance of human error via misentry of data.

The Ethiopia pilot test was an important milestone, as it expanded beyond the Pakistan experience. The Ethiopia team developed an open-sourced smartphone application using the built-in CMOS image sensors (the camera technology) commonly found on standard Android smartphones. Bar code scanning was performed through the CMOS camera via the mobile application, which then pushed the captured data from the bar code to Ethiopia's data mart and E2E dashboard. Real-time tracking

Table 1. Time for Scanning and Recording the Digital Bar Code Information, Ethiopia Pilot Test

Location	Transaction	No. of Scans	Time to Scan and Record Information From Bar Code	Comments
Central store	Inbound receipt	13 tertiary-level shipper boxes	3 minutes and 37 seconds	Recorded time included physically moving the packages and obstacles
Central store	Inbound receipt	63 secondary-level packages	24 minutes and 38 seconds	Software optimization made during the test; used smartphone torch feature and improved scanning technique based on experience at the central store
Addis Ababa distribution hub	Inbound receipt	13 tertiary-level shipper boxes	2 minutes	
Addis Ababa distribution hub	Inbound receipt	50 secondary-level packages	15 minutes	Quantity split between 2 local health centers
Addis Ababa distribution hub	Outbound to local health center	230 secondary-level packages	Less than 25 minutes	

and tracing was demonstrated from the central warehouse to 2 major distribution points: the Addis Ababa distribution hub and 2 subsequent health centers. Furthermore, the Android smartphone's GPS coordinates were integrated with a geographical information system to display transactional information—the issuance and receipt of products—onto a Google Map (Figure 3).

Lastly, UNFPA sent the bar code requirements to the supplier in advance of on-the-ground testing. This enabled the Ethiopia team to enter the standardized unique product information—the global trade item number, batch number, and expiry date—into the national health information system prior to receipt of incoming goods. The time for scanning and recording the digital information was measured and is summarized in Table 1. This preparation allowed the team to validate and cross reference the cargo received at the central warehouse in real-time once they scanned the bar codes. This pilot demonstrated the immediate benefits that could be achieved by using globally standardized bar codes and integrating data systems; namely, by reducing manual steps for recording inbound and outbound goods and reducing the chance of human error via misentry of data.

Reflections

While the 2 country experiences were distinct, they both showcased the potential and challenges in realizing E2E visibility. A comparison of the 2 pilots is summarized in Table 2.

The Ethiopia experience more realistically demonstrated what full E2E bar code track and trace could look like: A digital cargo manifest identifier is encoded in the bar codes at the tertiary-level shipper boxes. Upon arrival of the shipment, the receiving party can digitally

In Ethiopia, a team member at the Addis Ababa central warehouse uses a mobile phone app to scan bar codes on shipping boxes when receiving incoming goods.
© 2015 L Hara

Table 2. Comparison of the Pakistan and Ethiopia Pilot Tests

Features	Pakistan	Ethiopia
In-country electronic logistics management information system	cLMIS	HCMIS
Bar coding	Transition from proprietary to GS1 bar codes	GS1 bar codes, from the outset
E2E dashboard	Achieved by integrating RHI with cLMIS and incorporating data from bar code scanning	Achieved by integrating RHI with HCMIS and incorporating data from bar code scanning
Serialization	Not part of the pilot test	Serialization was done at the secondary package level
Scanning approach	Handheld optical scanners	Open-sourced Android smartphone app developed locally (HCMIS barcode scanner)
Where track and trace was pilot tested	Central Warehouse and Supplies, Karachi to Lahore district store	Central warehouse to Addis Ababa distribution hub to Woreda health center and Nefas Silk Lafto health center
Result	Full E2E track and trace was not achieved due to lack of inventory management system at the district level and lack of bar codes at the primary unit level	Full E2E track and trace via digital scanning demonstrated to the exact number of packages distributed between the 2 health centers

Abbreviations: cLMIS, contraceptive logistics management information system; E2E, end-to-end (supply chain); HCMIS, Health Commodity Management Information System; RHI, Reproductive Health Interchange.

Table 3. Comparison Between Smartphone and Handheld Scanners

Approach	Pros	Cons
Smartphone scanner	• Flexibility to customize and update app software • Ability to leverage existing personal smartphones • Ability to adopt or adapt the app (opensource)	• Poor ergonomic design for scanning • Slower scan speed rate • Function depends on mobile penetration in the country • Several mobile apps, which can be confusing for the user • Higher battery burn rate to smartphone
Handheld scanner	• Faster scan speed rate • Good ergonomic design for scanning	• Stable funding is needed to procure, maintain, and/or upgrade handheld scanners at all distribution touch points
Hybrid handheld scanner connected to a smartphone via Bluetooth (as an alternative for future consideration)	• Lower cost than traditional handheld scanner • Faster scan speed rate • Good ergonomic design for scanning • Can leverage smartphone app software	• Higher battery burn rate to smartphone

authenticate the cargo manifest by simply scanning the bar codes and automatically recording the data into the dashboard. Encoded data about the products from the bar codes on the secondary-level packages can continue to be scanned as the products move downstream inside the country so that track and trace can be achieved down to the last mile of the supply chain.

