The Global Language of Business

GS1 Healthcare Reference Book 2020-2021

Stories of successful implementations of GS1 standards

> Safer, more efficient care starts with a simple scan.

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:

- **Achê Laboratórios** – Márcio Reis Freitas, Brazil
- **Alexion** – Giovanny Cruz, Colombia
- **AmerisourceBergen** – Ameer Ali, US
- **APX Systems** – Fredrik W. Goborg, Norway
- **Cardinal Health** – Quentin Dittman, US
- **East Kent Hospitals University NHS Foundation Trust (EKHUFT)** – Andy Barrow, UK
- **Franciscan Missionaries of Our Lady Health System (FMOLHS)** – Sandi Michel, US
- **Hikma Pharmaceuticals** – Khalid Abughoush, Jordan
- **Johnson & Johnson Supply Chain** – Tom Jones, US
- **Leeds Teaching Hospitals NHS Trust** – Mark Songhurst, UK
- **Lovisenberg Diaconal Hospital** – Marit Glende Johnsen, Norway
- **Markhot Ferenc Teaching Hospital** – Dr. Robert Gyetvai, Dr. Krisztina Orosz, Dr. József Vácity, Hungary
- **McKesson Corporation** – Scott Mooney, US
- **Movilitas** – Marco Steinkamp, Germany
- **National Center for Global Health and Medicine (NCGM)** – Dr. Kengo Miyo, Japan
- **PinkRoccade Healthcare** – Maaike Langelaan, Netherlands
- **Radboud University Medical Centre (Radboudumc)** – Alex van der Putten, Netherlands
- **Rigshospitalet** – Søren Boesgaard, Marianne Kjellow-Andersen, Pernille Preisler, Denmark
- **St. Joseph's Hospital** – Cai-Cing Liao, Su-Chen Lin, Shu-Hui Wang, Chinese Taipei
- **Sydney Local Health District (SLHD)** – Matt Mohammadi, Jon Tang, Australia
- **Tallaght University Hospital** – John Donovan, Olivia Leigh, Ireland
- **Triple A MedTech Co., Ltd** – Kingsley Huang, Chinese Taipei

We would also like to thank the GS1 Member Organisations (MOs) who helped facilitate the creation of this book:

- **GS1 Brazil** – Marcelo Oliveira Sa
- **GS1 Chinese Taipei** – Josephine Chen, Nicolas Liou, James Perng
- **GS1 Colombia** – Alex Bedoya, Paola Morales, Leonel Pava, Alvaro Sánchez, Katherine Tabares
- **GS1 Denmark** – Camilla Aabye Hansen, Anne Aarslev Schmidt
- **GS1 Hungary** – Christine Hankó, Zoltán Krázli
- **GS1 Ireland** – Amanda Creane, Siobhain Duggan
- **GS1 Japan** – Fumi Maekawa, Hiromitsu Takai, Koichi Uemura
- **GS1 Jordan** – Mai Ali, Areej Rawashdeh
- **GS1 Netherlands** – Esther Peelen, Johanneke Wolters
- **GS1 Norway** – Stephen Bølstad
- **GS1 UK** – Glen Hodgson, Natasha Smith
- **GS1 US** – Salil Joshi, Peter Sturtevant, Shannon Sullivan

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What's inside

Healthcare providers

Suppliers

Healthcare provide experiencing amazi

US

At Franciscan Missionaries of Our Lady Health System, 85% of implants that come into its warehouse are identified with GTINs for improved inventory management and patient safety.

US

Results from AmerisourceBergen and McKesson barcode assessments showed a significantly higher year-over-year increase of nearly 52 percentage points, compared to the 2018 assessment. At Cardinal Health, the improvement ranged from 63.6 to 58.2 percentage points.

US

In support of UDI regulations, Johnson & Johnson companies have submitted 75,000 device records to the US Food & Drug Administration's Global Unique Device Identification Database.

Colombia

Alexion has achieved 100% traceability of pharmaceuticals, from factory to patient bedside.

rs and suppliers around the world are ng benefits with GS1 standards

Ireland

Tallaght University Hospital estimates the Scan4Safety solution has reduced stock waste by €7,000 in the first phase.

UK

- East Kent Hospitals University NHS Foundation Trust implemented GS1 standards, giving it real-time asset information like location details and service due dates.
- By using GS1 standards, patients can be tracked in real time throughout their care journeys at Leeds Teaching Hospitals NHS Trust.

Netherlands

- By using GS1 standards to identify medical devices and share data, the Radboud University Medical Centre is storing 25% less stock and saving €500,000 each year.
- GS1 Member Organisation experts, policy makers and healthcare workers participated in a project to define a minimum, internationally appropriate set of patient safety outcome measurements for evaluating, generating evidence and improving the implementation of GS1 standards.

Norway

Lovisenberg Diaconal Hospital has automated its ordering process that once took up to 2 hours a day, but now takes only minutes, and with increased quality.

Germany

Since all systems were based on GS1 standards, Bionorica spent 52% less in implementation costs to comply with Russian regulation.

Denmark

Cardiac Catheterisation Laboratory at Rigshospitalet has reduced stock levels and freed up time equivalent to 3 nurse positions.

Hungary

Markhot Ferenc Teaching Hospital precisely measures its use of pharmaceuticals and medical devices with GS1 standards, reducing inventory costs by 5% the first year.

Japan

At the National Center for Health and Medicine, 340 hours per year saved to record medical devices used in surgery.

Chinese Taipei

St. Joseph's Hospital has improved inventory management, saving 50% of the time to process an order.

Brazil

At Aché Laboratories, 180 million drug packages are labelled with GS1 DataMatrix barcodes each year.

Jordan

Hikma Pharmaceuticals has enhanced brand image and reputation in target markets by leading the way to meet regulatory requirements.

An unprecedented year in healthcare

As the collection of case studies were compiled for this 2020-2021 GS1 Healthcare Reference Book, the global healthcare industry was battling the COVID-19 virus.

While social-distancing measures have helped to "flatten the curve," the presence and impact of the coronavirus will continue to be felt for many months, and even years. The citizens of the world have never before depended as much on our healthcare systems as now.

Researchers are collaborating on vaccine developments and new treatments, healthcare suppliers are working overtime to provide urgently needed pharmaceuticals and medical devices, and healthcare providers are on the frontlines—millions of "healthcare heroes" caring for patients and saving lives.

While the COVID-19 pandemic is challenging the digital foundation of our global supply chain and national care systems, investments in GS1 standards by healthcare suppliers and providers have strengthened this foundation.

Hospitals are operating more efficiently and delivering enhanced patient-centric care.

Throughout this book, read how hospitals are using GS1 standards to provide better and safer patient care. Part of England's National Health Service, East Kent Hospitals University NHS Foundation Trust is providing timely and efficient patient care, since medical equipment, beds and other assets are proactively maintained and readily available.

With GS1 standards, the Franciscan Missionaries of Our Lady Health System in the US is using supplier-provided product data to analyse the cost of patient procedures and the effectiveness of outcomes. GS1 Netherlands and other GS1 Member Organisations are working with a healthcare consulting organisation to develop patient safety outcome measurements for evaluating and improving the implementation of GS1 standards in hospitals.

Leeds Teaching Hospitals NHS Trust is providing concerned relatives with real-time information for their patients' progress.

In Chinese Taipei, St. Joseph's Hospital is reducing the time for processing an order by 50%.

Vast improvements in stock management are helping to ensure that inventory is available, when needed.

With its progress in stock management, Ireland's Tallaght University Hospital is giving clinical staff more time to spend with patients. Out-of-stock situations are now virtually non-existent at the Cardiac Catheterisation Laboratory in Denmark and the Radboud University Medical Centre in the Netherlands.

At the Lovisenberg Diaconal Hospital in Norway, manual orders that once took up to two hours every day now take only minutes with automation supported by GS1 standards. The hospital has full visibility of its many pieces of surgical equipment for safer operations. In Hungary, the Markhot Ferenc Teaching Hospital is using GS1 standards to successfully measure its use of pharmaceuticals and medical devices for lower costs, yet highly effective patient care.

Progress continues in implementing GS1 standards for the traceability of medical devices, surgical equipment and pharmaceuticals.

Japan's National Center for Global Health and Medicine has successfully identified medical devices with GS1 standards and integrated this information across its hospital systems. As a result, 30% less time is now required to record medical devices used in surgery.

Suppliers are meeting traceability regulatory requirements and streamlining their delivery of products.

At Aché Laboratories in Brazil, 180 million or 100% of the company's secondary and tertiary packages are labelled with GS1 standards. Colombia's Alexion has successfully completed a pilot of its traceability system that enables visibility of pharmaceuticals throughout the supply chain.

Bionorica in Germany completed its implementation of pharmaceutical serialisation ahead of Russia's scheduled regulation deadline. In Jordan, Hikma Pharmaceuticals has successfully implemented a traceability system for its complete line of pharmaceuticals—one that can easily scale across its three global regions in response to emerging regulations.

Johnson & Johnson shares its perspectives and universal support of Unique Device Identification regulations, allowing healthcare providers to use UDI data in their procurement systems, inventory management systems, electronic health record systems and implant registries, while upholding the highest standards of patient privacy, quality and compliance.

AmerisourceBergen, Cardinal Health and McKesson Pharmaceutical conducted assessments of their suppliers' barcodes, showing a remarkable year-over-year gain of 52 percentage points in the presence of GS1 barcodes to meet the serialisation requirements of the US Food and Drug Administration's Drug Supply Chain Security Act.

During this time of uncertainty, we can depend on GS1 standards and each other.

While this time is unprecedented, it's also filled with many opportunities. For more than 15 years, we have worked together, as GS1 Healthcare, to digitally transform our healthcare supply chain and solve some of its greatest challenges. Together, we will continue to leverage standards, technology and our innovative spirit to accelerate this transformation, helping to put the world back on a healthy track.


Mölnlycke

Healthcare Providers

Healthcare institutions around the world are working to provide the best possible care for their patients, often under pressure to save time and money. GS1 standards are helping them do all this. Read the case studies over the next few pages to find out how.

Chinese Taipei

St. Joseph's Hospital: Unique Device Identification for better care and patient safety

Challenge

Like many hospitals in Chinese Taipei, St. Joseph's Hospital once used paper records, manual processes and no specific methodology to manage its medical devices and materials.

Approach

St. Joseph's Hospital launched a Unique Device Identification (UDI) project that automated its business and clinical processes by implementing GS1 standards to uniquely identify all medical devices and materials. With this foundation, the hospital was able to establish a traceability system for implanted medical devices and collect real-time data about their use and associated inventory levels.

Significant improvements in inventory management with automated processes

Increased patient safety with full product traceability and auto alert functionality

50%
of processing time saved per order

96%
scanning rate after only two months

St. Joseph's (Catholic) Hospital is located in Huwei township, Yunlin county, Chinese Taipei. It was established by Bishop Thomas Niu of the Chiayi diocese in 1955, and two young and energetic missionaries, Fr. George Massin from Belgium and Fr. Anthony Pierrot from the Netherlands, who became the first administrators of the hospital. Today, the hospital's mission is to provide comprehensive medical services to the residents—especially the poor—of Huwei and its neighbouring towns.

For many years, church-affiliated hospitals "filled the healthcare gap" by providing services to the poor who couldn't afford medical care. Today, even with Chinese Taipei's policy of national healthcare insurance, St. Joseph's Hospital remains focused on serving the needs of society. Driven by the values of "Total Sacrifice, True Love and Constant Joy," St. Joseph's Hospital offers quality medical care to all patients. Its outpatient treatment services cover 18 clinical specialties and sub-specialties, including internal medicine, surgical and other clinical departments. On average, St. Joseph's Hospital receives more than 1,300 outpatients per day.

With 700 caregivers and staff, and 378 beds, St. Joseph's Hospital is committed to the needs of all people of Huwei and surrounding areas.

Su-Chen Lin, Cai-Cing Liao, Shu-Hui Wang & Kingsley Huang

Transforming information management

Early in 2018, St. Joseph's Hospital started its UDI project after visiting the Kaohsiung Armed Forces General Hospital (See case study in GS1 Healthcare Reference Book 2019-2020, page 12.), well-known for its effective and efficient management of medical devices and materials after implementing unique device identification with GS1 standards.

St. Joseph's major goal was to achieve visibility and traceability of product information throughout its whole supply chain. However, its staff and nurses were accustomed to processing records and documents, using manual and paper-intensive procedures. Due to inconsistent product information, this often meant redundant, cross-checking work activities and issues in operations. Furthermore, the lack of disciplined resource management caused waste and unnecessary costs.

As a private regional hospital, St. Joseph's Hospital is faced with many challenges to maintain its mission of quality care and charitable spirit. Throughout 2019, the hospital staff worked with Triple A MedTech Co. Ltd. and GS1 Chinese Taipei, to ensure a successful UDI implementation for improved inventory and information management.

With this transformation, St. Joseph's Hospital aims to:

- Enhance its control of processes and information management via the implementation of the unique device identification of medical devices and materials, reducing opportunities for human error and increasing patient safety.
- Improve inventory management for medical devices and materials.
- Establish traceability for implanted medical devices used in patients.
- Integrate all existing systems used by each of its departments, so that consistent information can be shared.

In 2019, the hospital received the international certification of ISO 9001: 2015. The introduction of GS1 standards for UDI implementation and the smart management solution were two important indicators in the evaluation of hospital management's integrity and quality. This ongoing project will facilitate information security and reform process management, but will also pave the way to the ultimate goal of effectively controlling hospital operating costs.

Overcoming problems

Many problems occurring in Chinese Taipei's hospitals are often caused by using manual procedures when maintaining product information. This inefficient management of data results in issues like:

- Reduced visibility throughout communications that impacts traceability
- Human errors and inefficient processes due to a lack of complete product information
- Redundant activities for staff
- Uninformed decision-making caused by unavailable real-time information
- No real-time alerts about suspicious products or other anomalies
- Poor communication among different departments caused by of lack of consistent product information

Especially in operating rooms, there is a large number of medical items used with many different specifications and types of packages of the same items. Consignment sales for non-stocked, spare parts also makes control more difficult. High-risk medical devices with high unit prices often cause high costs for the hospital if the actual quantity of devices used is not recorded correctly and matched to suppliers' lists.

Another serious situation that St. Joseph's Hospital faces is the decline of surgical patients over the years. In response, the hospital must reinforce its strength as a hospital that offers specialised services, which helps to reduce costs and increase revenue.

An integrated solution supported by GS1 standards

All these challenges are related to the lack of data transparency. The solution must increase data visibility and enable the use of UDI data throughout the hospital's entire network of databases. To do this, UDI data must be captured efficiently and accurately by all systems—for their individual use, for purposes requiring interoperability and for updating electronic patient records.

St. Joseph's invested significant time, persistent effort and unwavering passion, working together with GS1 Chinese Taipei. Following are some of the key success factors:

- Support from the hospital's executive management team played an important role in facilitating the coordination and communication among different staff members and departments. It ensured that all personnel were involved and cooperated together for the same goal, when executing the plan.
- The hospital secured support from a third-party solution provider and assistance from GS1 Chinese Taipei to understand the feasibility and benefits of UDI implementation using GS1 standards.
- The team created awareness, engagement and commitment regarding the UDI concept in departments where implementations were taking place. This included delivering training, creating a staff working group and providing ways for staff to suggest improvements.
- Workshops and seminars were sponsored for the suppliers of medical materials and devices. The hospital explained the reasons for adopting UDI using GS1 standards, and especially the benefits such as access to accurate, real-time product data from the hospital's inventory management system.
- The implementation of the Smart Management Cloud solution, developed by Triple A MedTech Co. Ltd., was essential for the project since it provided the core of the hospital's information network system.

St. Joseph's Hospital has been working with Triple A MedTech Co. Ltd. to deliver the cloud solution enabled by UDI and GS1 standards. This includes the use of artificial intelligence (AI) with patented algorithm and machine/deep learning, to enhance cloud computing capabilities for UDI in clinical medical environments.

The solution allows St. Joseph's to automatically complete the synchronisation of data feeding services, including the clinical medical information system, supply chain management system, hospital management and logistics system.

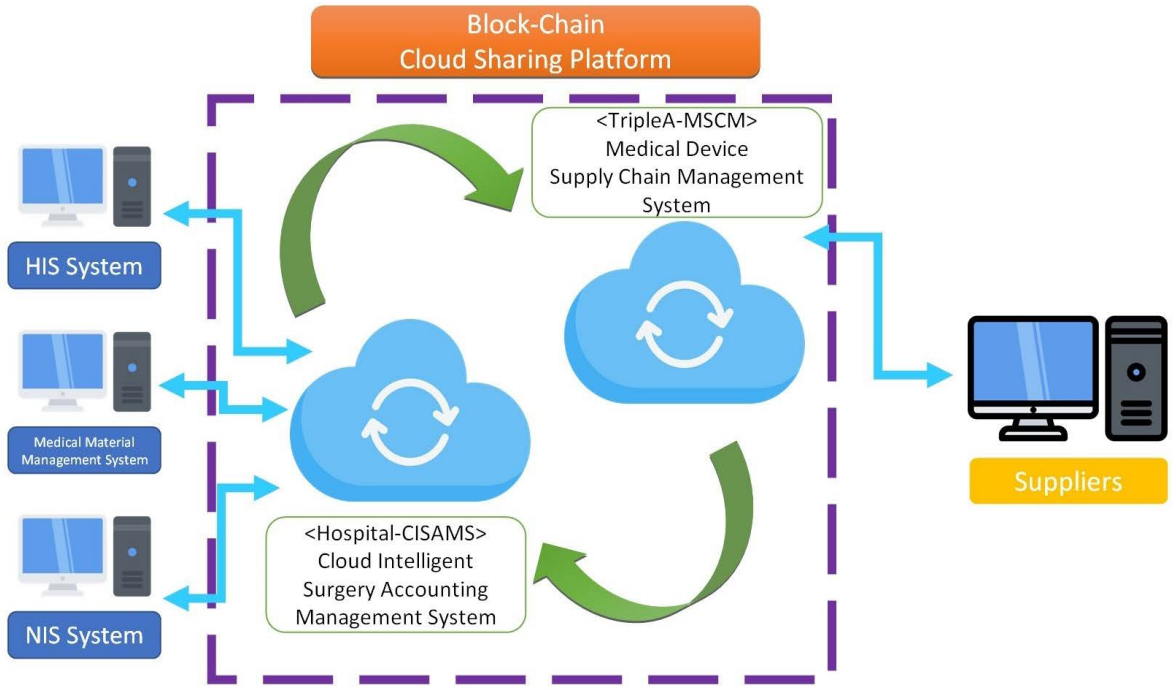

Figure 1: The Cloud Integrative Network of Hospital Information Systems

Tangible benefits and recognition

With the assistance of automatic identification at the front-end of the new service chain, problems associated with manual operations have been overcome by the smart management of information solution. This has elevated the quality of medical device management to a new level. St. Joseph's Hospital won the High Distinction Award of the "2018 Healthcare Quality Improvement Campaign in Chinese Taipei." In 2019, the entire hospital passed the international certification of ISO 9001: 2015.

Quantitative indicators include:

- The quantity of scanned items has grown from 87 to 4314, an increase of nearly 50 times.
- Efficient inventory management has resulted from the improved accuracy of real-time records of 96%. Also, e-statement reports have simplified the reconciliation process with suppliers, saving considerable processing time of hospital purchase orders for medical devices and materials.

Figure 2: In the preparation room, product items are all well arranged, especially for those bulk materials in the first-class category. They are easily identified by the staff scanning the card with the UDI barcode attached on the drawer. In the left photo, the quantity of products' usage over time can be recorded in the information system.

Figure 3: Preparing needed items before a surgery has become easier and faster when using the wireless portable reader to scan items' barcodes. The information system facilitates product data visibility in many processes, increasing administrative efficiency and patient safety. Now, St. Joseph's Hospital has achieved product traceability via effective product management based on GS1 standards for unique device identification.

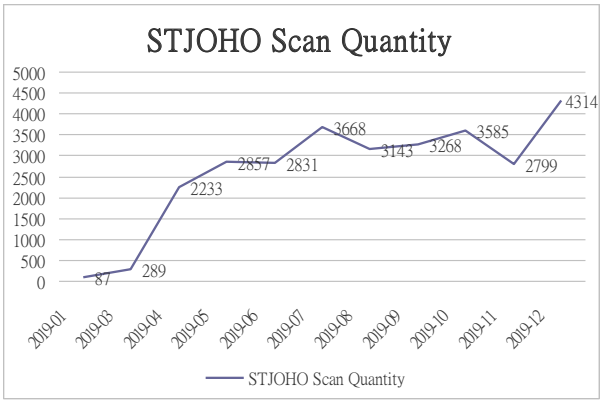

Figure 4: In 2019, the quantity of scanned Items per month increased from 87 to 4314, nearly 50 times more scans.

Figure 5: St. Joseph's Hospital thanks its UDI project team that worked tirelessly to make UDI and traceability a reality.

Every stakeholder benefits

By automating processes with the UDI implementation, healthcare professionals are now saving a significant amount of time that they can now spend on patient care. Using GS1 standards and simple scans to identify products, visibility of accurate product information and traceability of medical devices are now possible, enhancing quality of care and patient safety. In short, all stakeholders in the healthcare supply chain are benefiting from the St. Joseph's UDI implementation.

Next steps

St. Joseph's Hospital is planning additional projects for continuous improvements within the hospital and for patient safety.

Smart box for surgical kits

Many medical devices must be unpacked for sterilisation in advance of surgeries. In order to automatically identify these kits for data capture, the application of a smart box for each surgical kit will be adopted. Before sterilisation, the product information is first stored in the smart box by scanning the UDI encoded in a barcode on the label of the package. When a specific smart box is scanned in the operating room, the virtual box is matched to the physical one that will show on the screen, which displays the inside tools. The nurse touches the virtual items on the screen, then the pre-stored product info will be automatically input into the record of usage.

Electronic invoice for medical device suppliers

St. Joseph's Hospital not only applies UDI to clinical medical records, it also integrates the supplier's accounting information in the 2020 plan. When the medical materials provided by the supplier are used, the system will generate a unique reconciliation corresponding to the UDI used. This record will become the only information for invoicing between the hospital and suppliers. St. Joseph's Hospital will also introduce an electronic invoice exchange system, with the key for verification being the UDI.

Further integration of existing systems

For visibility and traceability among information systems, St. Joseph's next phase will use UDI as the sole identifier to integrate the hospital's clinical and administrative management. Not only can it be used in clinical e-records, accounting aggregation, medical device and material management, the UDI can also provide alerts of defective products.

UDI will continue to play a critical role in St. Joseph's Hospital. A core strategy of St. Joseph's Hospital management is to always be compliant with GS1 standards. The hospital is pushing forward with the concept of UDI-driven administration and management from the surgery operating rooms to all existing information systems for relevant departments and divisions. UDI will help St. Joseph's Hospital to efficiently control the inventory of medical devices and materials, effectively manage their suppliers and source channels, and accurately accelerate purchasing, pricing and financial processes.

With the implementation of GS1 standards and UDI, this transformation will lead to smart hospital management for high-quality healthcare services, not only solving challenges for St. Joseph's Hospital, but also delivering a promising future for innovative, quality care and patient safety.

About the authors

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Vice President of Administration
St. Joseph's Hospital

Su-Chen Lin has a doctorate in Industrial Engineering and Management, specialising in artificial intelligence and decision-making analysis. Dr. Lin is in charge of administration management at the hospital. She is also the CEO of the Catholic St. Joseph's Social Welfare Foundation, investing significant effort and time to care for elders in remote areas of Yunlin County.

Cai-Cing Liao
Head Nurse of Operating Room
St. Joseph's Hospital

Cai-Cing Liao is currently Head Nurse of Operating Rooms of St. Joseph's Hospital. She has been responsible for the UDI project execution and encourages her team members to cooperate with other departments to achieve the best results.

Shu-Hui Wang
Project Head Nurse
UDI Project Manager
St. Joseph's Hospital

Project Head Nurse Shu-Hui Wang is currently the UDI Project Managing Nurse of Operating Rooms of St. Joseph's Hospital. Since 2018, she has been responsible for the initiation of the in-house UDI project, including planning, monitoring and controlling. She is one of the pioneers who introduced UDI technology in the hospital.

Kingsley Huang, PhD
Founder and CEO
Triple A MedtTech Co., Ltd.

Kingsley Huang is the founder and CEO of Triple A MedTech Co., Ltd., which helps to integrate clinical systems with UDI concepts, using innovative solutions to medical merchandise management.

About the organisations

St. Joseph's Hospital is located in Huwei township in Chinese Taipei. Established in 1955 by Bishop Thomas Niu and two missionaries, the hospital has 378 beds with approximately 700 caregivers and staff. The hospital's mission is to provide comprehensive medical services to the residents of Huwei, especially the poor.

www.stjoho.org.tw

Triple A MedTech Co., Ltd. is a young, start-up company with research strengths and worldwide ambitions aimed to provide IoT, blockchain and cloud technologies as a smart solution to empower the outstanding medical services in major medical institutions. Its GS1 standards and UDI-oriented cloud solution offers over 30 hospitals in Chinese Taipei a wide range of clinical services and tracking and clinical assistant diagnosis tools to clinicians and healthcare providers.

www.triplea-medtech.com

Denmark

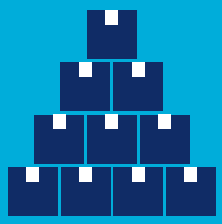
Cardiac Catheterisation Laboratory improves traceability, workflow and reduces items in stock

Challenge

The hospital department had a non-standardised manual process for handling stock inventory. The process was time-consuming and increased the risk for human error. In addition, the department had limited visibility of inventory levels, leading to low turnover of inventory on shelves and significant waste.

Approach

To optimise the reordering process while freeing up more time for patients, the department implemented a system using GS1 standards for scanning the barcodes of existing items in stock and all newly purchased items. The manual reordering process was replaced with one that was automated with nurses scanning all items that were used. This automatically generated a reordering list. All staff nurses were trained in how to use the new system, old scanners were reconfigured until they worked perfectly and new scanners were purchased.



Reduction in stock items

Increased level of staff satisfaction

3

nurse positions freed up due to the automated process

No cancellation of procedures due to out-of-stock items

Rigshospitalet

The Cardiac Catheterisation Laboratory is a highly specialised department at Rigshospitalet, Copenhagen, which performs 24 to 30 planned cardiac procedures a day as well as various emergency procedures on patients with cardiovascular problems. The department has nine operating rooms, making it one of the largest in northern Europe in this field of specialisation. Treatments include stent angioplasty and pacemaker implants. Most procedures are performed under local anaesthetic; many procedures leave an implant in the patient's body. The department has 50 permanently employed specialised nurses, dedicated technical staff and 20 to 30 staff physicians to ensure that patients get the best treatment possible.

For many years, the Cardiac Catheterisation Laboratory has been collaborating with one of its suppliers, Medtronic, a medical device manufacturer. To facilitate the use of its products by cardiology departments worldwide, Medtronic Integrated Health Solutions (IHS), offers multi-year partnerships with hospitals. Medtronic IHS is a division of Medtronic, which focuses on the cooperation and development of partnerships with health organisations.

The main goal of Medtronic IHS is to help healthcare providers optimise costs and outcomes while driving higher value and patient satisfaction. In cooperation with medical institutions, IHS develops innovative services and solutions to improve efficiency, reduce costs, facilitate patients' access to different types of treatment and improve outcomes.

Pernille Preisler, Søren Boesgaard & Marianne Kjellow-Andersen

Need for better stock management

In 2015, Medtronic IHS offered to review the Cardiac Catheterisation Laboratory's procedures and measure various factors. The department received high scores for patient satisfaction, job satisfaction and IT. However, there was one area that clearly fell short: stock management. Medtronic IHS discovered a high level of waste and far too many products on shelves.

"When we closed the door behind us in a procedure room, everything exuded professionalism. We provided excellent treatment, but everything around us was out of control."

Pernille Preisler
Managing Head Nurse,
Rigshospitalet

Goods were being reordered manually. Once an implant had been used, a nurse would attach a sticker to a piece of paper and give it to a secretary, who would then order the items in short supply. Nurses could also order the items themselves.

Based on the survey's results, the Cardiac Catheterisation Laboratory and Medtronic IHS embarked on a five-year collaboration in 2017, aimed at optimising the reordering process, while freeing up more time for treating and caring for patients.

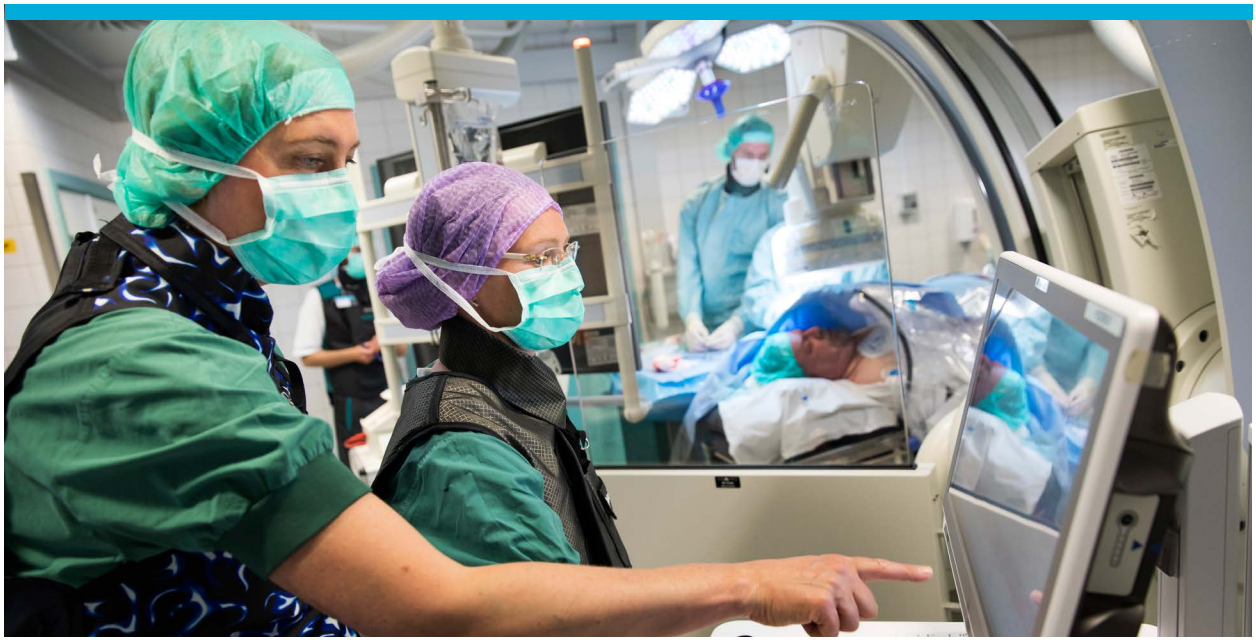


Figure 1: No cancellation of procedures due to out-of stock items.

Increased scanning and reduced waste

Medtronic IHS implemented a system for scanning barcodes of existing items in stock and all newly purchased items. By doing this, the staff knew exactly what items were in stock and which items would expire first. The manual reordering process was replaced by having the nurses scan all items that were used. This generated an automatic reordering list and enhanced traceability.

All staff nurses were trained in how to use the new system by Medtronic IHS' material management analysts, learning which package barcodes should be scanned (if there were more than one to choose from) and other routines.

Whenever new workflows are implemented, there is always a period of adjustment and training during which staff familiarise themselves

with and feel confident about using the workflows. This was also the case at the Cardiac Catheterisation Laboratory. The nurses had to get accustomed to leaving it up to others to manage the items in stock.

"In fact, we initially had to slightly increase the number of items in stock until the nurses were confident that there were enough items available so a procedure would never have to be cancelled due to out-of-stock items."

Pernille Preisler
Managing Head Nurse,
Rigshospitalet

This was also why the nurses initially tended to overstock the shelves in the different procedure rooms.

"It took a little while before the statistics actually showed us that the number of items in stock had actually declined."

"In addition, some items didn't have a barcode, and we didn't have enough scanners in the department, which slowed down the implementation of the new workflows."

Pernille Preisler
Managing Head Nurse,
Rigshospitalet

Shortly after the project began, the hospital switched to a new IT system "Sundhedsplatformen" (electronic health records) with many network flaws that caused the scanners to slow down.

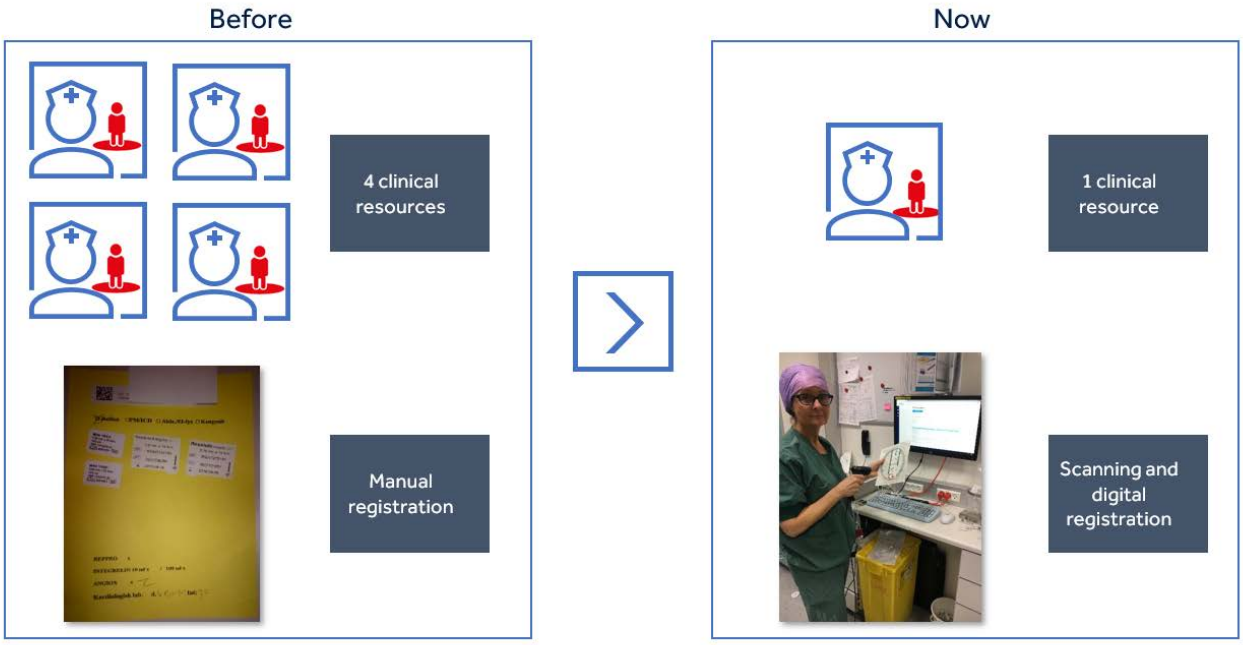


Figure 2: The new automated process has freed up three clinical resources to spend with patients.

New and updated scanners eased workflow

Management realised that the slow scanners were causing problems for the nurses. To comply with the nurses' wishes, the material management analysts reconfigured the old scanners until they worked perfectly and purchased new scanners for the department. At the same time, they redeployed the scanners exactly where the nurses needed them in the process.

When an item without a barcode was discovered, the package was collected to better understand which suppliers were not putting barcodes on their products. To maximise the number of items with functional barcodes, the department contacted the purchasers in the Capital Region and told them how important it was to emphasise the correct barcode necessity in tender requirements.

As a result, the department has seen an increase in the number of items with barcodes. Now, approximately 2,500 items have a scannable barcode, which in most instances includes a Global Trade Item Number® (GTIN®) and an expiry date.

During the five-year implementation period, the material management analysts from Medtronic IHS were present every day at the department. They still help nurses whenever they run into problems when scanning the items. In special instances, the nurses can put an item's package in a plastic bag and give it to a material management analyst, who then scans the information into the system, keeping the system up-to-date at all times.

Benefits of optimised workflows

Collaborating with Medtronic IHS has optimised the department's reordering workflows and traceability of the products. Now, nurses scan all the items they use during a procedure. Whenever an item is registered in the system as "used," it is automatically placed on an electronic reordering list, which is then processed by the material management analysts. The time freed up by the automated process equates to three clinical resources redeployed to patient-related work.

Previously, the reordering process was manual and very time-consuming, with a high risk of human error. Now, the nurses reorder the items simply by scanning their barcodes, taking only a few seconds.

"For example, whenever an implant runs out during a relevant period, it gets added to a digital list that is jointly followed up on by the material management analysts and the relevant physicians who use the items. This is important especially if the implant has a specific size and is not used often. This way, the physician has time to find a patient who needs the implant."

Marianne Kjellow-Andersen
Manager, Service Delivery
Medtronic Integrated Health Solutions

"This means that most items are registered in real time, giving nurses and physicians an overview of the items on the shelves. This has reduced waste in the department."

Søren Boesgaard
Managing Chief Physician,
Rigshospitalet

"The department has also experienced how physicians are interested in monitoring the statistics to see which items are available, and which items should be used first to reduce the department's waste even more."

Since the collaboration began in 2017, the department has not cancelled any procedures due to a shortage of items. Nurses have gradually become so confident about using the system and the new workflows that they no longer feel the need to stock more items than necessary in the individual procedure rooms.

Conclusion

The partnership between Medtronic IHS and the Cardiac Catheterisation Laboratory has been enormously beneficial for the department by reducing the items in stock, enhancing traceability and improving workflows—all which have increased satisfaction among both nurses and doctors. Since expiry dates are monitored and products are used before the expiry date, patient safety is enhanced as well.

About the authors

Pernille Preisler RN
Managing Head Nurse
Rigshospitalet

Qualified as a registered nurse in 1996 from Hvidovre Nursing School in Denmark. Pernille Preisler holds a degree in specialised business studies in staff development and is educated in management. She has worked at Rigshospitalet since 1999 and has been Managing Head Nurse at the Clinic for Cardiac Disease since 2016.

Søren Boesgaard MD
Managing Chief Physician
Rigshospitalet

Qualified as a registered physician in 1985, Søren Boesgaard specialised in the field of cardiology and became a registered cardiologist in 1998. Dr. Boesgaard works at Rigshospitalet and is Managing Chief Physician at the Clinic for Cardiac Disease.

Marianne Kjellow-Andersen
Manager, Service Delivery
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Marianne Kjellow-Andersen has a master's degree in Public Health from the University of Copenhagen. Since 2019, she has worked as a manager with Service Delivery of Integrated Health Solutions at Medtronic.

About the organisation

Located in Copenhagen, Denmark, **Rigshospitalet** is a university hospital highly specialised in treatment, research, development and education. The Cardiac Catheterisation Laboratory is one of the specialised departments at Rigshospitalet. The department performs 24 to 30 planned cardiac procedures a day, as well as a varying number of emergency procedures on patients with cardiovascular problems. The department is one of the largest in northern Europe in this field of specialisation and comprises nine operating rooms.

www.Rigshospitalet.dk


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Hungary

Markhot Ferenc Teaching Hospital: Measuring what's measurable to improve patient care and safety

Challenge

Most healthcare providers have significant amounts of information about their patients, yet they don't know the costs associated with caring for these patients. Today, hospital management needs to know exactly how much a treatment or a disease costs the hospital in order to effectively manage its budget.

Approach

There is a need for a new paradigm shift in healthcare where healthcare providers measure revenues and expenditures similar to profit-oriented businesses. With new technologies and standardised solutions, they can optimise their processes and make them cost-effective. With data recorded precisely at locations where patient treatments take place, hospitals can improve patient safety, reducing time spent on the administration of IT systems.

Case-level data management since 2019

5%
cost savings on medicines and medical device materials in the first year

Inventory of assets registered at locations throughout the entire hospital

Separating data collection from data entry saves time for caregivers to improve patient care

Throughout the 21st century, developments in the medical profession are advancing with the emergence of technologies like artificial intelligence (AI) and machine learning. Yet, in the fields of healthcare process control and management, there appears to be no unified paradigm shift among healthcare providers.

The collection and analysis of data related to the costs of patient-care processes are prerequisites for high-quality and cost-effective healthcare services. For this professional challenge, GS1 can provide an appropriate framework of standards—a mandatory foundation for the smart hospital.