Without a proper digital information system to receive the scanned data, the value of AIDC greatly diminishes.

The Pakistan experience, on the other hand, clearly demonstrated the barriers at the lower levels of supply chain, such as the availability of a consistent digital information system and use of bar codes at the lowest product unit level.

Depending on the product origin and product presentation, such as blister packs or vials, bar coding at the lowest unit level may be easier for some products than others. It is important to communicate this issue to the original manufacturer to begin dialogue for bar coding at the primary unit level.

However, without a proper digital information system to receive the scanned data, the value of AIDC greatly diminishes. Therefore, an ecosystem is needed that combines bar codes and the appropriate digital information system(s) and processes in place to ensure that scanned and recorded information are used for proper decision making.

Another point that needs consideration is deciding which scanning approach is most appropriate for the country context. In Ethiopia, the team used a locally developed open-sourced smartphone application, while in Pakistan the team procured new handheld optical scanners. Although both options served their intended purpose, we recommend that countries consider their national technology capacity, and then choose the approach and type of investment—short- or long-term—that best suits a country's needs. A brief comparison between smartphone and handheld scanners has been compiled in Table 3.

While the penetration of mobile services is on the rise in developing countries, according to the International Telecommunication Union, mobile cellular subscriptions for 2015 was reported at 43 per 100 people in Ethiopia and 67 per 100 people in Pakistan.[7] Based on the 2015 Pew Research Center analysis, Ethiopia and Pakistan were rated as having 2 of the lowest smartphone ownership rates globally (4% and 11%, respectively).[8] Ethiopia has the added challenge of being captive to only 1 operator, which supports 42.1 million mobile connections in the country.[9] In contrast, Pakistan has 8 operators supporting 127.9 million mobile

connections in the country.[10] These are important factors to consider when incorporating mobile technology into track and trace designs. If a country has insufficient mobile network coverage, then handheld optical scanners, which do not rely on mobile networks, should be considered. Along the same logic, if a high number of operators support a vibrant mobile network coverage, smartphones may be the best option to perform the scanning.

Conclusion

The collective experience from the Pakistan and Ethiopia pilots highlights the importance of adopting bar codes as part of a global standardized system for product identification and data capture that serves as a foundation for interoperability and data sharing that is essential to achieve end-to-end data visibility in the supply chains.

The pilots demonstrated the value of implementing an automated logistic management information system based on global standards and using bar code technology to improve the efficiency of the supply chain operation, address the data quality issues, and achieve near real-time data visibility. This ultimately helps to ensure that patients have continuous and consistent access to high-quality medicines at the right time and right place.

While there is still considerable work to do before countries can reach optimal E2E data visibility, the results from these and related pilots indicate that we can reach this goal by adopting the same global standards and practice for public health supply chains.

The pilots demonstrated the value of implementing an automated logistic management information system based on global standards and using bar code technology to improve the efficiency of the supply chain operation, address the data quality issues, and achieve near real-time data visibility.

7   TheWorld Bank. 5.11World Development Indicators: Power and Communications. World Development Indicators website. c2014. http://wdi.worldbank.org/table/5.11#. Accessed October 24, 2017.

8   Poushter J. Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies: But Advanced Economies Still Have Higher Rates of Technology Use. Washington, DC: Pew Research Center; 2016. http://www.pewglobal.org/files/2016/02/pew_research_center_global_technology_report_final_february_22__2016.pdf. Accessed October 24, 2017.

9   Ethiopia Data Dashboard. GSMA Intelligence website. https://www.gsmaintelligence.com/markets/1013/dashboard/. Accessed April 13, 2017.

10 Pakistan Data Dashboard. GSMA Intelligence website. https://www.gsmaintelligence.com/markets/2733/dashboard/. Accessed April 13, 2017.

About the Authors

Liuichi Hara is a Project Manager in Global Manufacturing and Supply at Takeda Pharmaceuticals leading the Supply and Launch Teams in regenerative medicine, vaccines and Access to Medicines. Prior to Takeda, he was the Supply Chain Innovation Specialist at UNFPA and Founder of the UNFPA Copenhagen Innovation Unit, which seeks to solve major public health issues in low- and middle-income countries by accelerating the use of tech innovation for social good. He has over 13 years of international experience having also held various roles at Samsung, Toyota and ITOCHU in charge of supply chain management of electronic materials and specialty chemicals. Liuichi received a BA in International Relations from the University of Southern California (United States), as well as a MS in Biotechnology Management and MBA with specialization in Innovation Management from the Grenoble Graduate School of Business (France).