Centuries of providing care

Founded in 1769 as the Eger Hospital of the Hospitaller Order, the Markhot Ferenc Teaching Hospital was named after Markhot Ferenc—a medical physicist who graduated from the University of Bologna and established the first Hungarian medical school in Eger on 25 November 1769.

Today, Markhot Ferenc Teaching Hospital is a leading healthcare provider in the region with a staff of 1,750. The hospital has 990 beds and offers the entire spectrum of medical services, except for cardiac and neurological surgery. In 2019, 10,600 patients were treated and cared for in the hospital.

Dr. József Vácity, Dr. Krisztina Orosz, Dr. Róbert Gyetvai

A clear view of costs

Most healthcare providers have significant amounts of information about their patients (e.g., medical history, diagnosis, investigations, medications), yet they don't know the costs associated with caring for these patients.

Today's hospitals need to take a new approach in providing care. They must measure revenues and expenditures in a similar way that profit-oriented businesses do in order to optimise their processes and increase their cost effectiveness.

In Hungary, in-patient care is financed according to homogeneous disease groups (HDG) based on the Diagnosis Related Groups (DRG) system developed in the United States. A diagnosis-related group is a patient classification system that standardises prospective payment to hospitals and encourages cost containment initiatives.

Using this approach, the hospital categorises patients based on their DRG-based homogeneous disease group, and the government pays for their care based on a set rate. However, in reality, every patient is unique and may need different resources for their treatment, even if the diagnosis (and DRG) is the same.

A major issue for Markhot Ferenc Teaching Hospital was that it couldn't be sure whether one disease was being over-financed while others were under-financed. To get a clear picture, the hospital decided to implement a case-level control system in 2019.

The hospital needed to implement the following tasks to achieve a complete accounting of costs:

- Change the organisational structure.
- Implement GS1 standards, identification keys and barcodes.
- Label the entire warehouse and departmental stock with GS1 barcodes.
- Build the data capture environment.
- Implement special paper based on GS1-barcoded lists of specific professional materials and unit-dose products to which barcodes cannot be added.
- Implement specialised software for data capture and data processing.
- Create an administrative "data entry" team.
- Integrate different healthcare systems and software (e.g., pharmaceutical and financial software).
- Train administrative staff.
- Train medical personnel.

Collecting revenues and costs by case

With the use of GS1 global standards, the hospital realised it had to make care processes more transparent and traceable. The goal was to determine the explicit revenues and costs based on valid data.

To achieve this goal, a case-level control system would be created. The management of the hospital recognised that it was appropriate to take a step-by-step approach to reach this goal.

Using a quote by Galileo Galilei, the key strategy for the solution was to: **"Measure what can be measured, and make measurable what cannot be measured."**

Detailed professional material and medicine administration

Since the costs of medicines and professional materials comprise the largest percentage of variable costs, the hospital started with the standardised identification and marking of pharmaceuticals and medical devices, to measure the use of these materials and record the use for each patient.

Using GS1 standards—the Global Trade Item Number® (GTIN®) and Global Service Relation Number (GSRN)—the hospital uniquely identified all pharmaceutical and medical devices used for each patient, not only in the departments but in the operating theatres, as well.

GS1 standards provided many new opportunities and possibilities for the hospital, its management, staff and even its patients.

One of the most important success factors of the project was the medical staff's engagement. Staff members are often afraid that introducing new technology means more administrative work. It's important not to burden the healthcare staff with further administrative tasks, since their primary job is to treat and care for patients.

"Our philosophy is that data are generated near the bedside where they should be collected, but data entry and processing must be separate from the actual patient care."

"That's why the hospital employs five colleagues called the 'barcode team,' who are responsible for entering data into the system. Based on their experience so far, one data entry colleague is needed for every 200 beds."

Dr. József Vácity MD
General Director
Markhot Ferenc Teaching Hospital

Regarding the administration of professional materials, the only task that the nursing staff members need to do is to put the packaging materials of every used professional material in a container. The container is marked with the name of the patient and is identified by a GSRN encoded in a GS1 DataMatrix barcode. Data entry is done by the barcode team by scanning the barcodes on containers and packaging materials once they have been collected.

Since implementing GS1 standards, the hospital has used standardised identification and scanned barcodes—not only for pharmaceuticals, medical devices and services, but also for transfusions, ordering antibiotics, diagnostics for the identification of patients and healthcare staff, and triage administration.

Markhot Ferenc Teaching Hospital's use of GS1 standards also supports EU regulations such as the Falsified Medicines Directive (FMD), Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). The hospital is taking advantage of the possibilities offered by GS1 standards and the benefits derived from them.

Location registered inventory

Before using GS1 standards, low-value and high-value assets were registered only at the organisational level; inventory picking was complicated, time-consuming and labour intensive for HR and, on several occasions, outcomes were inaccurate. It was imperative for the hospital to revise these practices.

To address this issue, every room of every department was labelled with a GS1 Global Location Number (GLN), which uniquely identifies the physical location and generated in accordance with GS1 guidelines.

In addition, every asset in inventory was uniquely identified with a GS1 Global Individual Asset Identifier (GIAI). Now, each of these assets can be followed throughout its life cycle.

The hospital purchased a laser-engraving machine so that all surgical instruments used in the operating theatre can now have its GIAI encoded in a DataMatrix barcode, engraved on the instruments by the summer of 2020. With the IT system, the medical devices will be properly assigned to operations, resulting in better patient safety. Each instrument in the operating theatre can be tracked throughout its life cycle and any failure can also be monitored.

In the future, the cost of repairing tangible assets – including medical devices – can now be linked to the physical instrument.

Case-level control system

Since 2019, the case-level control system has been operating in the hospital. The main tasks include the division of human costs (e.g., salaries, fees of suppliers) and the introduction of the utilisation of medicines and professional materials (e.g., data collection of expenditures) for the entire hospital.

Successful case-level control has six factors:

- Commitment of senior management
- Allocation of HR expenses (e.g., Fixed income of a surgeon is allocated: 70% surgery inpatient care, 20% outpatient care and 10% vascular surgery inpatient care. Flexible income (duty) is allocated: 50% general surgery and 50% vascular surgery.)
- Itemised data collection of expenditures of medicines and professional materials
- Effective IT system
- Professional advisors like GS1 and controllers
- Committed colleagues

Measurable results

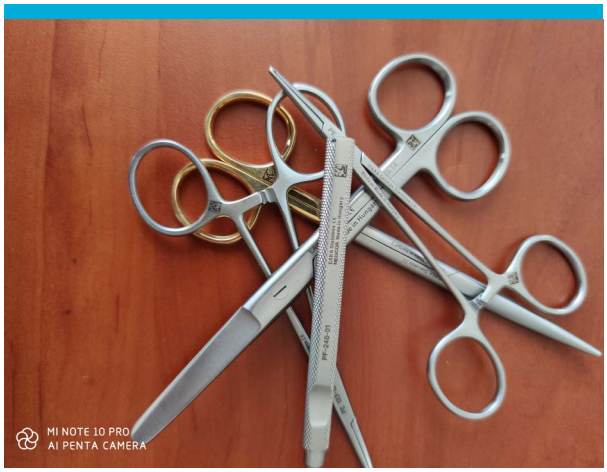
In 2017, Markhot Ferenc Teaching Hospital began the implementation of GS1 standards. The required information technology system was provided of bcMecial.

Tasks performed (in chronological order) included:

- In-patient case-level data entry of medicines and professional materials – September 2017
- Case-level data entry of transfusion data – January 2018
- Case-level data entry of surgical medicines and materials – March 2018
- Triage date entry – May 2019
- Individual identification of rooms with GLNs – July 2019
- Individual identification of tangible assets, room-level inventory with GIAIs – August 2019
- Individual identification with GIAIs via laser engraving of medical devices – October 2019 –August 2020
- Patient identification with GSRNs and wristband printing, and UHF-based RFID (radio frequency identification) patient identification – December 2019 – July 2020
    - The RFID antenna gates – December 2019
    - Wristband printing –March 2020
    - Patient tracking software –July 2020
- Notification process of antibiotics therapy – February 2020

Today, the hospital is experiencing numerous benefits, including:

- In the first year of using GS1 standards, the hospital achieved 5% cost savings on medicines and medical devices, due to improved inventory management.
- During the past two years, the hospital has been using controlling data at an organisational level.
- Since Q1 2019, the hospital has been using controlling data at the case level with certification by the case-level control system.
- By separating data collection from data entry, the hospital has reduced the administrative burden of medical staff to improve patient care and safety.
- For the 1,000 bed hospital, the five data entry colleagues need only 2.5 minutes per patient per staff to enter the daily use of pharmaceuticals and medical devices.
- Daily data of the pharmaceuticals and medical devices used for every patient are now available, enabling the administration of patient-specific device usage.
- As an additional advantage, medication administration is now better controlled, based on the accurate and reliable identification of medications and patients.
- With a unique GS1 identifier, each inventory item can be tracked throughout its life cycle.
- Location registration information is available for both low-value and high-value assets, for faster and accurate location activities.
- The hospital can readily address EU regulations (e.g., MDR) since it implemented a global GS1 standards-based system.
- Due to GS1 standards, the hospital has improved performance, order, discipline and patient safety. In addition, patient satisfaction has significantly increased, and medical staff are fully engaged with the new system.



Components of costs	HUF	EUR (330 Ft/EUR)
Medicine	5 970 Ft	18,09 €
Blood, blood products	1 567 Ft	4,75 €
Single use medical materials	2 586 Ft	7,84 €
Other special materials	90 Ft	0,27 €
Disinfectants	293 Ft	0,89 €
Total costs of medical items	**10 506 Ft**	**31,84 €**
Single use textiles	267 Ft	0,81 €
Costs of other items	**267 Ft**	**0,81 €**
Medicine, anaesthesia	1 027 Ft	3,11 €
Medicine, operating room (OR)	193 Ft	0,58 €
Implanted materials, OR	22 935 Ft	69,50 €
Single use materials, anaesthesia	10 343 Ft	31,34 €
Other special materials, OR	70 Ft	0,21 €
Costs of materials used in OR	**34 568 Ft**	**104,75 €**
VAT (value added tax)	**3 127 Ft**	**9,48 €**
Direct cost	**48 468 Ft**	**146,87 €**

Components of costs	amount	unit	cost/unit	HUF	EUR (330 Ft/EUR)
Doctors' salary, Traumatology	15,40 Ft	working hour	6 948,40 Ft	107 005 Ft	324,26 €
Nurses' salary, Traumatology	6,90 Ft	nursing day	9 868,30 Ft	68 091 Ft	206,34 €
Additional costs of patient care	6,90 Ft	nursing day	3 123,70 Ft	21 554 Ft	65,31 €
Mediacal ward's direct costs				**196 650 Ft**	**595,91 €**
Anaesthesiology	120,20 Ft	minute	410,60 Ft	49 354 Ft	149,56 €
Central OR	120,20 Ft	minute	580,30 Ft	69 752 Ft	211,37 €
Other materials, OR	1,00 Ft	case	330,00 Ft	330 Ft	1,00 €
Operation related costs				**119 436 Ft**	**361,93 €**
Diagnostics, laboratory	764,30 Ft	point	1,20 Ft	917 Ft	2,78 €
Diagnostics, radiology (US, CX, CT)	1 479,00 Ft	point	2,90 Ft	4 289 Ft	13,00 €
Diagnostics, pathology	54,10 Ft	point	1,40 Ft	76 Ft	0,23 €
Physiotherapy	5 388,00 Ft	point	0,40 Ft	2 155 Ft	6,53 €
Total costs of diagnostics				**7 437 Ft**	**22,54 €**
Consultation, traumatology	24,70 Ft	point	5,00 Ft	124 Ft	0,37 €
Consultation, ophtalmology	26,60 Ft	point	1,30 Ft	35 Ft	0,10 €
Consultation, anaesthesiology	998,80 Ft	point	1,10 Ft	1 099 Ft	3,33 €
Consultation, infectology	15,00 Ft	point	2,90 Ft	44 Ft	0,13 €
Consultation, musculosceletal rehabilitation	12,10 Ft	point	1,80 Ft	22 Ft	0,07 €
Consultation, neurosurgery	4,00 Ft	point	10,40 Ft	42 Ft	0,13 €
Consultation, dermatology	6,40 Ft	point	3,00 Ft	19 Ft	0,06 €
Total costs of consultations				**1 383 Ft**	**4,19 €**
Costs of the food and nutrition	6,30 Ft	nutrition day	1 426,80 Ft	**8 989 Ft**	**27,24 €**
Indirect costs				**333 895 Ft**	**1 011,80 €**

Figure 1: Shows cost data associated with Disease Related Groups (DRG) leg operations, collected by the Traumatology department between January and June 2019. Over the six months, there were 88 patients/cases spending 474 days in the hospital. The operations generated a total revenue of HUF 37.597 million (€113.930) Implementing GS1 standards, which made case-level control possible, helped the hospital precisely identify the costs associated with each of the 88 cases.

Data were further analysed and the average of all cases was calculated. The results showed that the average cost per case is HUF 44.145 or approximately €132. The hospital then checked how the expenses of the individual cases differed from the average.

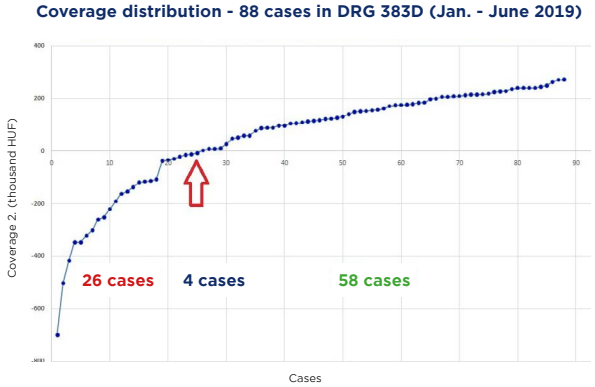


Figure 2: In 34% (26) of the cases, the costs of the operations were lower than average, while in 66% (58) of the cases the revenue of the operations covered the costs. All of this information offers very important input for improving the management of the hospital and making better decisions—all for more effective hospital processes.

Average cost per case is HUF 44.145 or approximately €132

Next steps: patient and staff identification

Markhot Ferenc Teaching Hospital's new project is UHF RFID-based patient and staff location identification. By analysing the measured results of patient journeys and the movement of staff within the hospital, processes and space can be optimised for time savings. This will ultimately help the hospital improve patient safety and efficiency in the workplace.

- Every in-patient wears a UHF RFID-based identification wristband. Based on the detection of data provided by 56 antennas in the hospital, it can always identify the location of each patient. Each staff member also wears a UHF RFID-based badge so that the hospital can identify the exact location of each person. In both cases, the GS1 identification keys will be applied—the GSRN for patient and staff identification and the Global Location Number (GLN) for location identification.
- Another short-term project is the creation of a room maintenance and repair worksheet system. This will include the identification via GS1 standards of notifiers, rooms, faulty instruments and repairmen as well as recording the duration of repair—all done by scanning GS1 DataMatrix barcodes. With precise data provided, the maintenance process can be analysed and verified, and as a result, the quality of work is expected to improve.
- Verification of hand disinfecting is also planned. With a networked RFID reader by each hand disinfectant dispenser identified with the GS1 GIAI, staff members can identify themselves—via GSRNs encoded in barcodes on their name badges—prior to washing their hands. This solution will also help to track the hand disinfection of staff members.

Taking a measured approach

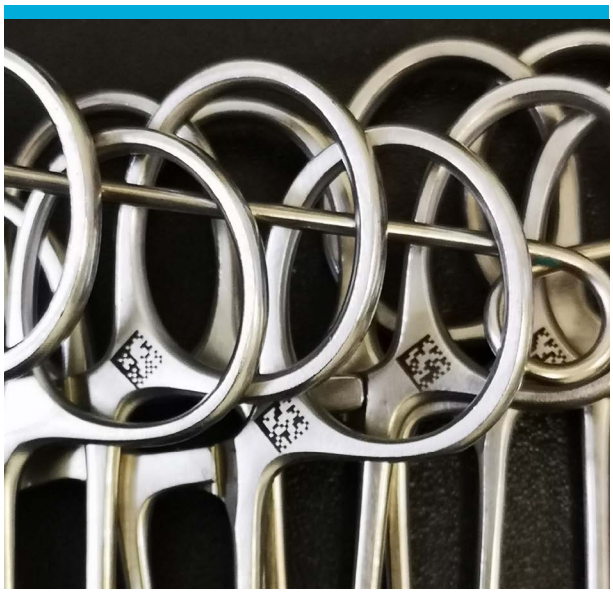
The hospital has implemented GS1 standards, step-by-step. It started with a small project that paid for itself within one year.

Key factors for success include:

- Change the organisational structure.
- Set clear goals. Gain commitment from hospital leadership.
- To motivate teams, involve those impacted by the changes.
- Include pilots as part of the implementation to test the concept and technical feasibility.
- Integrate IT systems into the total solution.
- Get support from GS1—the experts when it comes to standards.

"GS1 Hungary supported us during the whole implementation and development phase. We remain closely connected to them and keep in touch. We really appreciate their help."

Dr. Krisztina Orosz
Strategic Director, Hospital Pharmacy
Markhot Ferenc Teaching Hospital



About the authors

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General Director
Markhot Ferenc Teaching Hospital of Eger

Dr. József Vácity graduated in 1984 as a General Practitioner, obtained Pediatrics Specialist Certification in 1988, ENT Specialist Certification in 2001 and his Healthcare Manager degree in 2014. He started his medical career in the Hospital of Baja. From 1993 to 2006, he practiced as a full-time private doctor. Dr. Vácity worked as Controlling and Financial Manager at the Hospital of Baja from 2009 to 2011. He was the General Director of the Hospital of Nagyatád from 2011 to 2016, and since then, he has been the General Director of the Markhot Ferenc Teaching Hospital of Eger. Special courses include Hal Krause, Bulletproof Manager, Manager with Catholic Values degree at the University of Kaposvár; Franklin Covey, The 7 habits of Highly Effective People and the 7 Habits Leader Implementation; Franklin Covey coach.

Dr. Krisztina Orosz PharmD
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Dr. Krisztina Orosz graduated as a pharmacist at the University of Szeged in 1996. She obtained a Healthcare Economist and Manager degree in 1999, and completed Medicine Technology Specialist Certification in 2001 and Clinical Pharmacy Specialist Certification in 2019. Dr. Orosz worked as an intern at the University of Szeged from 1996 to 1998. She was a Product Line Manager then Sales Manager at Alcon Pharma Division from 1999 to 2012. She has been with the Markhot Ferenc Teaching Hospital of Eger since 2012, and as Hospital Pharmacy Director since 2015. She was Deputy Medical Director between 2018 and 2019. Since 2019 she has been Strategic Director. She has participated in several clinical research programs and trials. Special training programs and courses: GMP, GCP in 2018; Hal Krause, Bulletproof Manager in 2019; Franklin Covey, The 7 habits of highly Effective People and the 7 Habits Leader Implementation; Franklin Covey coach in 2020; GS1 expert.

Dr. Robert Gyetvai MD
Head of the Department of Anaesthesiology and Intensive Therapy
Markhot Ferenc Teaching Hospital of Eger

Dr. Robert Gyetvai MD, DEAA is a consultant anaesthetist and currently the Head of the Department of Anaesthesiology and Intensive Therapy in Eger, Hungary. He is a Diplomate of the European naesthesiology Academy. Dr. Gyetvai has gained extensive experience while working in one of UK's National Health System's hospitals in 2008, during which he used in his practice upon returning to Hungary. With an interested in his own speciality, Dr. Gyetvai is focused on how to achieve high standards in the processes of patient care.

About the organisation

Markhot Ferenc Teaching Hospital was founded in 1769 as the Eger Hospital of the Hospitaller Order. The hospital was named after Markhot Ferenc—a medical physicist who graduated from the University of Bologna and established the first Hungarian medical school in Eger. Today, the 990 bedded hospital is the leading healthcare provider in the region with a staff of 1.750 providing comprehensive medical services, except cardiac and neurological surgery. In 2019, 10,600 in-patients were treated and cared for in the hospital.

www.mfkh.hu

Ireland

Scan4Safety: Giving time back to patient care at Dublin's Tallaght University Hospital

Challenge

Clinical staff at Tallaght University Hospital (TUH) were spending a large proportion of their time per week managing inventory. They found that they had little visibility into what item was used and with what patient. Also, the tracking of stock levels and expiry dates was difficult. This posed a significant risk to patient safety. In the two theatres where Scan4Safety had been initially implemented, the Clinical Nursing Manager was spending more than a day per week on re-ordering and managing stock. This was taking valuable clinical time away from patient care.

Approach

While this reflects processes in many other hospitals in Ireland, the TUH team looked to address these issues by implementing barcode scanning in theatres, with the aim of improving patient safety and giving time back to patient care. This is made possible by making it easier for nursing staff to re-order products as they have greater visibility on stock levels and expiry dates. With the successful roll out of Scan4Safety across many sites in the UK, and in St. James's Hospital, Dublin, the team at TUH had many sites to reference for best practices. Added to this, with the introduction of Unique Device Identification (UDI) regulations across the world, most medical devices now have unique device identifiers—the Global Trade Item Number® (GTIN®), lot number, expiry date and sometimes serial number—enabling a simple scan at the point of care.

Full visibility of what products were used for which patients in operating theatres

Increased patient safety via alerts if products have expired when scanned

1

working day saved per week to redeploy on patient care

Leaner inventory processes through automatic reordering

Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

Built in 1998, Tallaght University Hospital opened serving a community of approximately 62,000 people. Just over 20 years later, this has increased 10-fold with the hospital now serving a population of more than 640,000 people.

TUH has planned a series of developments to continue to provide quality service to patients, with patient safety always being its top priority.

At the forefront of change is the "Scan4Safety" project within the theatres, part of a new digital strategy in the hospital with the objective of improved patient safety, with the added benefits of giving time back to patient care and increased operational efficiencies.

The project was initiated by the Finance Directorate and moved quickly to a collaboration model between the areas of clinical (Theatre), Quality, Safety and Risk Management (QSRM), and non-clinical (Finance and Logistics). Genesis Automation is the solution provider that is providing the software to implement the Scan4Safety programme.
All products used in the theatres are scanned to the patient record prior to use, which is safer as the device can then be tracked to each individual patient in the event of a recall. This can also prevent the issuing of expired or recalled stock. This is enabled by modern standards-based track and trace technology to scan manufacturers' barcodes on medical products used during procedures.

Olivia Leigh & John Donovan

By implementing product barcode scanning in the theatre, TUH aims to:

- Return time to clinical staff to focus on patient care since the re-order process is very manual and time consuming.
- Achieve traceability, which in turn improves patient safety.
- Implement a system that is very easy to use and does not create duplication of effort.
- Provide automatic reordering and stock replenishment.
- Increase quality of data and reporting methods, which will allow more in-depth business intelligence.
- Link patient-level costing with patient activity to ensure the hospital receives the appropriate level of funding—not just for activity levels, but also for complexity of care.

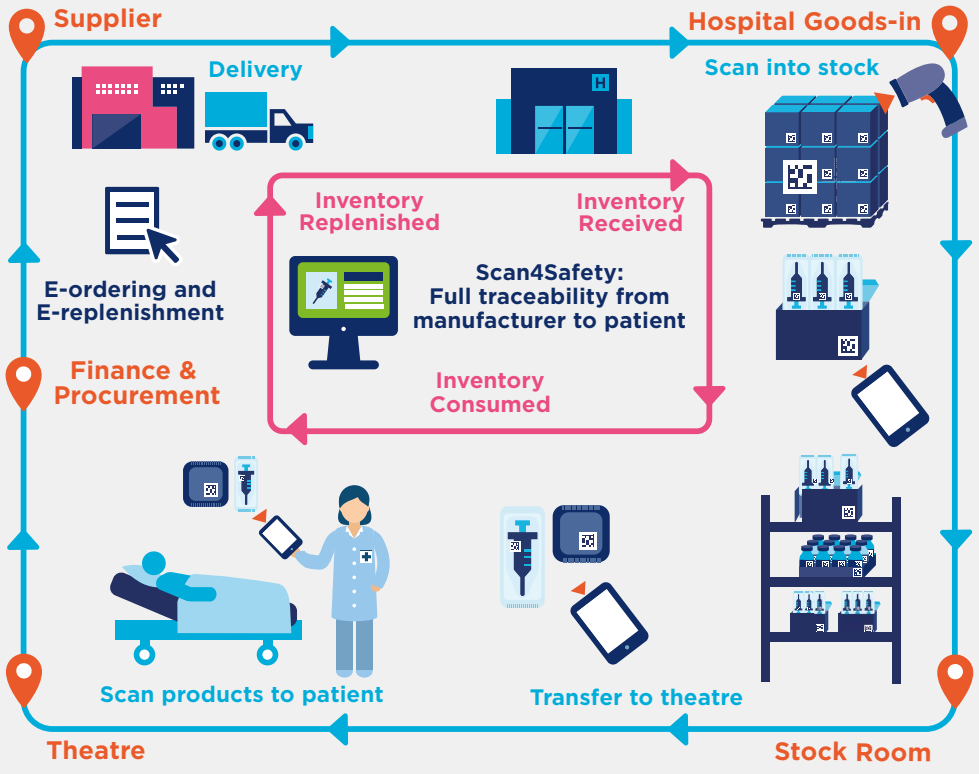
"Scan4Safety is a key priority for Tallaght University Hospital. The success of the project has been driven by the strong collaboration across clinical and non-clinical areas. Scan4Safety is demonstrating real benefits by improving patient safety and giving time back to patient care."

Lucy Nugent
CEO
Tallaght University Hospital

"Scan 4 Safety will change how the Hospital manages its stocks. End to End automation of the supply chain will deliver efficiencies, and real time data. This will help TUH to reduce waste, improve our working capital, and make optimal use of our clinical resource."

Dermot Carter
Director of Finance
Tallaght University Hospital

The new Scan4Safety process at TUH



Methodology

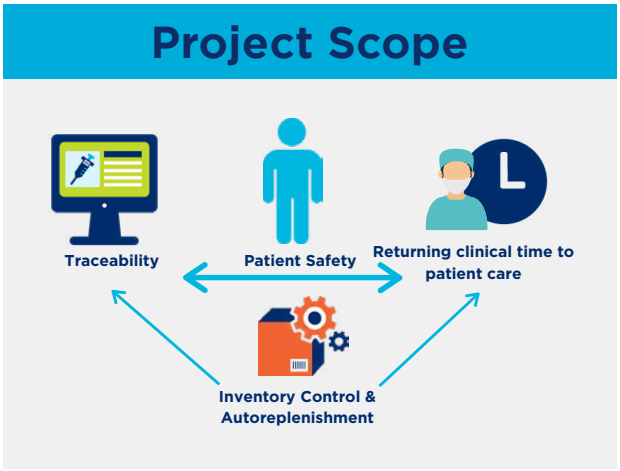
A phased approach

The hospital is implementing its Scan4Safety programme, taking a phased approach. They successfully went live in two theatres in General Surgery in October 2019. Throughout 2020, TUH is continuing to expand across other theatres, including the Cath Lab (which went live on the 6th of July 2020). These additional theatres will involve emergency procedures, which may add a level of complexity to the process.

An important part of the process is that products are scanned just before they are used in theatre. This enhances patient safety by allowing for active recall management, which would not be possible if scanning was to take place after the operation.

All products in theatre are scanned and linked to the patient for each procedure.

Ultimately, this data will be populated in the clinical electronic patient record (EPR) when it is rolled out for the hospital (project underway currently). The roll-out of the auto replenishment of stock is limited to high value "nonstock" items at present. When one of these products is scanned in theatre, a replacement is ordered automatically from the warehouse so that the hospital does not run out. Additional controls help ensure that products do not go out-of-date. Consumable inventories are managed using a Kanban process, from the warehouse to the storeroom.



Building the team

Prior to implementation, the team set out to learn from other healthcare providers who had already implemented scanning in theatre. They looked at guidance from successful Scan4Safety implementations across the UK. The successes of these implementations, as well as the Scan4Surgery project in St. James's Hospital in Dublin, helped them to build their business case.

A major learning from Scan4Safety in the UK was the importance of creating a multidisciplinary team with a focus on clinical leadership, and the value of someone from Finance spending time in theatre. The team at Tallaght recognised the importance of clinical endorsement. The leadership and involvement of the Clinical Director and Clinical Nurse Manager has been instrumental in the implementation of the programme.

It was important that team members in Finance and Logistics spend time in theatre, and whilst they were restricted in terms of resources, the assignment of a dedicated Scan4Safety officer in theatre proved to be key in its success. TUH has also dedicated a Scan4Safety manager to provide oversight on the project.

L to R:
Roshan Wijesinghe, Senior ICT Project Manager; **John Donovan,** Scan4safety & Purchasing Manager; **Cait Tobin,** Theatre Nurse Manager; **David Addie,** Deputy Director of Finance; **Cathy Elworthy,** SAP Support; **Karl Doran,** Scan4Safety Officer; **Olivia Leigh,** CNM2 General/Vascular Theatre; **Conor Kenna,** SAP Support; **Ger Connolly,** Scan4Safety Supplies Officer

Data management

Getting started

The hospital was required to undertake a large piece of work in order to create a master data file that links the existing data from its ERP system and SAP to the barcode information, e.g., GTIN and units of measure.

As the system is utilising an auto replenishment feature that links to SAP, it was critical that units of measure and hierarchies were accurate, not only for this feature, but also for wider inventory management and information quality. Data quality and the maintenance of master data are key components to the ongoing success of any scanning system, and members of the Scan4Safety team at TUH have been actively managing this.

The hospital worked with the team at Genesis Automation to clean the master data. Initially the hospital used Microsoft Excel to register the barcodes to the products. However, now that TUH has the Genesis system in place, it has the functionality to do this, and makes it much easier for the team to maintain existing data and handle new product onboarding. For products with no barcode, the hospital maintains a separate sheet of barcodes, which are scanned in theatre as products are used and a default lot and expiry date barcode is also scanned. **The hospital would prefer if all products had one barcode with GTIN, batch and expiry date information**.

Interoperability

The project team recognised the value of having quality data, and the importance of maintaining this for the ease of use of the system. The project manager stated, “It should be as simple as scan, scan, scan!”

The link between their SAP financial management system and the Genesis scanning system is a vital component. Master data is housed in SAP and feeds in and out of the Genesis system for the ordering process. Interoperability between systems is enabled through the scan of the UDI barcode on the product packaging. Due to UDI regulations most medical devices now have unique device and production identifiers encoded in GS1 compliant barcodes.

The process

The Genesis system consists of multiple modules that manage the process—from receipt of goods to use of products in theatre for a patient. There is a barcode manager module for adding and changing GTINs and linking them to SAP codes. The inventory management module has various stock management functions. The point of care module allows for the linking of products, processes, consultants, procedures and patients. And, there is a reporting screen that produces reports on various efficiencies. The hospital procured necessary hardware such as handheld scanners and PCs on which to install the new scanning system. The system runs on both the Windows and Android operating systems.

To date, the success of the project has been driven by the excellent engagement between the clinical and non-clinical teams. The key stakeholders have been the Perioperative Clinical Director and Clinical Nurse Manager (CNM), and representatives from Finance, SAP, Supply Chain & ICT. The CNM has been heavily involved and gives briefings to the Nursing staff so that everyone is trained on the process. There has also been a focus on having a solution that is very easy to use and where there is no duplication of work. Once products are received into the storeroom, each item is tracked directly to consumption in theatre.

Figure 1a: Store room before Scan4Safety implementation

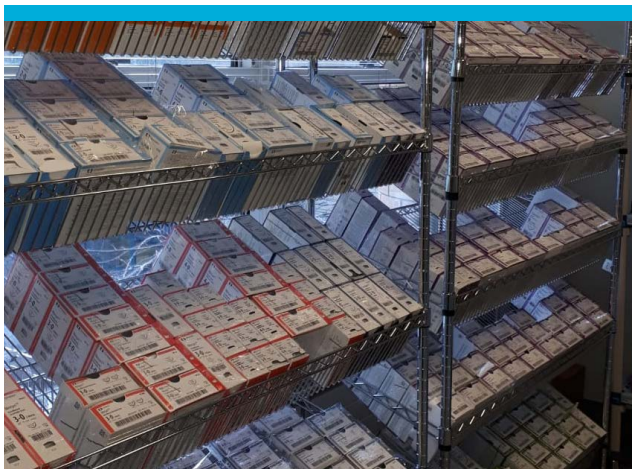


Figure 1b: Store room after Scan4Safety implementation

"This is such a dream. I don't need to worry again. We have the products ready for when the consultant arrives. It is safer for patients, and it gives me more time for patient care."

Olivia Leigh
Clinical Nursing Manager (CNM2)
Tallaght University Hospital

Goods in and out

All goods are checked in by the stores team. All Scan4Safety items are sent up to theatre for receipting. Receipting is carried out on a Zebra scanner using the Genesis software. Receipting involves capturing the items relevant to the purchase order, and importantly, the lot, expiry date and serial numbers.

General surgery storeroom

All goods are received into the store area by entering the PO number and scanning the GTIN encoded in the product barcode as well as batch and expiry date information (sometimes this can be in a second barcode). If all this information is encoded in one barcode, it is much easier to receive since it requires just one scan. Each product is received and tracked on the system, using batch and expiry dates. If a product is expired, the system will alert the hospital at any time the product is scanned prior to use.

Call to action for suppliers

All products must have GS1 unique identifiers encoded in GS1 barcodes. The best barcodes are GS1 compliant barcodes, preferably a 2D GS1 DataMatrix barcode as all the information is easily captured in one scan!

The need for dynamic data encoded in GS1 barcodes

GTIN (01)05391234560015
Expiry Date (17) 151231
Batch (10) 987654321ABCD
Serial Number (21) ABCD1234

GTIN with Batch, Expiry Date and Serial Number encoded in a GS1 DataMatrix

Theatre scanning

Each product that will be used is scanned in the theatre preparation room. Products that are in reserve are left unopened under the trolley, and they are only scanned if they are opened and used. This allows a tighter control of stock usage by the theatre staff. Each time a product is scanned in theatre it triggers an adjustment in the stock levels and, once stock hits a preset minimum level, a replenishment order will be sent from the Genesis system to SAP. The order is then emailed to the supplier.

"When a product is scanned to the patient, a replacement is ordered automatically, which means we do not run out of products and products do not go out-of-date."

John Donovan
Purchasing and Scan4Safety Manager
Tallaght University Hospital

Outcomes and benefits

Increased patient safety through batch-level traceability

The primary aim of the Scan4Safety programme at TUH is to increase patient safety through standards-based traceability. Prior to the implementation of Scan4Safety, there was little to no visibility of what products were in stock and what products were used, with which patient. Now, the hospital has full visibility of what product (including batch traceability) went to which patient in the theatres where Scan4Safety has been rolled out. If a product is expired, the system will alert them at the time the product is scanned prior to use on the patient.

Returning time to clinicians for patient care

Patient safety is also improved by returning time to clinical staff for patient care. Previously, the management of the inventory was managed by the Nursing department with support from supply chain. Through the implementation of Scan4Safety in two theatres, the hospital estimates that one working day per week has been returned to the Clinical Nursing Manager.

This is recognised not only as a time saving, but an increase in the overall quality of care. As this is rolled out across more theatres, TUH is expecting that more clinical time will be released to concentrate on patient care.

Operational efficiencies

As the implementation of Scan4Safety continues across more theatres, the team at TUH recognises the value of operational efficiencies, financial reporting accuracies and business intelligence capabilities. The hospital plans to realise these as the roll out continues.

Such benefits include:

- Automatic stock replenishment
- Reduction in wastage
- Space optimisation
- Streamlining and control around the new product introduction process

Education and hospital-wide approach

As Scan4Safety is being rolled out in TUH, the concept of scanning in theatre and the terminology "Scan4Safety" is becoming the "normal way of working." This is further evident as a Scan4Safety module has been built into the nursing induction programme. Communication and staff involvement have proved key to the success of Scan4Safety. The team regularly run breakfast education sessions for theatre staff and there is an open invitation to all involved.

As a result, there is high staff engagement throughout the hospital with many staff taking the initiative to share their learnings. For example, when scanning in theatre began, a nurse produced a phone video of the process to share with colleagues.

Collaboration

New inter-departmental relationships have been developed as a result of the Scan4Safety implementation. The strengthened links between finance, supply chain and clinical personnel have proven very beneficial with significant knowledge gained and shared. Members of the project team have stated that it "should have happened years ago," now that they see the profound benefits of having the ability to analyse data and report on stock usage.

Challenges

1. **The need for 2D barcodes**
An integral part of the process is the receipt of product into the theatre storerooms, by entering the PO number and scanning the GTIN in the product barcode, including batch and expiry date. The hospital's preference is to have this information in one barcode, which makes the scanning of products in theatre simpler and quicker for clinical staff. Some products don't have a barcode or GTIN. In these cases, the team has created a look-up folder where it has a picture of the product combined with the internal code for the product in a 2D barcode. When the product is used, the barcode in the folder is scanned and linked to a "default" batch and expiry date. The hospital doesn't want to add any extra work for the clinical staff so this is seen as the best compromise. **The preference is for suppliers to provide scannable GS1 barcodes, preferably in 2D format with a GTIN, batch number and expiry date.**

2. **Resources**
The biggest challenge was executing the project, using existing resources. One of the project's key successes, to date, has been the strong clinical leadership. The nursing staff have been actively involved in adopting Scan4Safety. The hospital found that there was a high level of digital maturity among staff, which meant that they appreciated the benefits of implementing scanning in theatre.

3. **Knowledge**
The hospital understood the importance of using GS1 standards for traceability and as a foundation for its wider digital strategy. TUH engaged with GS1 Ireland at an early stage in the implementation process. This started with GS1 training warehouse staff for inventory management and location management. This enabled them to better engage with suppliers and confirm that products entering the warehouse were identified, using GS1 standards-based identification. As a result of these learnings, TUH has specified in tender documents that products need to be identified using GS1 standards. This requirement is further supported by the fact that the implementation of UDI across Europe means that most products will use compliant identification methods.

4 Software and interoperability
TUH recognised the importance of choosing a software provider that was GS1 compliant and could integrate with legacy systems across the hospital as well as patient information systems.

Following engagement with many providers, they carried out a pilot with Genesis Automation, a GS1-certified solution provider that resulted in the implementation of the Genesis solution in the hospital to be rolled out for its Scan4Safety programme.

Next steps

Following the success of the go-live in two General Surgery theatres, the TUH team will continue to expand implementation of Scan4Safety into other theatres in 2020, including both general and specialised surgical areas, and the Cath Lab (which went live on the 6th of July 2020). The campus is expanding and the new implementations—dedicated day surgery for elective procedures—brings opportunity to build in traceability from the start, and possibly look at the transition to fully sterile implants.

For example, some theatres in orthopaedics have proprietary scanning solutions for a couple of individual suppliers. This is not a sustainable solution as it means the theatre has to manage multiple proprietary scanning solutions. It has been proven that scanning at the point of care needs to be simple and supplier agnostic. There is also a national joints registry (hips and knees) being set up for clinical audit purposes, and the hospital would like to be able to share a file for the audit from its scanning system. Added to this, the hospital is in discussion with other hospitals to look at a joint approach to managing their product catalogues.

TUH estimates that the Scan4Safety solution has reduced €7,000 worth of stock waste in the first phase.

Conclusion

While the focus is on patient safety, TUH has experienced a number of operational efficiencies. Previously, there was a significant amount of waste with sutures. Since they were all ordered under a "bucket code," there was very little visibility on stock levels and usage related to sizing.

Now, because the hospital has this data, it can return surplus stock to suppliers when needed. TUH estimates that the Scan4Safety solution has reduced €7,000 worth of stock waste in the first phase.

The hospital recognises the importance of GS1 standards for the identification at all possible sources, including not only product and batch traceability, but also the identification of patients, staff, locations and assets. The TUH team will continue to work with GS1 Ireland for guidance on best practices during its further implementation of Scan4Safety.

"This is a new digital strategy which has improved patient safety, increased operational efficiencies and reduced costs. All products used in the theatres are scanned to the patient. If needed all products can be traced electronically to the specific patient episode."