Dr. Guirguis holds a Ph.D, M.Sc., and B.Sc. in Computer and System Engineering. He has over 30 years of professional experience in information and communications Technology. Currently a Senior Information Technology Advisor with USAID's Global Health Supply Chain, where he advises countries with respect to design and implementation of their national-level public health supply chain information systems. Dr. Guirguis also advises various countries in adoption of global supply chain standards and design of national pharmaceutical traceability system. He also provides an oversight to USAID's global supply chain information systems. Prior to USAID, Dr. Guirguis contributed to the transformation and modernization of several large enterprises and government agencies spanning many diverse sectors including: Telecommunications, Financial, Health, Defense and Development Sectors. Dr. Guirguis played a visible and discernible leadership role in several key US governments' Biometrics Architecture, and Interoperability committees and working groups. Dr. Guirguis established and chaired the DoD Biometrics Standards Working Group and represented the DoD at several standards bodies, at both the US and international level. He was a member of the US expert delegation at several ISO standards meetings. Dr. Guirguis authored & co-authored four Patents, presented several papers at international conferences. He is an IEEE Senior Member, Senior Fellow at GMU International Cyber Center, Certified Project Manager Professional and Adjunct professor at Georgetown Technology Management and System Engineering Management Master Programs.

Keith Hummel Jr.'s early career was spent in advertising and marketing in Tucson, Arizona. After spending time in the Peace Corps in Haiti, he joined Travelers Insurance Group working in both regional and national positions responsible for key account service delivery. In 1996, Keith accepted the CEO position at Frederick Mennonite Community, a senior services provider in Pennsylvania. He led the organization through a $30 million strategic expansion including Alzheimer's care, hospice care, inter-generational day care center and expansion of the home health care program. In 2005 Keith accepted a Mission assignment in Tanzania as consultant to the Shirati KMT Hospital during successful transition from International Missionary leadership to Host country leadership. In 2008 Keith joined USAID/Tanzania Health System Strengthening team as Senior Technical Adviser for Health Commodities and Logistics and Health Information System Advisor. He has worked with both Tanzania and Ethiopia government counterparts to increase capacity in commodity supply chain, Health Care Financing, Human Resources for Health, Health Information Systems and Public Private Partnerships while supporting USAID PEPFAR, PMI, Reproductive Health, Maternal Child Health and TB programs. He also works extensively in donor coordination and collaboration to support and coordinate service delivery programing. Keith has served on various national, regional and local boards of directors including board chair, treasurer and secretary. He received a BA in cultural anthropology and archeology from the University of Arizona and earned a Masters of Health Administration from St. Joseph's University in Philadelphia, PA. Keith is married, with two sons and a daughter.

Monica Villanueva is the Deputy Director of USAID/Nepal's Health Office. Prior to Nepal, she served as the Maternal and Child Health Team Lead of the USAID/Pakistan Health Office (2014-2017) and served as the Family Planning and Reproductive Health Advisor of the USAID/Malawi Health Office (2011-2014). Prior to joining USAID, Monica worked for Save the Children in Bolivia and worked domestically in the U.S. on migrant health issues. She received a MPH from the University of North Carolina and a BA from University of Virginia.

Government Initiatives

Using Global Location Numbers for a unique identification system in Swiss healthcare

In the early 1990s, a group of visionaries stated that the current way to identify actors in the Swiss healthcare industry was far from sustainable and very inefficient. Every actor—such as healthcare manufacturer, distributor, hospital, pharmacy or medical doctor—was identified in multiple ways. For example, a medical doctor might have been identified differently by the national accident insurance, by a group of health insurances, by different private (accident) insurances, by the federal military insurance, by federal disabilities insurance, by the federal narcotic control, by groups of manufacturers, by each wholesaler, to name a few! In short, the doctor had to manage many different identification codes when corresponding and invoicing each of these organisations. With this lack of standardisation, accuracy was impossible and efficiencies in healthcare processes were nonexistent. The visionaries understood that new processes would only be possible if a robust, accurate and scalable identification system was provided by a neutral source for all of the Swiss healthcare industry.

Now, for nearly 30 years, this solution enabled by the GS1 Global Location Number (GLN) has been in place. Global Location Numbers support the needed identification system by uniquely identifying each of the actors and their locations. The GLN has proven to be the "right choice" in standardising and simplifying the identification of all stakeholders, offering significant benefits for the Swiss healthcare system. By choosing the GS1 GLN as the global identification key, the visionaries have strengthened the use of GS1 standards in the healthcare industry and helped stakeholders understand how globally unique identification can link master data and improve logistical and clinical processes.

HCI Solutions

By Nicolas Krattinger and Christian Hay

The GLN and GSRN as identification keys

The first objective was to revise Switzerland's federal narcotic control system, which was fully paper-based until 1992. The Federal Office of Public Health (FOPH), which was at that time in charge of maintaining the national control system, was a key partner to ensure that each stakeholder secured authorisation for the trade of narcotic prescription drugs and was provided entry into the reference database, called RefDatabase.

As a member of the database, each stakeholder is identified with its own GLN, allocated by a neutral organisation, the RefData foundation. This complete list or database of healthcare stakeholders also needs to be constantly updated.

One critical challenge was to secure the complete, countrywide identification of healthcare stakeholders concerned with narcotic control as well as for supply chain processes. Standard operating processes had to be developed to organise the management of this data, avoiding duplication and other potential mistakes such as when a stakeholder's name is spelled differently according to a different language (e.g., French, German, Italian).

In the late 1990s, GS1 adopted a new identification key—the Global Service Relation Number (GSRN)—that uniquely identifies individuals such a provider of care services in an organisation like a hospital.

Several times, GS1 Switzerland and its partners investigated if the GLN identification keys for these individual care services providers could be migrated to GSRN identification keys. This shift would mean making significant changes in user databases, in healthcare provider ID cards, and more, since the GSRN has more characters than the GLN.
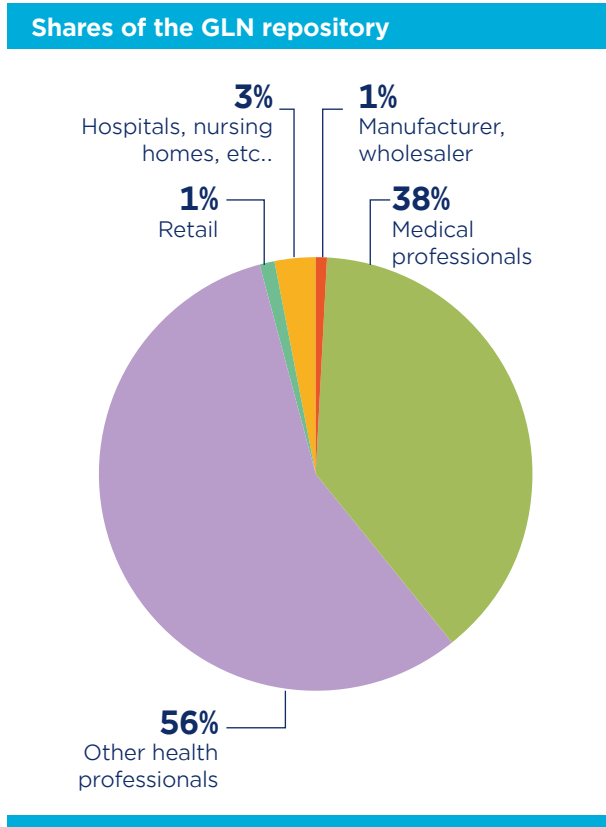
Ultimately, the decision was made to continue using the GLN, based on its deep adoption and use in existing healthcare provider processes and IT systems. Yet, as new initiatives are launched, it is recommended to use GLNs for legal entities like hospitals and GSRNs for individuals like nurses or medical doctors.

Introducing the RefDatabase

RefData foundation has a dedicated office that manages partner identification across Switzerland's healthcare system with its RefDatabase. This small office has set up procedures to meet the market requirements for completeness and accuracy, by establishing and maintaining relationships and link with national organisations for cross-checking data (manual or automated).