David Addie
Deputy Director of Finance
Tallaght University Hospital

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Olivia Leigh is currently Clinical Nursing Manager (CNM2) in the General and Vascular theatres in Tallaght University Hospital since 2013. Olivia qualified as RGN in 1996 from Beaumont Hospital in Dublin and Post Graduate Diploma Specialist Nursing (Perioperative) Trinity College Dublin in 2005. She has worked in both operating theatres and wards in Guernsey, Saudi Arabia, Meath and Beacon Hospitals. She is passionate about safe surgery.

John Donovan
Purchasing and Scan4Safety Manager
Tallaght University Hospital

John Donovan is an accomplished Supply Chain & purchasing Finance Manager with 34 years of diverse experience gained in the Irish healthcare industry. A track record of managing complex, high scale projects on time and within budget in the purchase and materials management area. He has over two decades experience at Tallaght University Hospital. During this time John has worked in numerous management roles within Supply Chain, Purchasing and Finance. He has gained huge experience across multiple roles and is now one of the most senior and experienced managers within the Finance directorate.

About the organisation

Tallaght University Hospital provides access for patients to over 20 medical and surgical specialities, with comprehensive on-site Laboratory and Radiology support services. Currently, there are 495 adult beds and 67 paediatric beds, 12 theatres and 14 critical care beds in operation. The hospital has in excess of 420,000 patient attendances a year and has one of the busiest Emergency Departments nationally with a catchment population of approximately 640,000 people (80% of which are located in South Dublin and parts of Kildare). It serves approximately 200 General Practitioners in surrounding communities. In addition, Mental Health services operate an on-site inpatient unit under HSE governance structures, with close operational alignment to Tallaght adult services. The campus is 31 acres in size, with significant future development capacity. Tallaght University Hospital has a diverse and experienced team of staff, employing over 3,000 people from over 40 different countries across the world.

www.tuh.ie

Japan

Successful implementation of electronic health record system for traceability of medical materials

Challenge

Most medical devices in Japan have a GS1 barcode on their packages. However, due to the lack of functionality in electronic health record (EHR) systems to effectively use barcodes, medical staff in hospitals often face difficulties when identifying products used for surgeries, and it takes time to calculate the fee-for-service claim. The National Center for Global Health and Medicine (NCGM) faced the same situation.

Approach

NCGM organised a team with members from medical device suppliers, solution providers, many departments in the hospital and GS1 Japan. The team has modified the hospital's EHR system and other related IT systems to provide an easy-to-use system that can process all data in a GS1 barcode.

Improved, user-friendly EHR system suitable to process all data in a GS1 barcode

340

hours per year saved when registering medical devices used in surgeries

Achieved in-hospital traceability of medical devices

70%

less time spent when processing reimbursements of catheters

NCGM

Dr. Kengo Miyo, Chief Medical Informatics Officer at NCGM, led a team to implement the traceability of medical devices throughout the hospital, where comprehensive data is captured about the history of each device's use. This included the department in which each medical device was stored after purchase, the patient operation during which it was used, when and what type of surgery was performed, and other medical devices that were used in the same operation.

Kengo Miyo

Barcodes and EHRs

In Japan, GS1 barcodes have been used in the healthcare industry for decades, specifically by medical device and pharmaceutical companies. Today, most product packages are labelled with GS1 barcodes that are consistently scanned as these packages travel throughout the supply chain. If a medical device is found to be defective, a recall can be easily and quickly performed in the supply chain—from manufacturers to wholesalers and then at hospitals.

Yet, for tracking and tracing the use of medical devices, Dr. Miyo thought NCGM needed higher level traceability. He wanted access to information about the life cycle of each medical device.

To establish such a traceability system, the NCGM team decided that capturing and processing medical device data encoded in barcodes or by RFID tags (Radio Frequency Identification tags) would be one of the most effective ways. However, there were several obstacles.

One of the biggest problems is using barcodes with EHRs. More than 80% of hospitals with over 400 beds in Japan use EHRs. Yet, by scanning GS1 barcodes, EHR systems do not typically have the ability to record lot numbers or serial numbers, even if these data are encoded in the barcodes.

Also, the commonly used procedure of scanning barcodes into EHRs is cumbersome due to the complicated process of manually inputting the patient name, patient status, procedures and more into the EHR before using barcodes to automatically input product data into EHRs. This makes it difficult to use barcodes since these additional manual processes interrupt the flow of care.

Furthermore, current EHR systems are comprised of multiple and various other IT systems in a hospital. Systems related to medical devices, for instance, include procedural ordering, surgical ordering, surgical, medical accountability, logistics management and more.

Each of these systems holds master data about individual products—information like product name, local code, quantities and cost of the product, to name a few. Many of these master databases are manually maintained and often do not match each other. At NCGM, there were five master data systems in place that were not synchronised.

Flow of information and EHRs

Order processing with the EHR system was a complex bottleneck that did not support the optimal use of barcodes.

First, a doctor created an order in a patient's EHR (e.g., prescription, examination, procedure), and then medical treatment information was added to the order by other doctors and nurses caring for the patient. All treatments were processed as a fee-for-service claim at the Medical Affairs division.

Information could also be added to the EHR by scanning the barcode of any medical device used in a surgical operation.

To do this, a caregiver had to first find the doctor's order, review the order to check the content, set up a screen to register the device, activate the barcode reading function, and then scan the barcode to read and register the data.

The medical staff had to manually record the lot number and expiration date of the medical device (even though the GS1 barcode contained this data) since most EHR systems sold in Japan lack this functionality.

Dr. Miyo established a task force to improve the process. This team decided to modify the process to scan the medical devices' barcodes

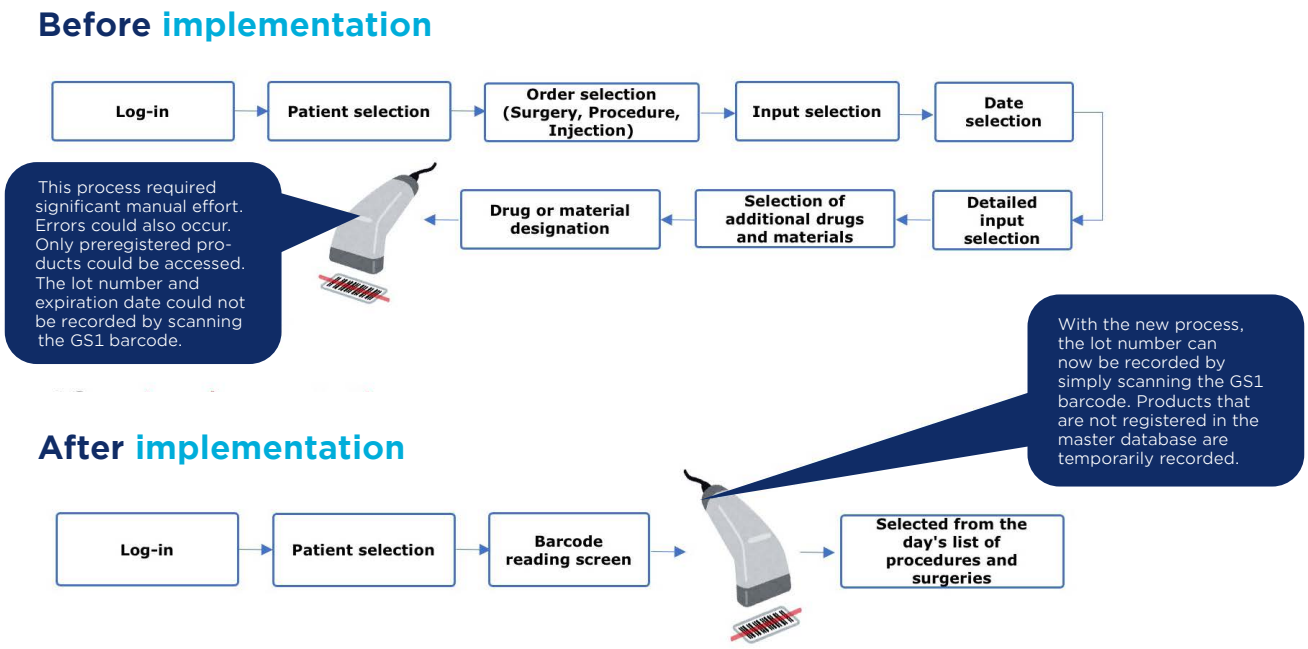
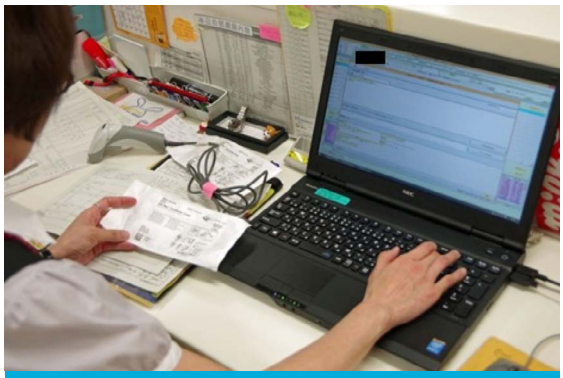


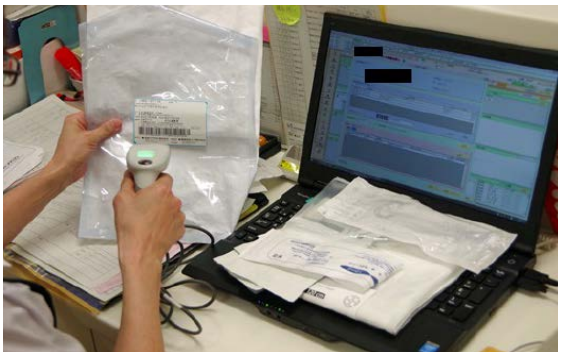
Figure 1: Modification of barcode reading process in EHR after implementation

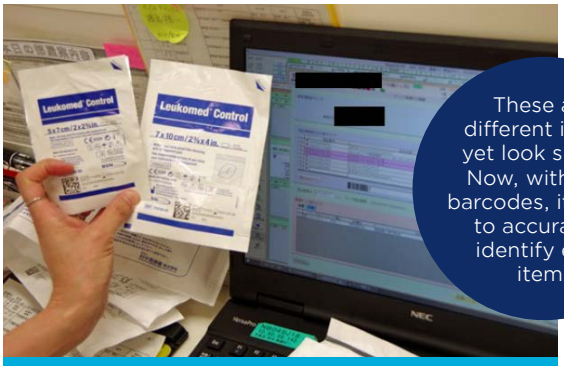
used in an operation first and, then register the corresponding information within the patient's scheduled procedure list in the EHR. (See Figure 1.) The team also decided to integrate the registration steps and flow of medical device information for surgical orders with procedure orders, each of which were done separately before. (See Figures 2a and 2b on page 46.)



While looking at the package of medical materials used during an operation, the data of the medical device is manually entered via the keyboard. The Medical Affairs department manually searches the reimbursement number from the entered product name, and inputs it into the medical accounting system.

Figure 3a: The manual process





These are different items, yet look similar. Now, with GS1 barcodes, it's easy to accurately identify each item.

By scanning the source-marked GS1 barcode, the hospital can record the data (GTIN, lot, expiration date) of the medical device used in the operation room. The data is automatically transmitted to the Medical Affairs department for accounting.

Figure 3b: The automated process

Figure 3a shows the previous registration process of medical devices used in operations. Watching the screen of the surgical system and medical device packages, the information (product name, model, version and other information) of the devices used was entered manually by a staff member at the operating theatre. A staff member of the Medical Affairs division manually searched for a reimbursement code based on the information provided. Then, the staff would input the reimbursement code into the medical accounting system.

With the modification, it is now possible to register the medical devices used for operations quickly and accurately by just scanning GS1 barcodes—GS1-128 and GS1 DataMatrix barcodes. (See Figure 3b.) In addition, the registered data is automatically transmitted to the medical accounting system, and the Global Trade Item Number® (GTIN®) encoded in the GS1 barcode, is automatically converted into a reimbursement code. Since in Japan reimbursement codes are required for drug and medical device reimbursements, the GTIN needs to be replaced by the corresponding reimbursement code. In the new system, this conversion is automated.

NGCM calculates that the time required to register medical devices used in surgeries has been reduced by approximately 3.5 minutes per operation, which equals 340 total hours per year.

NGCM calculates that the time required to register medical devices used in surgeries has been reduced by approximately 3.5 minutes per operation, equaling 340 total hours per year.

Before implementation

Select each order (procedure/surgery) and scan a barcode, but not use the barcode scanning function because of cumbersome procedure. In the OR, paper documents are sent to the Medical Affairs Division after the used device information is manually registered.

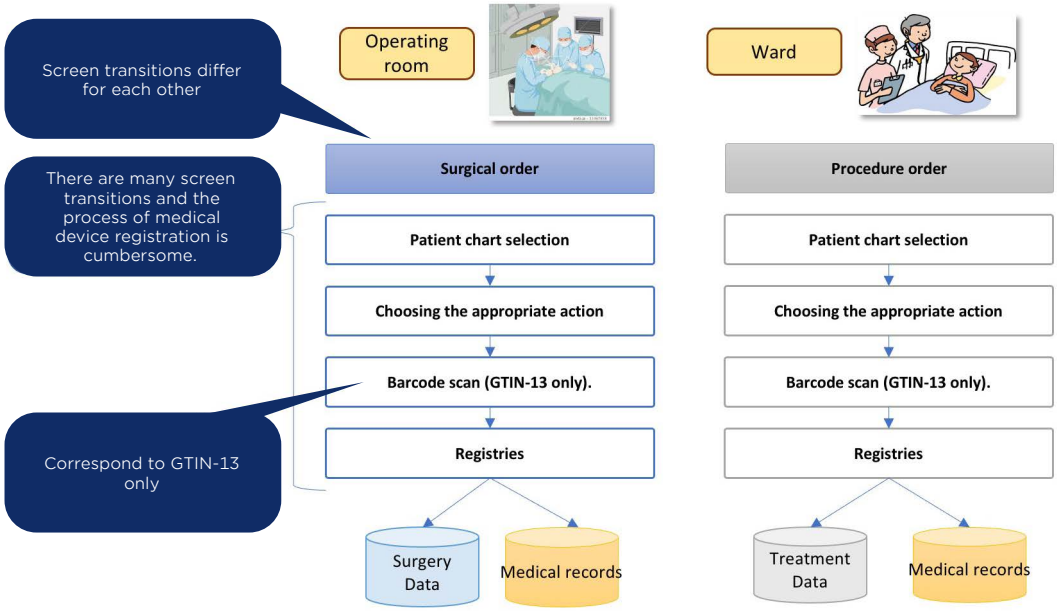


Figure 2a: Integration of use recording flow of medical devices in EHR (before)

After implementation

Intuitively manipulated design centered on the function of barcode scan. Correspond to GS1 barcodes to allow the lot number and expiration date to be registered.

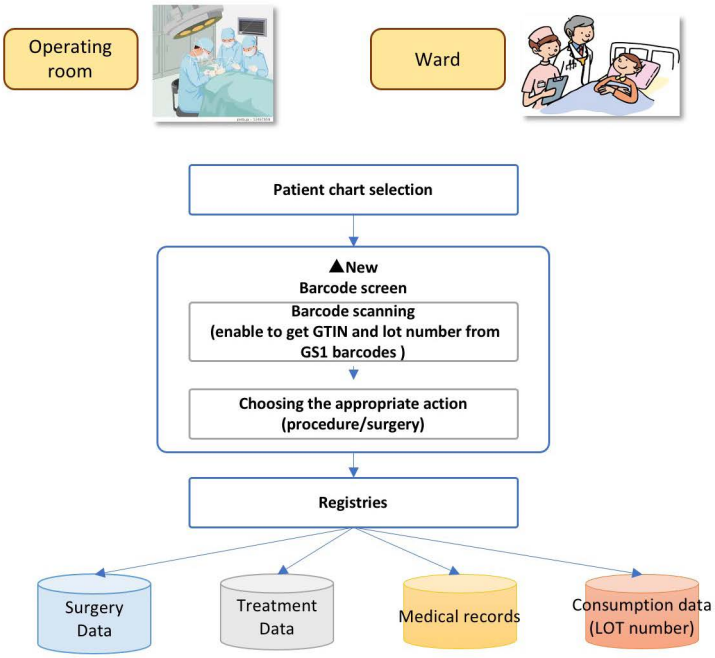


Figure 2b: Integration of recording flow of medical devices in EHR (after)

Catheter management

Since some medical devices such as catheters and orthopedic devices have a significant number of different types and sizes, they are labelled by manufacturers or wholesalers and are stored in hospitals as consignment items. When previously managing catheters, nurses would cut out catheters' labels used in an operation, placing the label on the hospital's accounting sheet. Staff in the Medical Affairs division had to input the data manually and check the accounting sheet for the medical service fee. The workload was heavy and susceptible to errors.

The delivery and management of consignment device inventory was performed by wholesalers; however, the timing of the movement and use of these products was different from the timing of checking and replenishment. As consignment devices were lost, it was hard to determine whether the wholesaler or hospital was responsible for these losses.

To automate and improve the control of consignment devices, the NGCM team decided to attach an RFID tag linked to the GS1 barcode's data—the GTIN, expiration date, lot number and serial number—on every package of catheters. The packages are now placed on an intelligent rack with RFID readers. (See Figure 4.) By linking the packages to the new EHR system, it has become possible to trace the movement of catheters as they are delivered to the rack and removed from the rack. The catheter consumption data is then transmitted to fee-for-service claims. Scanning GS1 barcodes on catheters in the operating theatre provides information about the actual use for specific patients, and the data is checked at the Medical Affairs division based on the data from the catheter rack.

This new catheter logistics system has reduced nurses' time to register used catheters by approximately 30%. The time associated with reimbursement operations in the Medical Affairs division has been reduced by about 70%. These reductions in working hours mean that medical staff can redeploy their time to focus on patient care and other purposes.

In Japan, source marking with RFID tags and GS1 standards is currently being conducted for orthopedic medical devices and catheters[1]. It is anticipated that once source-marked RFID tagging is fully deployed, the hospital will no longer need to attach their own RFID tags.

[1] GS1 Healthcare Reference Book, 2019-2020, page 87.

The new catheter logistics system has reduced nurses' time to register used catheters by approximately 30%. The time associated with reimbursement operations in the Medical Affairs division has been reduced by about 70%.

New system

① Collaboration with EHR; ensuring correct data for consumption and reimbursement
② Availability of consumed data; GTIN and Lot number can also be registered and is traceable on a lot-by-lot basis

Figure 4: RFID helps to improve work in the catheterisation room and supports traceability.

Integration of master data

The NCGM operates five data systems with master data for its medical devices: logistics code transformation, surgical items, procedural action details, treatment items and medical interface. Maintaining these master data systems posed a significant burden on the responsible staff. When registration errors occurred, this led to inconsistencies between the databases.

Today, NCGM is using the GTIN as the key standard to help drive consistency among the five master data systems. As a result, the hospital has gained visibility about the movement of medical devices within its facility, using the GTIN in the Logistics Management division, Operation and Treatment division, and Medical Affairs division.

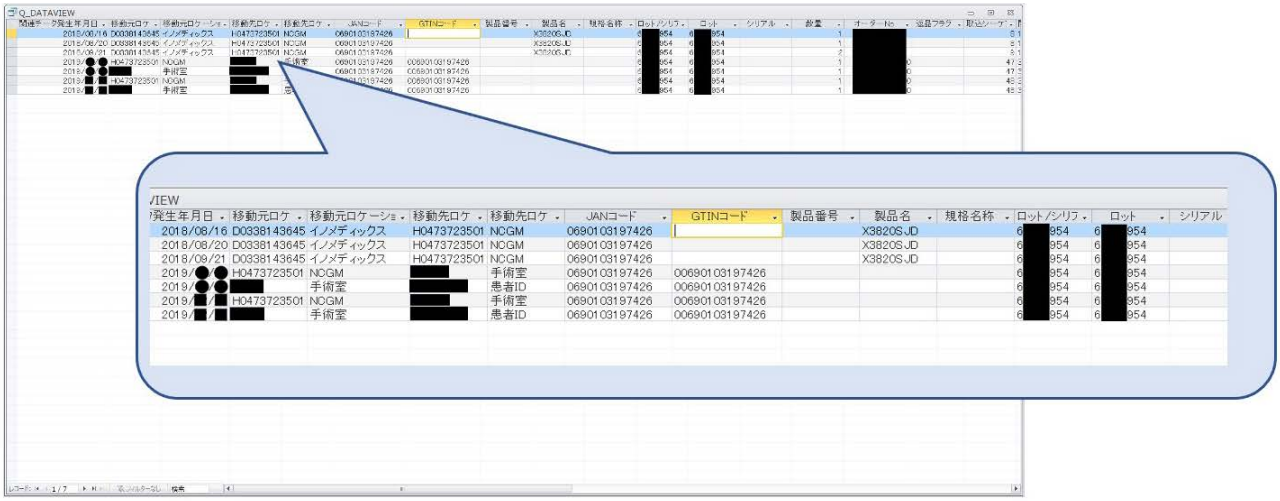


Figure 5: Trace Information Screen of the medical device traceability data bank. Four medical supplies with GTIN 0690103197420, Lot number 6*** 954 were delivered by a wholesaler on August 16, 20, and 21 (one on August 16 and 20, two on August 21). One of them was used for a patient with Patient ID *** in the operating theatre.

Medical device traceability

The main pillars of the implementation are EHR and master data integration. At NCGM, healthcare providers, system vendors and wholesalers collaborated to establish a "traceability data bank" that provides visibility of medical devices and medical products as they move throughout the hospital, with data provided to the EHR and logistics systems.

The traceability data bank contains:

- Distribution information that mainly includes the distributor's delivery data
- Consumption information that includes data about the delivery and use of medical devices in the hospital, and medical information that includes the types of surgeries and procedures in which the medical devices are used and patients' ages and gender

Figure 5 shows the results of confirming the movement of a product (GTIN is 0690103197426 and lot number is 61416954) within the traceability data bank. On 21, 20 and 16 August, four products were delivered by a wholesaler on three separate occasions—two of the four were delivered to an operating theatre and used for two patients, respectively.

In case of recall, using the traceability data bank, it is possible to identify the products to be recalled and easily find their storage locations. The lifecycles of medical devices—from delivery to consumption (which was once determined from ordering information)—can now be "visualised" by NCGM, using the traceability data bank and by being able to compile what types of surgical procedures were used for which subcategories of patients.

Future perspectives

Modification of the EHR system and integration of master data systems based on the GTIN, as well as RFID usage for catheters, have made it possible for NCGM to automatically collect the information generated from work in each of the hospital's departments.

To capture this valuable information, the medical device traceability data bank relies on GS1 barcode scans or RFID readings from the locations such as delivery locations, operating theatres and catheter cabinets, and does not require manual entry of additional data. The data generated by each operation is combined with data from the traceability data bank since all medical devices are uniquely identified with GTINs.

The medical device traceability data bank not only supports patient safety and logistical efficiency at NCGM, it can also have a large-scale impact on other healthcare providers, manufacturers and wholesalers in the medical device industry. The data bank can deliver the data that supports research and innovations in the development of new medical devices, in hospital management and in clinical practices, as well as improve the distribution of medical devices. The next target is to expand NCGM's experience to other hospitals, collaborating with them, manufacturers and wholesalers to share its learnings.

Staff members at NCGM are currently evaluating a new system developed by Dr. Miyo's team that is designed to improve operations through the use of GS1 standards. Dr. Miyo believes that by increasing the number of medical institutions participating in the traceability data bank project, the data collected in the data bank will be even more valuable for healthcare providers, the medical industry and society.

About the author

Dr. Kengo Miyo ??
Chief Medical Information Officer
National Center for Global Health and Medicine

Dr. Kengo Miyo is the CMIO at the National Center for Global Health and Medicine where he has been leading the implementation of GS1 standards.

With over 20 years of experience in medical informatics, Dr. Miyo has worked with many solution providers to develop and improve the hospital information systems (HIS). He has also helped many hospitals implement HIS, contributing to the improvement of medical efficiency and patient safety.

About the organisation

National Center for Global Health and Medicine (NCGM), located at Shinjuku in Tokyo, Japan, is one of the six national centres established to provide the most advanced medical care in Japan. The medical care system includes specialists, doctors and staff working together in all medical care fields. NCGM is the only general hospital that is also a national centre. Opened in 1868, NCGM has 763 beds, 43 departments and performs 5,700 operations per year.

www.ncgm.go.jp

Netherlands

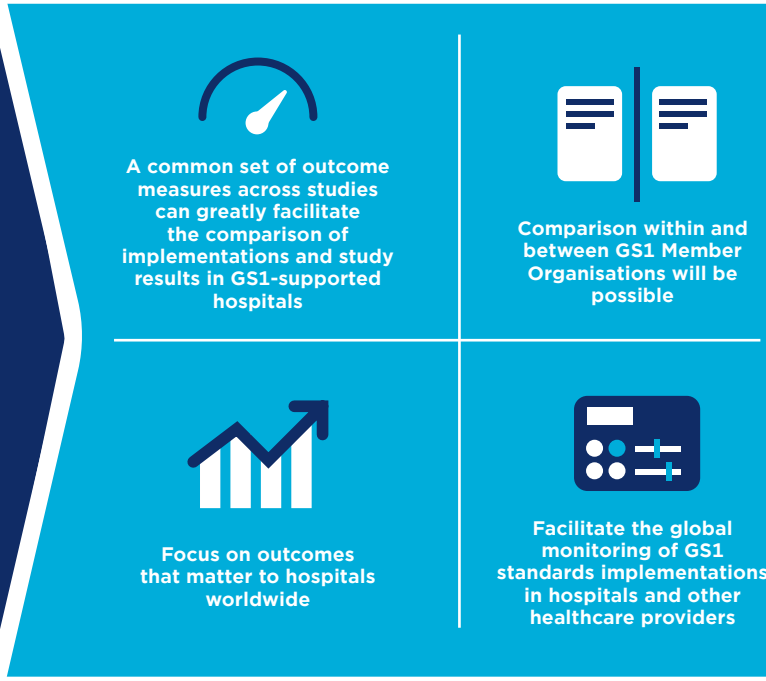
Developing the GS1 monitoring tool: a standardised set of patient safety outcome measurements

Challenge

While some studies have investigated the efficacy of barcoding, the outcomes assessed across trials are different. This inconsistency in measured outcomes poses concern when evaluating the effects of barcoding on patient safety and quality of care.

Approach

The objective of this work was to define a minimum, internationally appropriate set of patient safety outcome measurements for evaluating, generating evidence and improving the implementation of GS1 standards.

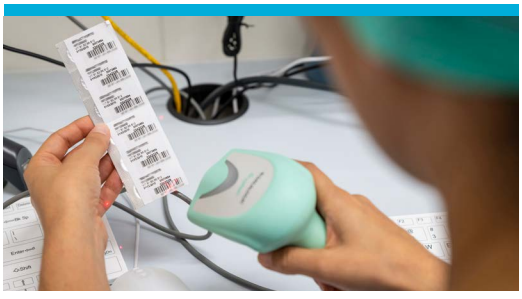


Barcode systems are designed to contribute to patient safety, improve quality of care and increase the transparency of medical processes. While barcode systems are increasingly being used in healthcare, the level of evidence for efficacy in patient safety and quality of care is unclear due to differences in the outcomes assessed across trials.

Introduction

Since the 1970s in worldwide retail barcoding via Automatic Identification and Data Capture (AIDC) standards, using globally accepted barcodes has played a crucial role in the supply chain, ensuring that the right products are available at retail stores and significantly reducing the time for customer check-outs.

In the recent years, global healthcare regulations on pharmaceuticals and medical devices—which include implants—are aligning to global standards for product identification. Regulatory agencies and jurisdictions (e.g., in Australia, Canada, China, Europe, UAE and US) acknowledge the necessity of global barcoding standards in healthcare for procurement and traceability reasons. In addition, there is growing evidence for the efficacy of barcode solutions in improving overall patient safety.



Maaike Langelaan &
Esther Peelen

Monitoring tool

Medication-related adverse events and high-risk medical device-related adverse events are important priorities for patient safety. Incidents in the medication distribution process or with medical devices, such as implants, have occurred at regular intervals in the past. These incidents have resulted in a significant number of patients harmed and great cost incurred by the healthcare system due to the necessity of additional medical treatment or corrective surgeries. Human error is an important factor in medication-related and medical device-related adverse events. Therefore, information technology solutions are often explored to mitigate the risk of human error.

The implementation of global standards in hospitals is associated with higher quality of care, greater patient safety and better supply chain management. And so, new safety programmes focus on barcode medication administration systems and medical implant traceability.

Robust evidence from well-designed prospective studies is required in order to further consolidate the implementation of GS1 standards as an accepted intervention applicable to hospitals. To date, there has been no formal investigation of the impact of implementing GS1 standards on the quality of care—the disease-specific process of care indicators, hospital costs and resources related to actual budgetary expenditures.

The development of a core monitoring set of evidence-based, standardised, outcome measures would help researchers, policy makers, healthcare managers and caregivers come together with a uniform approach. This would make comparing implementations within and between GS1 Member Organisations (MOs) possible.

The purpose of the project is to develop a set of core outcome measures for the evaluation of global standards-based barcoding in hospitals worldwide—measures that are considered relevant for researchers, policy makers and hospitals. A core set of outcome measures is the *minimum* set of outcomes that should be consistently measured and reported in all studies. However, this does not restrict researchers from adding additional outcomes. A minimum set of outcomes will provide greater uniformity of reporting in clinical trials and more data to impact meta-analyses. It will reduce study heterogeneity and the risk of reporting bias by consistently measuring and reporting these outcomes. A core set of outcomes would not only result in a standardised set of *which* outcomes to measure and *how*, it could also improve the coordination, communication and knowledge transfer between research groups, policy makers and healthcare professionals.

"Our literature review revealed heterogeneity in outcomes."

Maaike Langelaan
Business Consultant
PinkRoccade Healthcare

Identification of potential outcomes

To identify potential patient safety outcomes related to the implementation of GS1 standards, a systematic review of relevant publications was the first phase of the project.

This search retrieved 288 articles. After screening titles and abstracts, 46 PubMed-indexed articles published as of 1 January 2010 were included for review. An additional literature review was performed to identify studies in the five most recent *GS1 Healthcare Reference Books.*

Each article was scanned for patient safety outcomes. This resulted in a lengthy list of 69 patient safety outcomes.

The literature review revealed significant differences in outcomes. Yet, there was also an overlap in outcomes collected by trials, registries and those reported by GS1 experts.

The outcomes from the review were categorised into six major groups:

- General outcomes (8 outcomes)
- Medication-related outcomes (34 outcomes)
- Medical device and implant-related outcomes (11 outcomes)
- System or procedure outcomes (5 outcomes)
- Specimen-related outcomes (11 outcomes)

Delphi study

The next step of the project, performed by a global working group, was an initial Delphi study that resulted in a short list of outcomes. The working group consisted of GS1 experts from six GS1 local offices in Australia, Denmark, France, the Netherlands, Poland and UK, and a healthcare expert from GS1 Global Office.

This first step involved a series of two online rounds of data collection and analysis to condense the opinions of the working group members on what outcomes should be measured.

The team used an online survey tool to create and administer the questionnaires. For each major group of outcomes, experts were given the option to provide free-text comments to support their decision, or to suggest changes or additions to the outcomes.

During the second round, experts were given the mean scores of each outcome in round 1 and the answer provided by the expert. Three outcomes that were suggested by the experts during the first round were then added.

To be included in the short-list standard set required that at least 80% of the experts voted an item as "essential," which meant it had a mean score of 7 or higher on a 0-10 point Likert scale. This resulted in a short list of 43 outcomes.

The long list of potential outcomes and statistical scores were presented to the global GS1 Healthcare Interest Group (experts from all GS1 MOs working in healthcare) for discussion during a teleconference meeting.

"The methodology allowed for worldwide participation of GS1 MO experts, policy makers and healthcare workers."

Maaike Langelaan
Business Consultant
PinkRoccade Healthcare

Considerations

This methodology allowed for creation of a core set of outcomes that is relevant to measure the effectiveness of GS1 standards implementations worldwide.

Specifically, the methodology allowed for worldwide participation of GS1 MO experts, policy makers and healthcare workers. Discussion at the consensus meetings provided additional, in-depth consideration of important aspects such as the definition of outcomes, practicality of the measures and their global relevance—all which will enhance the potential use of the core metrics for quality improvements among specific risk groups.

Next steps

The 43-item short list will be sent to GS1 MOs and care workers in hospitals. They will be asked to rate their confidence regarding several elements of the set on a 10-point Likert scale, with an open field for comments.

Outcomes with a mean score of 7 or higher will be included in the final set of outcomes (the monitoring set). This set will be worked into a monitoring tool, an IT-based tool to be shared with the GS1 MOs. The next step will be to conduct a pilot study to validate the core set of outcomes in a daily hospital practice.

The final stage of this project will be to promote the implementation of the set of outcomes, using the monitoring tool.

Major hurdles to be overcome include:

1. **Gaining agreement of local research teams willing to use the set**
2. **Ongoing evaluation of what is and is not being measured**
3. **Ensuring efficient and user-friendly means of collecting and storing clinical data**
4. **Confirming systematic and consistent collection of data**
5. **Budgeting**

"A common monitoring set of outcome measures across studies would greatly facilitate the comparison of implementations and study results within and between GS1 Member Organisations."

Maaike Langelaan
Business Consultant
PinkRoccade Healthcare

Benefits and conclusion

In the end, a common monitoring set of outcome measures across studies will greatly facilitate the comparison of implementations and study results. This could also improve the coordination, communication and knowledge transfer between research groups and professionals and, thus, facilitate implementation of GS1 standards in hospitals.

The cross-MO team will develop a consensus recommendation for a standardised set of outcomes that is deemed most important to healthcare providers using GS1 standards. This recommendation is targeted for integration into implementation research and publication of evaluation studies. Use of the standard set may enable researchers, policy makers, healthcare managers and caregivers to monitor, compare and improve the implementation of GS1 standards worldwide.

About the authors

Maaike Langelaan, PhD
Business Consultant
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Maaike Langelaan works as a business consultant of patient safety and quality of care. She is the project leader of the implementation of patient safety indicators based on routine data in hospitals. She carried out several (systematic) reviews for the development of evidence-based medicine and several guidelines. Her fields of interests are quality in healthcare organisations, patient safety, and the development and validation of methods for measuring patient safety and adverse events.

Esther Peelen
Manager, Healthcare Providers
GS1 Netherlands

Esther Peelen is Sector Manager, Healthcare Providers at GS1 Netherlands. Ms. Peelen supports providers in implementing GS1 standards in the operating room, pharmacy and other departments. She uses the experience and insights from the providers to create tools and to facilitate knowledge exchange between providers. Ms. Peelen works closely with other standards organisations in healthcare and with provider associations to spread this knowledge and, thus, take implementation a step further.

About the organisation

PinkRoccade Healthcare is a provider of software solutions in the Netherlands. The business unit, Hospitals BI, ensures that hospitals have the necessary data management at their disposal. Hospitals BI has an extensive data warehouse as well as ample knowledge of quality and patient safety. Its solutions include:
- Performance monitor: current total overview of the quality indicators in a hospital
- Datadash: anonymize data to support the GDPR legislation
- Geniq: complete data warehouse for the most critical flows in the hospital

www.pinkroccade-healthcare.nl

Netherlands

Fewer bricks and more clicks result in optimal medical device inventory at Radboudumc

Challenge

Radboud University Medical Centre (Radboudumc) wanted to eliminate out-of-stock situations for its operating theatres to ensure better patient care and outcomes. The hospital recognised that human behaviour would be a major challenge when implementing GS1 standards and the necessary change processes.

Approach

Radboudumc designed optimal processes, secured systems and connected people, using GS1 standards to uniquely identify medical devices and share valuable data throughout its hospital—from receiving goods to patient use.

25%

less stock in the hospital

€500,000

annually in savings

Out-of-stocks are nearly non-existent. Stock loss has been greatly reduced.

Staff are able to locate products within two minutes in the Radboudumc environment.

Radboudumc

A situation of "being out-of-stock" is not an option in a hospital. If a crucial medical device is not available at the right time, this can make the difference between life and death. For the best care, more control over stock was needed at Radboud University Medical Centre. Today, enabled by GS1 standards, the medical centre's processes are optimally running, systems are correctly connected and people are working differently and better.

"Fewer bricks and less walls" means that people no longer work for just their own departments, but together. Everyone focuses on the goals of increasing efficiency in processes and safety of care, all while reducing costs.

Alex van der Putten

Processes conforming to standards

In 2015, Radboudumc did not yet have complete control when managing its stock levels. The various stock locations throughout the hospital were managed in different ways by healthcare professionals with no logistics background. Everyone managed the inventory as well as they could, often using manual processes and with systems that were not interconnected. The chance of an out-of-stock situation was highly probable.

Alex van der Putten, Head of Procurement & Supply Chain at Radboudumc, wanted to improve inventory management for better patient care. He understood that the inventory management processes would need to be redesigned and supported by GS1 standards and integrated systems.

"At the beginning of the project, various barcode formats were in use," says Mr. van der Putten. "This led to problems with scanning; sometimes, we had to enter item numbers manually. It was crucial to have a record about which implant was used in which patient."

Now, Radboudumc only accepts and uses GS1 barcodes—the GS1-128 barcode and two-dimensional (2D) GS1 DataMatrix. By using GS1 standards to uniquely identify medical devices, they can be easily scanned in the operating room, capturing valuable information for use throughout the hospital. Stock management processes have also been revised to include scanning as an efficient way to safeguard medical supplies with GS1 standards. The information collected when scanning barcodes is also linked with the various systems and databases at Radboudumc.

Fewer bricks, less walls

"There is no doubt that standards are needed in the future. There are three factors that shape the future in hospitals," says Mr. van der Putten. "The first factor is 'fewer bricks.' Due to several factors, including reduced length of in-patient-stay, we see our hospitals literally shrink. We are working on a new construction in Nijmegen, where we will 'hand in' 100,000 square meters. That means that the hospital will soon have a quarter less space—less space also for inventory."

"We can implement beautiful processes, systems and standards, but it is ultimately people who have to work with ithem. That's why agreements are needed."

Alex van der Putten
Head of Procurement & Supply Chain
Radboudumc

The "virtual walls" between departments have also been removed at Radboudumc. "Previously, each department had its own processes and methods," continues Mr. van der Putten. "Now, we have one logistics organisation responsible for inventory management in the entire hospital. Before implementing GS1 standards, if an employee (responsible for stock in a specific department) went on holiday, additional inventory was sometimes stocked in that department in advance. This would lead to extra stock that would eventually expire. Now, there is uniformity in inventory management processes that are more efficient, resulting in less waste and fewer risks."

Growing assortment of medical devices

Another factor driving change in hospitals is the exponential increase in the amount of data. This is partly due to the growing types of medical devices.

"We used to have a certain set of medical devices and instruments that we could use for different treatments," explains Mr. van der Putten. "Today, a certain procedure increasingly has its own specific set of medical devices and instruments. Moreover, the medical devices become obsolete faster. In the past, the useful life was perhaps five years, now sometimes only twelve months."

As a result, data becomes outdated faster. By using GS1 standards and GS1-approved data pools, healthcare providers like Radboudumc can more readily update and control their medical device data and guarantee the quality of the data.

Human behaviour

The third factor is the behaviour of people in hospitals. “We can implement beautiful processes, systems and standards, but it is ultimately people who have to work with them. That is why agreements are needed,” says Mr. van der Putten.

In the past, consumption of materials in Radboudumc’s operating rooms was only registered after treatment. The medical devices were prepared in advance for a planned procedure, but not yet deducted from stock levels. Logistically, that was not efficient nor desirable since there was not a real-time view of what devices were available for procedures. Now, every physical movement of a medical device and other medical supplies is recorded in real time by barcode scanning. Barcodes are scanned in all steps of the process, on arrival in the store room, on picking for a procedure and before use in the operating room. Interoperability of the IT systems fully supports the real-time view.

Paralysing syndromes

Mr. van der Putten also knows that human behaviour has a major influence on change processes. A pattern of behaviour that many organisations are familiar with is the “not invented here” syndrome. “If people have not invented something themselves, they consider the solution as not being good enough,” explains Mr. van der Putten. “Logistics is a unique area of discipline in itself.”