The RefDatabase managed by the RefData foundation has established links to other national organisation databases for cross-checking stakeholder data.
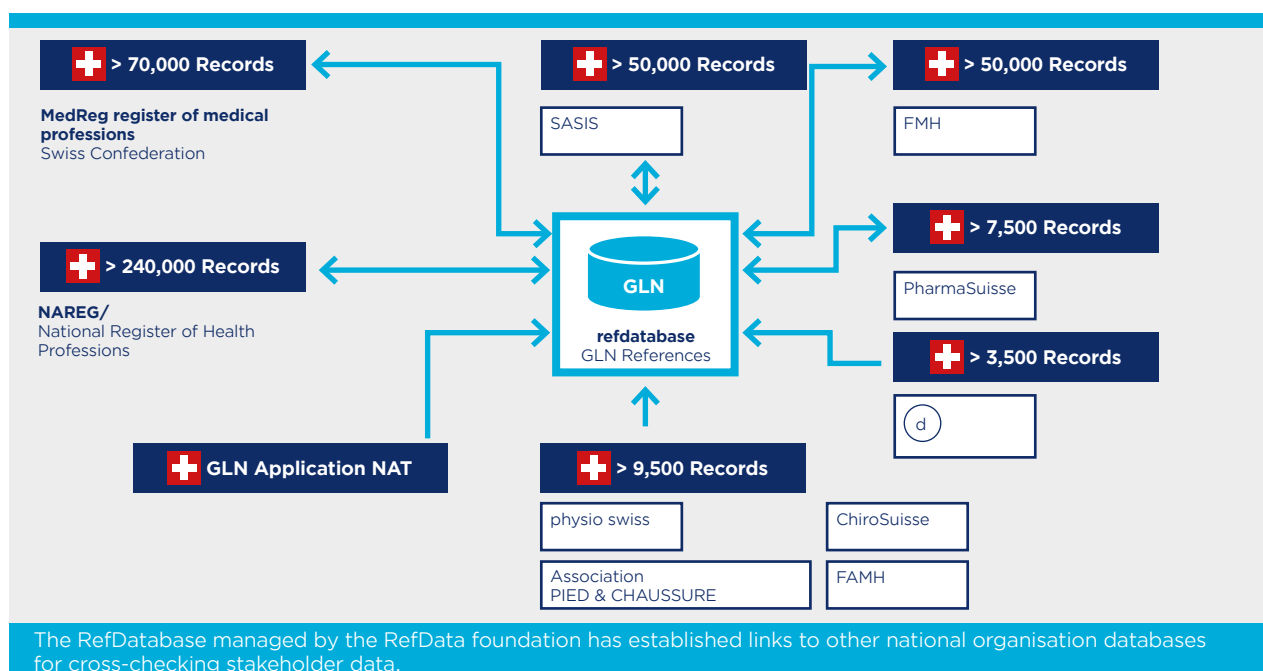
RefDatabase is the "identification manager" for stakeholders in the Swiss healthcare. It addresses more than 300,000 active entries as detailed in the graphic on .

Shares of the GLN repository

3%
Hospitals, nursing homes, etc..

1%
Manufacturer, wholesaler

1%
Retail

38%
Medical professionals

56%
Other health professionals

The process to obtain a GLN from RefDatabase consists of posting a request. This request for information is cross-checked with various stakeholders such as the Register of Commerce for commercial entities (e.g., pharmacy, laboratory). The national narcotic control body will indicate if there is authorisation provided for that commercial entity. For individuals, the cross-check is made with the appropriate trade association, (e.g., for medical doctors, dentists, pharmacists, physiotherapists), and with the national register for health professionals.

In turn, the consulted registries receive the GLN allocated by RefDatabase and, in turn, document if the GLN is relevant for their own database and publish the GLN if it is appropriate to their mission.

Most data exchanges between RefDatabase and other registries are processed electronically, with very limited human involvement.

This improves data quality by reducing the time associated with processing and verifying the data.

RefDatabase is publicly accessible and provides a limited amount of information about identified entities. This is due to RefData's mission, which is limited to this identification process. However, RefDatabase includes additional information that is needed for the cross-matching of entries and the detection of possible duplications.
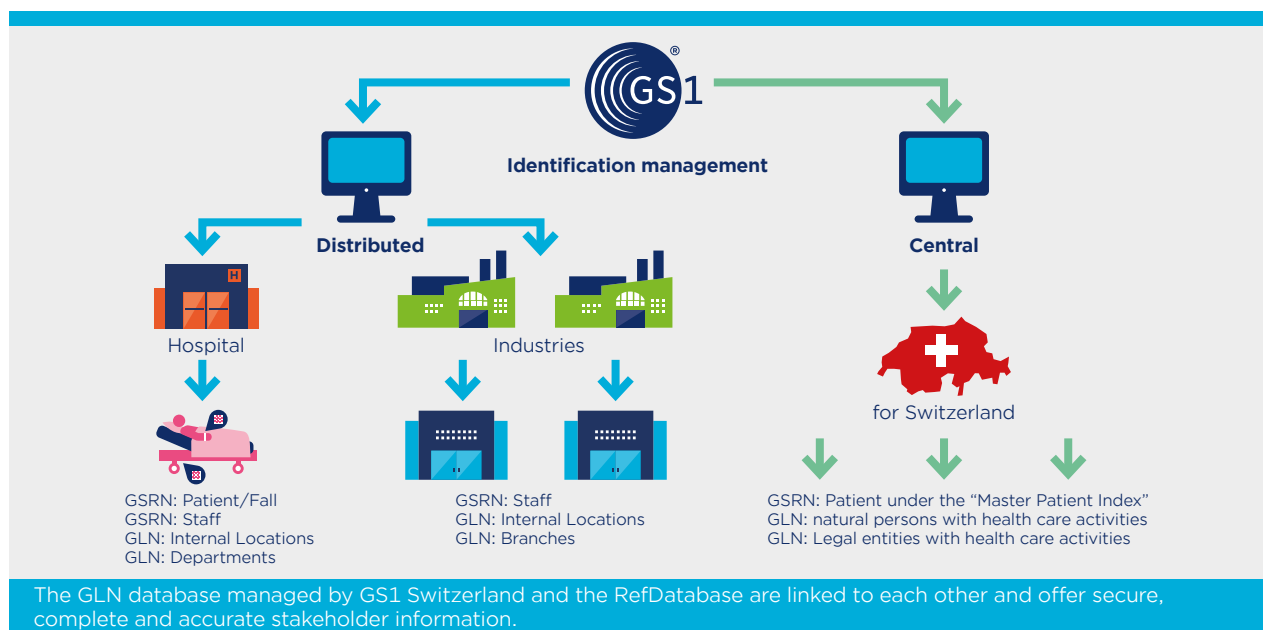
Each RefDatabase entry is classified to facilitate search capabilities and use across the industry. For individuals, 47 codes are currently used, which are taken from ISCO-08 (International Standard Classification of Occupations, published in 2008 by the International Labour Organisation). These classification codes are further linked to the Swiss Federal Statistical Office's (FSO) profession classifications. Organisations are classified in 30 categories, as defined by the Swiss FSO.