“Previously, each department had its own processes and methods. Now, there is one logistics organisation responsible for inventory management. There is uniformity in inventory management processes that are more efficient, resulting in less waste and fewer risks.”

Alex van der Putten
Head of Procurement & Supply Chain
Radboudumc

“The Six Sigma syndrome can also be paralysing. If a hospital strives for perfection, it will not get there. Choices must be made—what is facilitated in the process and what is not. Here at Radboudumc, we have chosen to support a realistic view of 95% process support and not feel pressured to achieve 100%.”

Many people are so busy with the daily activities and solving issues that participation in change processes could become secondary. However, the involvement of all disciplines is crucial for sustainable change, support and, ultimately, the success of the change process.

Becoming a hospital of the future... today

Radboudumc is working to achieve "hospital of the future" status. Work is underway to automatically link data with data pools, so that data from manufacturers is automatically deposited in the hospital's enterprise resource planning (ERP) system.

In addition, work is being done to apply RFID (radio frequency identification) tags to all devices. The unique GS1 identifier is still crucial, but will now be encoded in the RFID chip, making automatic detection possible.

"And we would like to do more with the data we collect," says Mr. van der Putten. "With our Bill of Materials—a type of 'shopping list' that we prepare with typically a large number of medical devices and instruments—it clearly shows some of these are ultimately not used during the procedure. By analysing the inventory data, we can provide targeted advice on the medical devices and instruments to be prepared per procedure. By having a clear view, this helps reduce potentially dangerous situations, increasing safety, decreasing waste and being much more efficient."

> *"By implementing GS1 standards, our hospital staff knows exactly where specific products are, identified by serial numbers and expiration dates—but, most importantly, they know exactly which patients received them."*
>
> **Alex van der Putten**
> Head of Procurement & Supply Chain
> Radboudumc

Remarkable results

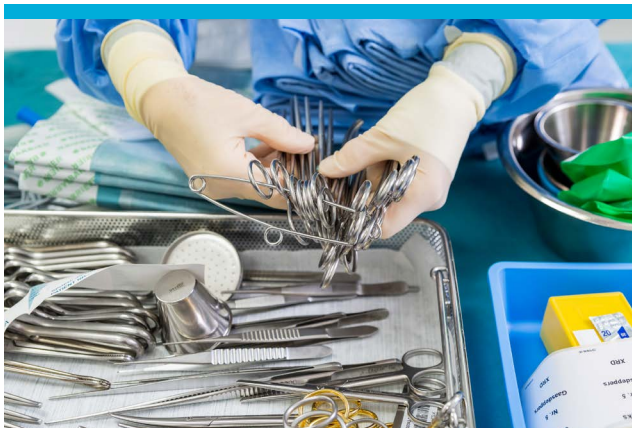
By using GS1 standards in its inventory management processes, Radboudumc has experienced remarkable results. Inventory levels have decreased over three years by more than 25% and the cost savings are significant at approximately €500,000 annually.

"Improvements in our processes have delivered tangible benefits," says Mr. van der Putten. "We are realising lower emergency room costs since we are in total control of our inventory for emergency procedures. Costs are also lower since we are ordering the right quantities, at the right time . . . and we're preventing waste. Our GS1 standards-based processes have led to an estimated 25% reduction of inventory levels and a 25% reduction of waste (due to expiration)."

Since out-of-stock item situations are basically non-existent, patient safety has improved considerably. In case of a recall, Radboudumc knows exactly which implant has been used with which patient. "Scanning takes time but we save a lot of time elsewhere in the operation," says Mr. van der Putten. "By scanning barcodes combined with the accurate recording of data in the patient's file, for instance, retrieving data for a recall or for other purposes is very easy."

By using the Global Data Synchronisation Network™ (GDSN®) to exchange medical device and other product data, Radboudumc readily complies with and is prepared to comply with healthcare regulations such as the Dutch Implant Registry (LIR) and the Medical Device Regulation (MDR).

Radboudumc clinical and administrative staff are spending less time on non-clinical tasks. For example, instead of looking for the model of a medical device, the scannable label based on GS1 standards makes this information readily available. "And now, automated processes for data entry and electronic medical records releases more time for physicians and nurses to focus on patients," confirms Mr. van der Putten.



About the author

Alex van der Putten
Head of Procurement & Supply Chain
Radboud University Medical Centre

Alex van der Putten is an experienced procurement and supply chain professional with a demonstrated history of working in the retail, convenience and hospital & health care industry.

He has worked since 2012 as Head of Procurement and Supply Chain for the University Medical Centre Radboudumc, in Nijmegen in the Netherlands. Radboudumc aims to be a pioneer in shaping a personalised, innovative, affordable and sustainable healthcare system for generations to come. Less “bricks”, the right use of data and different behaviour in procurement and supply chain are in his opinion crucial matters to make a significant next step.

About the organisation

Radboud University Medical Centre (Radboudumc) in Nijmegen, the Netherlands is a university medical centre dedicated to three core activities: (tertiary) care, education and research. Care is organised in more than 50 care departments and several centres of expertise recognised by the Ministry of Health, Welfare and Sport. Radboudumc is also one of the major trauma centres in the Netherlands. The Radboudumc Health Academy coordinates, regulates and monitors all education in the Radboudumc. Scientific research is organised within three research institutes: Radboud Institute for Molecular Life Sciences, Radboud Institute for Health Sciences, and the Donders Center for Medical Neuroscience.

www.radboudumc.nl/en

Norway

Lovisenberg Diaconal Hospital achieves significant efficiency improvements and traceability for surgical equipment

Challenge

Lovisenberg Diaconal Hospital in Norway needed to streamline its processes associated with the handling of surgical equipment. Highly trained surgical staff was spending valuable time on manual tasks like sorting, packaging and the replenishment of equipment used in surgical procedures.

Approach

Staff in the Surgical and Sterile department collaborated with GS1 Norway and APX Systems to develop and implement a traceability solution based on GS1 standards. The system has automated the department's surgical, ordering, replenishment and recall processes for impressive improvements.

Staff training time reduced from 1 year to 3 months

Traceability and transparency through the whole supply chain, from manufacturer to patient

Manual ordering process that once took 2 hours per day is now automated, taking only minutes with increased quality

Increased patient safety and quality assurance

Lovisenberg Diakonale Sykehus

Established in 1894, Lovisenberg Diaconal Hospital is publicly financed, but operates as a non-profit facility by two trusts. The Surgical department competes for patients with all publicly funded orthopaedic hospitals in Norway and, therefore, relies on its flawless professional and clinical reputation to continually attract patients. To improve efficiencies and patient safety, the hospital wanted to improve and streamline the handling and traceability of its surgical equipment.

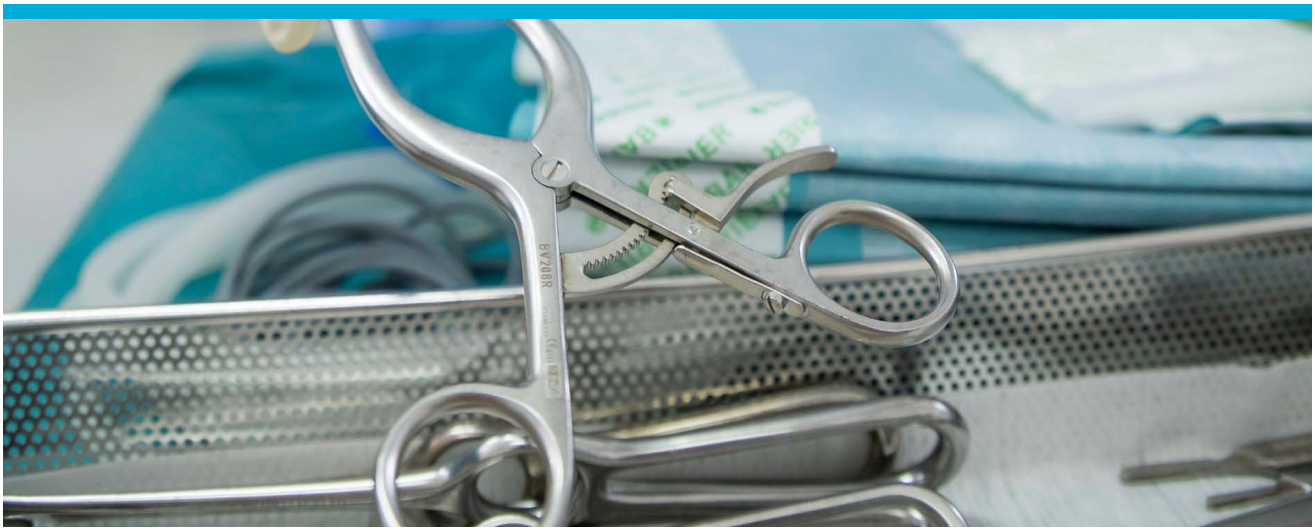
Marit Glende Johnsen & Fredrik W. Goborg

Streamlining traceability with GS1 standards

Started as a pilot project in 2013, GS1 standards were implemented and fully operational in the Surgical and Sterile department by spring 2017. During this timeframe, representatives from the hospital, APX Systems, a solution provider, and GS1 Norway collaborated to develop the traceability system.

Healthcare professionals in the department prioritised the needs that had to be addressed, and then shared their ideas and suggestions with APX Systems and GS1 Norway as part of a joint team effort to identify a potential solution and outcome.

APX Systems developed the solution supported by GS1 standards, helping the department to successfully transition from manual registrations and operations into digital scanning and tracking.



Medical device management in a hectic environment

Surgical nurse Marit Glende Johnsen was Head of the Surgical and Sterile department until 2019. She recalls that the surgical staff spent a significant amount of time executing manual, non-value added routine work, especially when it came to sorting and packaging instruments. Being part of the surgical staff demands a high degree of proficiency, with specific skills that take a substantial amount of time to master. Trained staff is, therefore, difficult to replace and must be retained. Ms. Glende Johnsen noted that these manual tasks took available surgical staff away from other critical responsibilities in the department.

Another daily challenge faced by the staff was the replenishment and re-ordering of components and implants after surgeries. Each implant surgery often requires a large number of different types of medical devices, components and instruments, comprised of an immense set of variables. Therefore, it's crucial that the warehouse is able to supply operating theatres with the right medical devices, components and instruments—at the right times and in the right amounts.

"We needed to optimise our warehouse volumes—not only for purely economic reasons, but to also make the best use of available physical storage space."

Marit Glende Johnsen
Former Head of Surgical &
Sterile Department
Lovisenberg Diaconal Hospital

It is important that the department promptly replenish all the components that have been used during a surgical procedure, so that all needed items for scheduled future surgeries are always available.

Until the implementation of GS1 standards, replenishment was a manual routine that consumed a considerable amount of time. Hours were spent on ordering the right items, as well as on the tedious work of checking and registering items when they arrived at the hospital's warehouse. This was done by comparing the purchase order and suppliers' packing lists with the delivered items manually.

Healthcare personnel were spending time doing simple, time-consuming manual warehouse routines and administrative tasks such as receiving, stocking, picking, packing and dispatching. These manual processes resulted in a high-level risk of human errors.

There was an important need for a solution that would keep track of devices and components. "We were continuously trying to figure out how to better manage the proper supervision of packaging components, how to keep a lean and manageable inventory, as well as just understand where the various components were, at any given time," says Ms. Glende Johnsen.

By implementing GS1 standards, the department wanted to realise the following improvements:

- Tracking and tracing medical equipment, as well as how to correctly package the right components
- Streamlining the scanning and integration of data throughout several, different working processes
- Storing processed data
- Achieving an automated digital ordering system, especially for prosthetic surgery that requires daily orders that are complex and, when manually executed, result in a very high risk of human error
- Integrating data with the hospital's electronic health record (EHR) system and Norway's national quality registers
- Tracking implants and medical supplies, according to the EU's Medical Devices Directive

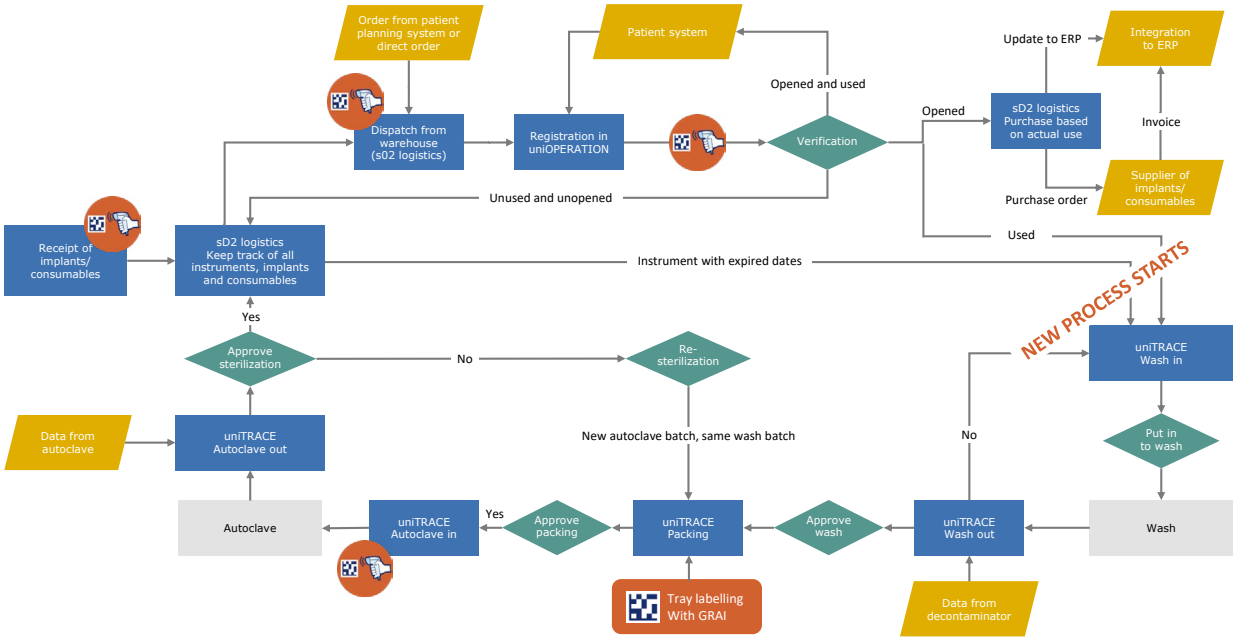


Figure 1: Tracking system for sterile equipment in CSSD, including warehouse management, registration in operation and purchase of goods used in operations

Initiating the implementation of the GS1 identification standards

The traceability solution was implemented in the entire Surgical and Sterile department by 2017. The system relies on GS1 standards for the identification of surgical equipment, providing data that can be automatically updated throughout the system, and then subsequently routed to relevant directories and registers. APX Systems also brought to the project its comprehensive expertise about logistics, traceability and GS1 standards.

A fundamental requirement of the solution is the GS1 Global Returnable Asset Identifier (GRAI) that enables the tracking of trays with individual medical instruments throughout the Surgical and Sterile department. By scanning the GRAI, staff can collect data at both the decontamination and autoclave points in the process.

"The suppliers product catalogues were in urgent need of GTIN codes. We implemented them with the help of APX Systems."

Marit Glende Johnsen
Former Head of Surgical & Sterile Department
Lovisenberg Diaconal Hospital

Sterile equipment, implants and consumables are registered via scanning the GRAI barcode in the operating theatres and automatically uploaded to systems like the hospital's EHR system, the Norwegian Arthroplasty Register and other relevant registries.

Other equipment and components are uniquely identified based on GS1 standards like the Global Trade Item Number® (GTIN®) encoded in GS1 barcodes such as the linear GS1-128 and two-dimensional (2D) GS1 DataMatrix barcodes.

As equipment and components are delivered to operating theatres, each item's barcode is scanned to extract and store information about that item—its GTIN, batch number, serial number and expiration date. At the same time, the expiration date is automatically checked to ensure the item has not expired and can be used.

Information about items—either used in operating theatres or just opened—is also utilised in the replenishment process to verify the need to purchase these used items. Item data automatically helps to create purchase orders that are then sent to the appropriate suppliers for fulfilment. This automated replenishment process ensures that the correct items are ordered for delivery to the hospital's warehouse.

Healthcare staff can now easily monitor the ordering process and know when to expect equipment deliveries. In addition, many tasks are now delegated to other roles since they no longer require a highly skilled and trained healthcare professional.

"It is of utmost importance that we have the tracking system, and the GTINs, because when we utilise this system, all information is automatically routed to the national quality registers, as well as being transferred to our hospital's EHR system."

Marit Glende Johnsen
Former Head of Surgical &
Sterile Department
Lovisenberg Diaconal Hospital

Benefits from the deployment of GS1 barcodes

The benefits of the GS1 standards implementation have been substantial, including:

- There has been a reduction in staff training time from 12 months to 3 months, for each healthcare professional.
- The time spent ordering medical equipment has been reduced. Manually ordering medical devices and products once took up to 2 hours per day, but now only takes minutes with the automated process.
- The traceability solution automatically uploads equipment and component data to Norway's national implant registers and the hospital's EHR system, giving healthcare professionals access to valuable statistics and historical data used for clinical studies and further improvements of medical protocols—increasing the quality of surgeries and patient safety.
- Medical devices and implants used in surgeries can be traced back to specific patients. Identifying the right patients in case of medical equipment recalls was once done manually before implementing GS1 standards. This could take days, but now takes only minutes.
- Traceability of surgical equipment throughout the department has significantly increased safety during the sterilisation process.

‘During the process of implementing the new processes and the traceability solution with GS1 standards, we saw the importance of contacting all of our suppliers in order to implement and streamline with the use of GS1 standards,” explains Ms. Glende Johnsen. “The suppliers’ product catalogues were in urgent need of GTINs so we implemented them with help from APX Systems.”

“Today, we scan everything we use during a procedure and when that is done, the information is automatic transferred to the EHR, in a readable pdf-type file,”

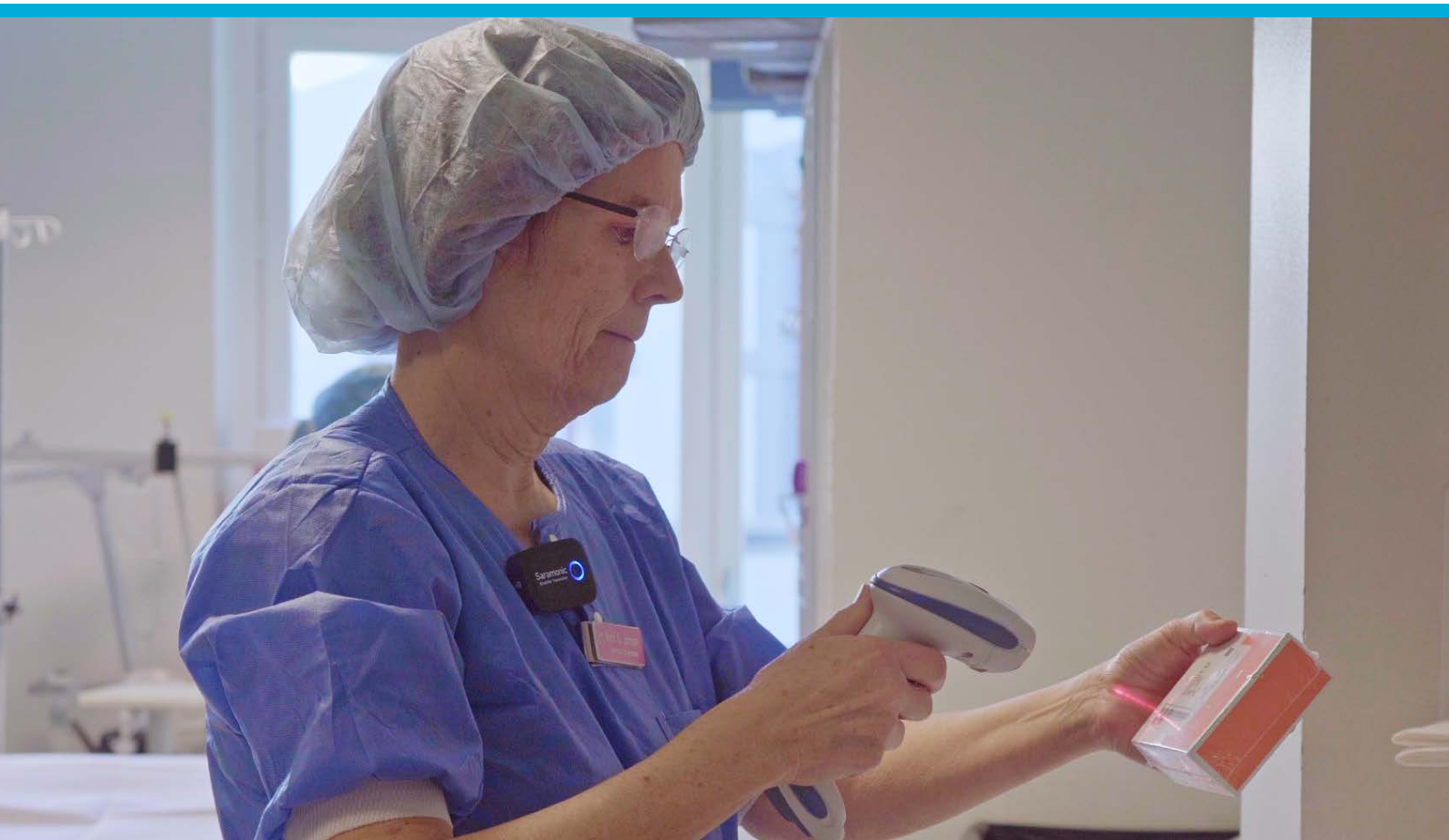
“This is extremely helpful for us in case a supplier contacts us regarding the recall of a batch of implants or other kinds of medical devices. We can now readily log on to the APX Systems solution and search the batch number to locate whether there are any hits or uses of that particular batch in our department. We can even trace the implant of a medical device directly back to the specific patient.”