Identification management: centralised vs. decentralisation

Centralised identification management can ensure the accuracy of top-level identification, e.g., between 3 and 10 GLNs assigned to a hospital. When one organisation decides to implement GLNs across its facilities and departments, that organisation is accountable for maintaining these GLNs as accurate and complete.

This is why GS1 Switzerland encourages organisations such as hospitals to develop their own GLN master data base, and decide which of these identifiers should be made public and published through RefDatabase. GS1 Switzerland has further developed its own GLN database to serve not only the Swiss healthcare industry, but all GS1 users from all industries in Switzerland.

The two databases—the GLN database managed by GS1 Switzerland and the RefDatabase—are linked to each other and offer secure, complete and accurate stakeholder information. For example, the mass upload of GLNs is a service offered by GS1 Switzerland's GLN service, as well as maintenance with an API. These services help support the needs of healthcare stakeholders for seamless upload procedures.

GS1

Identification management

Distributed

Hospital

Industries

Central

for Switzerland

GSRN: Patient/Fall
GSRN: Staff
GLN: Internal Locations
GLN: Departments

GSRN: Staff
GLN: Internal Locations
GLN: Branches

GSRN: Patient under the "Master Patient Index"
GLN: natural persons with health care activities
GLN: Legal entities with health care activities

The GLN database managed by GS1 Switzerland and the RefDatabase are linked to each other and offer secure, complete and accurate stakeholder information.

Similar rules apply for the identification of patients. Whereas the national patient identifier, the GSRN, is maintained centrally through a master patient index, stakeholders such as hospitals or nursing homes are encouraged to embed or replace their current identifier with a GSRN maintained locally. This causes no process disruption and increases standardisation of patient identification within the organisation as well across organisations.

Benefits of GS1 standards in healthcare

Implementing GS1 standards in the healthcare industry takes time, particularly when it comes to users such as hospitals. This is because their IT systems have very long life cycles.

Having developed this vision in the early 1990s, global unique identification has progressively demonstrated benefits. Hospital and retail pharmacy software packages come with GS1-compatible releases.

Narcotic control continues to be managed by a small team with strong IT support. The progressive deployment of eHealth processes is built on a solid, robust track record. With this progress, authorities have come to understand that the increased use of GS1 standards provides a sustainable and scalable system for unique identifications.

Considering clinical processes, stakeholders have adopted recommendations[1] for the identification of primary packages and manufacturers' implementations have continued to grow year-over-year. Add to this the adoption of the GS1 GSRN, as a patient identification key, combined with the GS1 Service Relation Instance Number (SRIN)[2], in healthcare provider environments.

The use of GS1 standards will continue to strengthen data capture processes at points of care since scanning GS1 identifiers like the GSRNs or SRINs encoded in GS1 barcodes reduces uncertainties and IT complexities. What's more, doctors and nurses are quickly becoming familiar with GS1 DataMatrix barcodes and the benefits of scanning for safer processes and documentation.

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1   *"Joint recommendations for the avoidance of confusion concerning the primary packaging and labelling of solid pharmaceutical dosage forms"*
    http://www.patientensicherheit.ch/dms/de/themen/ Sound-a-like-look-alike-Empfehlungen/x3199_ Gemeinsame- Empfehlungen_Prim-rverpackung_Beschriftung_feste_ Arzneiformen_2012_E/x3199_Gemeinsame-Empfehlungen_ Prim%C3%A4rverpackung_Beschriftung_feste_ Arzneiformen_2012_E.pdf

2   *A Service Relation Instance Number (SRIN) may be added to the GSRN; for example, to identify the phase of a medical treatment for a patient.*

Next steps

For GS1 Switzerland, the need to create greater awareness, interest and adoption of the GS1 identification system by stakeholders remains high. The RefData foundation contributes by explaining the benefits of global unique identification. As a result, for example, the new Swiss Medication Verification Organisation (www.smvo.ch) is adopting GLNs for the verification processes against medicines falsification. Other opportunities to demonstrate how global identification standards provide benefits still exist and remain a top priority for GS1 Switzerland.

It is expected that the next time the national authorities print prescriptions sheets for narcotics (a process which is centralised for regulatory reasons), they will adopt another GS1 identifier, the Global Document Type Identifier (GDTI), since it offers yet another "best solution" for unique identification worldwide.

About the Author

Nicolas Krattinger has been Referencing Manager at HCI Solutions Ltd. for over 17 years.

After studying earth sciences and obtaining a degree in geological engineering, Nicolas worked in the oil industry for several years. Throughout his career, he had the opportunity to develop skills in computer science and database management.

In the late 90s, he reoriented his career and joined the healthcare sector, initially working in project management for an association of the pharmaceutical branch, then joining HCI Solutions Ltd., a master data company for the Swiss health market.

Nicolas is currently responsible, among other things, for the management and development of the RefDatabase (www.refdata.ch), the public database on actors in the health sector in Switzerland consisting of more than 300,000 records referenced by GLN codes. This task is carried out under mandate from the RefData Foundation.

Christian Hay is Senior Consultant Healthcare with the GS1 Global Office. For more than 25 years, Christian has worked in the healthcare industry. In 1990, he played an instrumental role in the establishment of narcotic control, by using the GS1 system of standards in Switzerland.

In 2000, Christian founded Medinorma LLC with business colleagues. As a consultant, he works for GS1 Switzerland, GS1 Global Office and other GS1 organisations, focusing on interoperability for IT standards in the healthcare industry. Christian currently represents GS1 in organisations such as ISO TC 215 (Chair of Working Group 6 "Pharmacy" in the technical committee of Health Informatics), CEN TC 251, HL7 and ICCBBA (transfusion and transplantation). In his role with ISO TC 215, Christian is involved in development of IDMP standards and implementation guides. .

Christian contributes to the board of the Swiss Society for Medical Informatics and was the first chairman for IHE Suisse, which included the organisation of a European Connectathon in Bern

Christian gives lectures on healthcare logistics at the Bern University of Applied Sciences. In April 2015, Christian was asked to contribute to the INTERPOL World conference in Singapore.

About HCI Solutions Ltd.

HCI Solutions Ltd. is the master data company for the Swiss health market and develops management solutions for pharmacies as well as tools to securely manage, communicate and distribute sensitive health data. The database includes over 200,000 products and allow all healthcare providers, the authorities and insurers to communicate on the same database. It also offers a professional POS software for pharmacy chains and a solution for single pharmacies and drugstores. HCI Solutions works further on contract basis for the RefData foundation.

https://www.hcisolutions.ch/fr/index.php

Government Initiatives

Scanning the horizon: the evolution of Scan4Safety in the NHS

Two years, four phases and six trusts on: the Scan4Safety programme has demonstrated the benefits of adopting standards in the National Health Service (NHS) in England. Through Scan4Safety, which has been called a world first, the Department of Health (now the Department of Health and Social Care or DHSC) funded the implementation of GS1 and PEPPOL standards in six acute NHS trusts (hospitals). As the demonstration phase draws to a close, it is timely in 2018 to reflect on the challenges and achievements of these six organisations.

By Steve Graham

Introducing Scan4Safety

Six acute NHS demonstrator sites were funded through the GS1 and PEPPOL implementation programme that launched in 2016. It began under the banner of eProcurement. However, early implementation in NHS trusts highlighted the need for the programme to be badged more appropriately given its benefits; hence, Scan4Safety was born.

The six successful trusts that were selected through a competitive bidding process are diverse: some large, metropolitan centres and other district hospitals serving largely rural populations, spanning from the tip of Cornwall to Hartlepool in the north of England. This diversity resulted in the implementation process where these trusts went through being tested in very different healthcare environments—a strength that stands subsequent trusts in good stead. It meant that the learnings that each trust captured would provide knowledge that could help in future implementations, no matter the demands on their own local health populations.

Global standards, specifically GS1 and PEPPOL, are difficult to make tangible. However, in its more basic form, Scan4Safety involved uniquely

identifying, usually through the use of barcodes, each constituent's input to the delivery of healthcare. Scan4Safety was about identifying and tracking "patients, products and places" in hospitals and coupling the scanning of these with common and best-practice "processes." Thus, the "Scan" and the "4" Ps in Scan4Safety become clear.

The implementation of standards in healthcare is a potentially vast and unwieldy objective. A key success factor for Scan4Safety was in breaking this objective down into methodical and manageable tasks. These tasks were grouped into four phases, with a DHSC review panel keeping the trusts on track and assessing the actual progress made against plan.

Safety, operational productivity and efficiency

The key to successful implementation was in Scan4Safety becoming more than just an exercise in procurement and efficiency. These gains, despite their operational utility, were not enough to secure the hearts and minds of doctors, nurses and healthcare assistants working in the NHS.

Securing the buy-in of senior clinicians was critical to ensuring a smooth implementation without interruption to business as usual. Through the appointment of trust board sponsors and clinical champions, these six sites garnered widespread support under the banner of Scan4Safety.

Linking the power of barcode technology to a greater ability to deliver improved patient safety and greater visibility of a patient's pathway through the hospital (and eventually even through the complete NHS system) was an argument that was able to convince those on the frontline of the benefits of Scan4Safety. The full benefits could only be realised through the full and seamless embedding of Scan4Safety across the length and breadth of a hospital's day-to-day activity.

Additionally, the application of Scan4Safety through a structured and coherent methodology, which has since been built upon, captured and documented through the learnings of the demonstrator sites, was a key success factor.

At a national UK level, Scan4Safety underpins a range of initiatives designed to tackle some of the most persistent challenges facing the NHS today, such as the Carter programme, Paperless 2020 and the European Union's Falsified Medicines Directive (FMD).

Demonstrable benefits

In applying GS1 and PEPPOL standards to patients, products and places, the six demonstrator sites quantified and captured the true costs and benefits across their organisations. As the trusts complete final phase requirements and pass through the audit process in 2018, there is a chance to reflect on their pioneering achievements.

Scan4Safety is delivering hard financial benefits, which sit ahead of forecast at the end of the two year programme. Furthermore, there are yet-to-be-quantified benefits relating to time released to care, staff satisfaction, and indications that points to the programme's significant contribution to patient safety. In just one department at the Royal Cornwall Hospital NHS Trust, five extra cases a week have been completed in interventional radiology as a result of Scan4Safety. In all sites, product safety recalls can be conducted almost immediately and now cost the NHS less than £10 each—a marked improvement.

The opportunity

Barcode technology is proven and economic, yet the case for its effectiveness was yet to be made in the NHS before the demonstrator sites. This demonstration has only just begun to touch the surface of the possibilities of barcode technology within the NHS.

What began as a highly ambitious and challenging programme has evolved to a place where the demonstrator sites are looking to continue their work beyond the funded two year period and to extend the scope of Scan4Safety to include further use cases and enabling standards. Scan4Safety has brought into vision the opportunity to reduce the occurrence of medical errors and "never events" and has buy in from senior managers in hospitals whereby they are committing longer term resources and funding to Scan4Safety. With 148 trusts and a multitude of undiscovered use cases to go, the wide horizon of Scan4Safety is beginning to materialise.

What's next?

While the eProcurement Strategy remains relevant and recognisable source material, Scan4Safety has evolved into an internationally recognised programme. With the benefits now demonstrated, it is essential that next steps and the potential for rollout are undertaken in a similarly structured and methodical manner. The full potential of the programme—the release of £1 billion of benefits over seven years as well as organisational and patient safety benefits—will only be realised with continued perseverance as the NHS and its supplier base moves towards GS1 and PEPPOL compliance.

The full potential of the programme—the release of £1 billion of benefits over seven years as well as organisational and patient safety benefits—will only be realised with continued perseverance as the NHS and its supplier base moves towards GS1 and PEPPOL compliance.

About the Author

Steve Graham *leads on NHS eProcurement policy at the Department of Health and Social Care 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 whilst reducing costs. Steve 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.

As a Member of the Chartered Institute of Procurement and Supply (MCIPS)—qualified procurement professional, Steve has led national, regional and local procurement teams in the NHS, and has set up and managed several regional NHS procurement organisations. He has managed warehousing and distribution operations, and led the national procurement of medical devices and services, particularly in the cardiac and disability sectors.

About GS1 Healthcare

GS1 Healthcare is a voluntary and global User Group leading 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.

Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare can help to improve patient safety, boost supply chain efficiency and improve product traceability from manufacturer to patient. The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. GS1 Healthcare members include over 100 leading Healthcare organisations worldwide.

For more information about GS1 standards in healthcare go to www.gs1.org/healthcare.

(01)09506000134307