“The suppliers’ product catalogues were in urgent need of GTINs so we implemented them with help from APX Systems.”

Ms. Glende Johnsen also underlines that invoicing and accounts payable are other areas where the traceability solution has led to impressive improvements. Having a large amount of vendor invoices and packing slips in need of her approval was both impractical, time consuming and led to potential errors. Now, Ms. Glende Johnsen just needs to access information via her computer to see if equipment has been ordered and received.

“Our administrative workload is so much lighter,” Ms. Glende Johnsen explains. “We only have to scan the equipment’s barcode one time and it is then directed to anywhere we would want the information to be stored and shared.”

Mr. Fredrik Goborg, APX Systems representative, explains why the system combined with GS1 standards provides many advantages for the Surgical and Sterile department. “The combined efforts of GS1 and APX Systems is streamlining all processes with no bottlenecks. The system is fully integrated with the hospital’s complex hardware and software already in use at the hospital.”



Quality assurance with traceability

Requiring the use of a GS1-128 barcode or GS1 DataMatrix on all medical devices, components and instruments coupled with a new and innovative Warehouse Management System (WMS) has more than met the requirements of medical staff. It has also produced added value by reducing training time for the staff along with a much more productive workday.

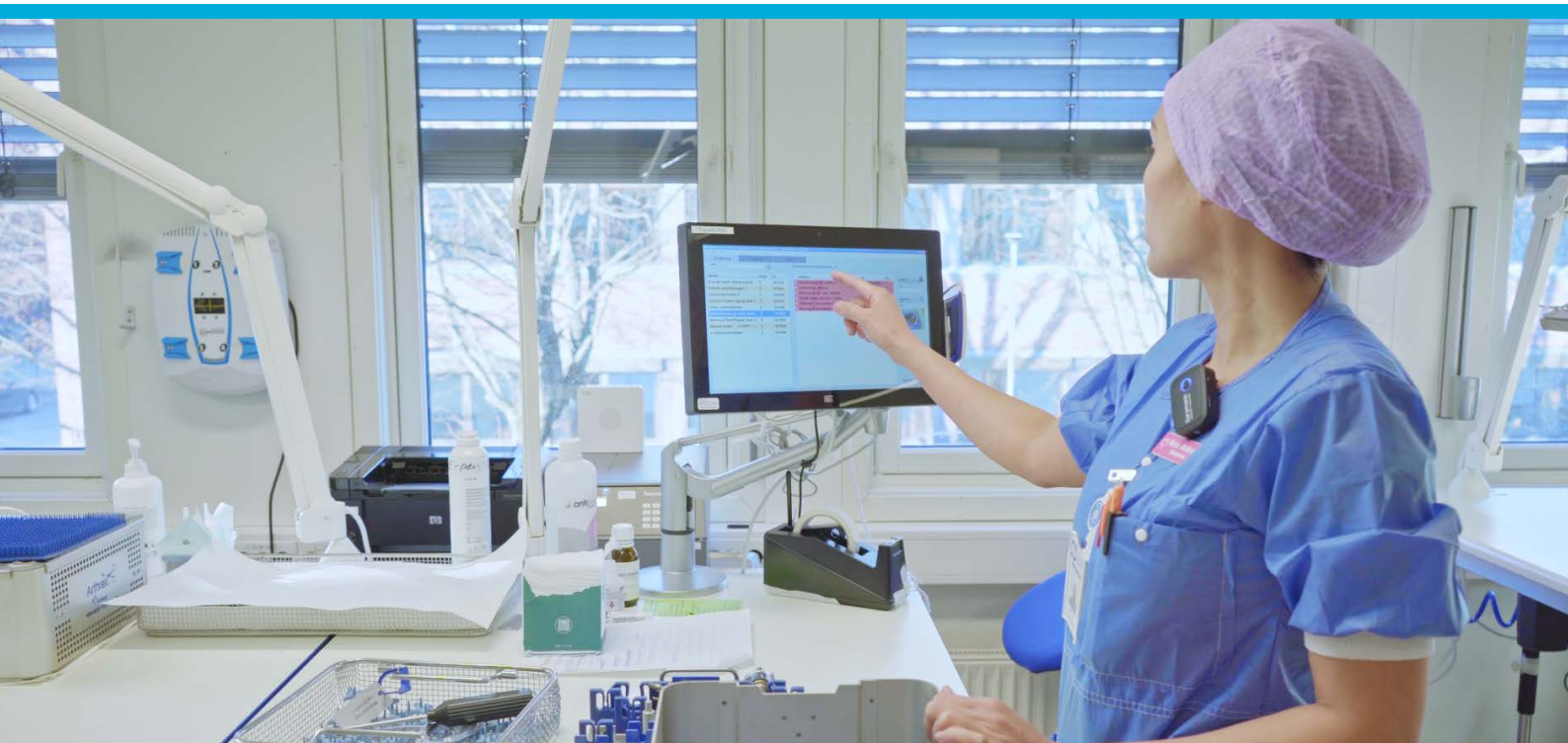
The solution also meets the requirements of traceability addressed in the new EU medical device regulations.

“Lovisenberg Diaconal Hospital depends on providing the utmost quality in everything we do. Our patients have to choose our services specifically, or else they will be transferred to one of the public hospitals,” says Ms. Glende Johnsen. “This means we need to make continuous improvements.”

“It is of utmost importance that we have the tracking system, and the GTINs, because when we utilise this system, all information is automatically routed to the national quality registers, as well as being transferred to our hospital’s EHR system,” emphasises Ms. Glende Johnsen. “If there is an increase in certain complications, we can easily seek out what kind of components have been used by monitoring potential anomalies in these registers.”

“The collaboration between GS1 and APX Systems is unique,” continues Ms. Glende Johnsen. “We scan each of the components with a single scan in the operating theatre. After that, the components can be traced in any area— inventory, patient journals, registers, invoicing and any other area of choice.”

“It is of utmost importance that we have the tracking system, and the GTINs, because when we utilise this system, all information is automatically routed to the national quality registers, as well as being transferred to our hospital’s EHR system.”



About the authors

Marit Glende Johnsen,
Former Head of Surgical and Sterile Department Lovisenberg Diaconal Hospital

Marit Glende Johnsen was Head of Lovisenberg Diaconal Hospital's Surgical and Sterile department until 2019 and currently provides consultation services to the department. She was the initiator in the development and implementation of the GS1 standards-based solution, including collaboration with APX Systems, which made the transition highly successful.

Fredrik W. Goborg
Key Account Manager
APX Systems

Fredrik W. Goborg has 30+ years within the computer industry. Last 10 years working in APX Systems with logistics and tracking systems. The areas are in health-vertical and also other verticals, like the food-industry. For the project at Lovisenberg, Fredrik W. Goborg was the project leader and continued as main contact for the hospital after the project was put in full production.

About the organisations

Lovisenberg Diaconal Hospital was established 1894 and is located in the Norwegian capital of Oslo. It is the leading hospital in Norway in the department of prosthetic surgery and complex shoulder surgery, and in the field of complex nose and sinus surgery, as well as in paediatric surgery.

The Surgical department consists of 12 operating theatres, which perform 38 surgeries per day. They handle predominantly orthopaedic cases; at least eight arthroplasties on a day-to-day basis, in addition to arthroscopic shoulder and knee surgery. It also has a substantial ENT-department that handles sinus surgery, as well as nose and ear surgery. In addition, they perform hernia and gall bladder surgeries.

lovisenbergsykehus.no

APX Systems delivers intelligent system solutions, including software and hardware for production and logistics needs. The company is located in Oslo, Norway and has departments in Oppdal and in Colombo, Sri Lanka. Within the health sector, APX Systems provides solutions—uniTRACE, uniOPERATION and uniORDER for sterile departments. These are used in several hospitals in Norway and Sweden, and are in demand rom several countries worldwide. The solution includes full equipment tracking in a sterile department with extraction of data from decontamination and autoclave. Sterile equipment, implants and consumables are registered in the operation theatre, and automatically updated to systems like EPJs, implant registers and other systems.

www.apx-systems.com

United Kingdom

EPC/RFID: An effective method for real-time asset management

Challenge

East Kent Hospitals University NHS Foundation Trust (EKHUFT) had thousands of assets and medical devices to manage across the trust's three acute sites. But with no digital or automated solution in place, efficiently tracking its extensive asset inventory of 1,470 beds and 37,000 medical devices became a near-impossible task.

Approach

Given the benefits of RFID (radio frequency identification) in retail to provide accurate stock visibility, the trust opted to introduce passive UHF EPC/RFID tagging as a means to track and trace the high-value equipment in the trust's medical equipment library.

5,000
medical devices and 1,470 beds tagged as a starting point

RFiD Discovery platform was directly integrated into the single, trust-wide medical engineering system

Real-time access to asset information, which included details of location and service due dates

98%
of very high-risk device compliance achieved for planned preventative maintenance

2gether support solutions

Following an inspection by the Care Quality Commission (CQC), the UK's care regulatory body, East Kent University Hospitals NHS Foundation Trust noted that a change was needed when monitoring its high-value pieces of equipment.

The asset management process in place at that time made tracking and tracing high-value items a challenge. Much of the equipment was managed manually and, as a result, pieces were frequently misplaced or registered as "missing."

By introducing RFID technology, the trust was able to mostly automate its asset management processes, to improve efficiencies and traceability across the organisation.

Andy Barrow

Limited visibility impacting patient safety

Similar to many NHS trusts in England, EKHUFT found it challenging to track its valuable assets across each of the trust's three individual hospital sites.

Following an inspection by the CQC in 2014, the trust realised it needed to make a change. The CQC had submitted a recommendation to improve the trust's asset management processes, particularly for high-value items.

One of the most prominent problems was the limited availability of clean infusion pumps. Since there was no visibility of where equipment was located throughout the hospitals, it meant that wards had to regularly borrow vital equipment from others—a situation that posed a risk to patient safety.

Taking its cue from the retail industry, EKHUFT decided to introduce RFID technology into healthcare. For years, retail stakeholders have benefitted from using RFID, enabling the industry to gauge visibility of stock in real time. Applying similar principles to its equipment stock, the trust implemented RFID in order to track and trace individual assets across each site.

Delays in patient care

EKHUFT had thousands of assets to manage and keep track of across the trust: 1,470 beds and 37,000 medical devices.

Monitoring where each individual piece of equipment was, whether the service date was due or whether it was even still in date and fit for purpose were all labour-intensive tasks.

When conducting audit trails of equipment due for service and maintenance, EKHUFT found there was no way of monitoring any of its assets in a quick and effective manner.

Often, staff were left using equipment with no indication of whether it was safe to use on patients. Equipment frequently went missing, leaving staff wasting valuable time in search of the machinery they needed to do their jobs. The inherent inefficiencies of this process resulted in delays to patient care.

Without complete visibility of what assets were available and where they were located, staff resorted to purchasing additional equipment to compensate that, in turn, increased the trust's procurement costs.

Access to real-time asset information

The medical engineering team decided to implement RFID technology to resolve the trust's equipment management challenge, supported by track and trace solution, RFiD Discovery. Using EPC/RFID tags would allow them to quickly identify equipment while receiving real-time traceability information.

To enable them to do this, the medical engineering team used the GS1 Global Individual Asset Identifier (GIAI) to uniquely identify each item separately. Each of the tags is encoded with a GIAI-96 EPC, in compliance with the GS1 EPC Tag Data Standard (TDS), and read in the 865-868 MHz band by means of the GS1 UHF EPC/RFID air interface protocol.

Initially, active RFID tags were used to individually label the assets, starting with approximately 5,000 medical devices and 1,470 beds in the medical equipment library. However, following the successful use of active RFID tags, the trust then decided to expand the process to use passive EPC/RFID tags, also incorporating two-dimensional (2D) GS1 DataMatrix barcodes to efficiently track and trace all necessary devices.

To synchronise records, the RFiD Discovery system was integrated into the single, trust-wide medical engineering system. By integrating these two individual systems, the medical engineering team was able to gain access to real-time asset information, including location information and planned preventive maintenance (PPM) due dates of each of the products.

Now with passive RFID tagging in place, a larger, portable reader machine is wheeled around each of the hospital locations. The reader interacts with each of the GS1-compliant passive EPC/RFID tags on the equipment and automatically registers the transmissions from each asset to update the medical engineering system in real time. This enables staff to quickly scan the ward and determine what equipment they have, and which pieces have an overdue service date. A notification is sent directly to the ward manager and the medical engineering team for action and reporting.

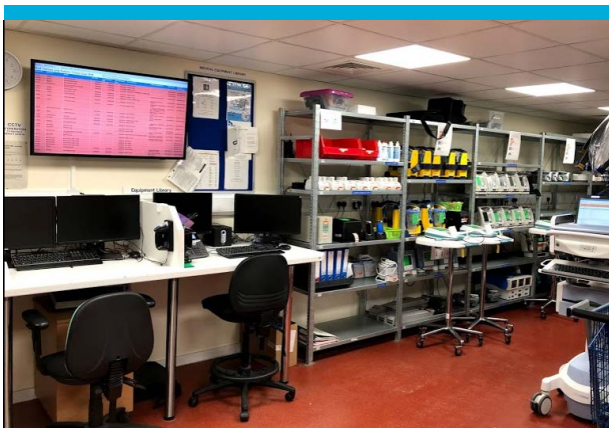


Figure 1: EKHUFT's medical equipment office

"GS1 standards and EPC/RFID-based tracking have taken medical engineering to another level, enabling higher compliance of preventative maintenance and spend on medical devices."

Andy Barrow
Head of Medical Engineering and Radiology Maintenance
East Kent University Hospitals NHS Foundation Trust

Improved productivity and patient safety

The asset management process that is supported by GS1 standards-based EPC/RFID has had a direct, positive impact on both the medical engineering and clinical teams, as well as on patients.

Time is no longer wasted looking for medical devices, allowing medical engineers to quickly identify and locate devices within minutes. And clinical staff now has access to the right equipment, in the right place and at the right time, thus preventing unwarranted delays to patient care.

The trust has realised a consistent increase in overall PPM compliance, achieving 98% of very high-risk device compliance.

Fewer medical devices have been purchased since all standard devices are managed through the medical equipment library. With locations tracked alongside them, the trust can ensure that just the right amount of equipment is available and in operation, with nothing sitting in cabinets or hidden and unused in wards.

Now, critical PPM activities can be performed on time and even ahead of schedule, so that clinical teams can rest assured that any equipment they use has been assessed and validated as safe for patient use.

From a financial perspective, the new asset management process has reduced the amount of money spent on procuring surplus equipment to replace missing items—driving operational efficiencies throughout the hospitals. The real-time reporting alerts the team of any discrepancies so that swift action can be taken.

The trust is now in a better place to monitor the 37,000 medical devices in operation across the three acute trust sites. In recognition of its great work, EKHUFT received the Lord Carter Innovation Award in 2017, and continues to adopt GS1 standards as part of its aim to drive efficiencies across the trust.

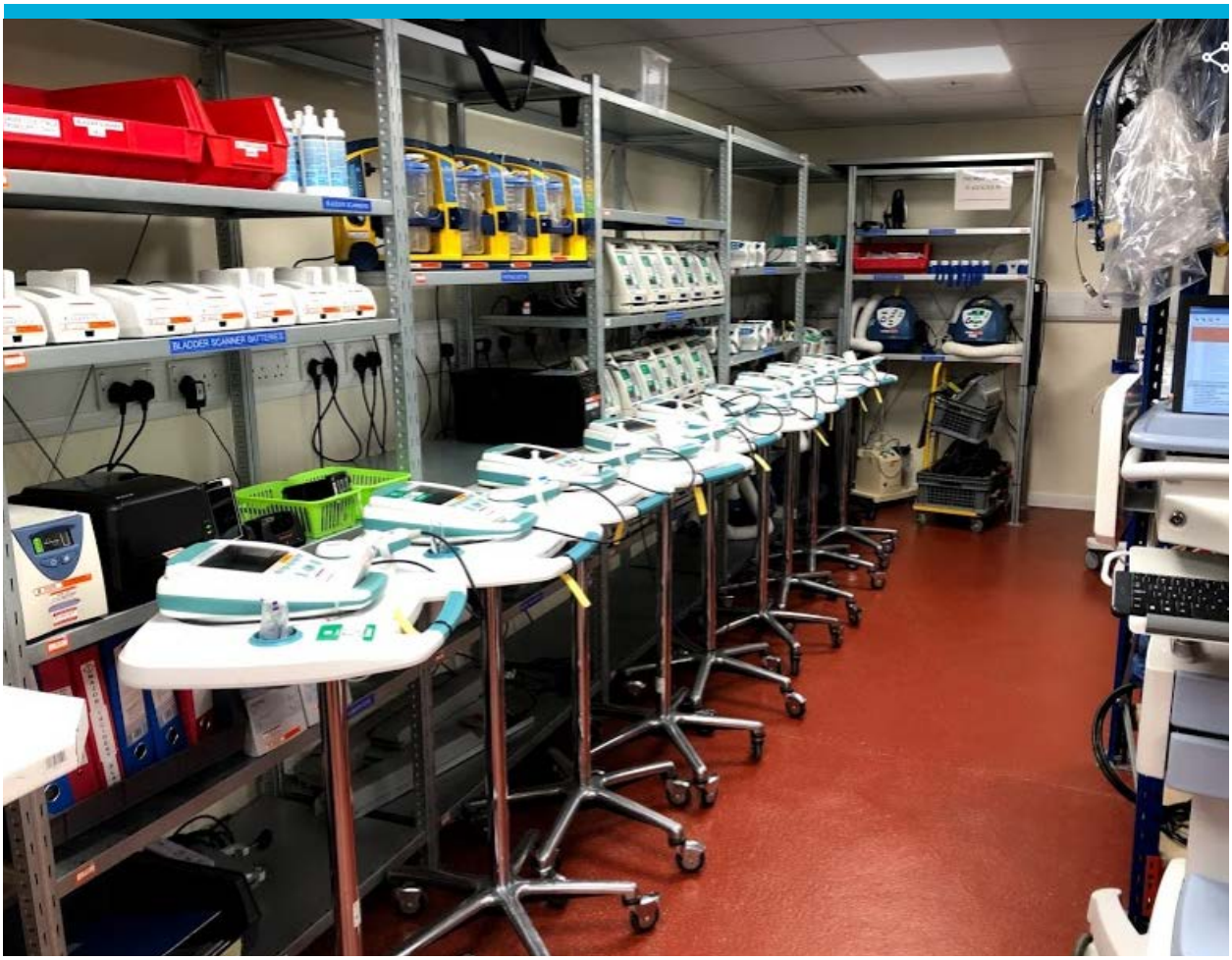


Figure 2: RFID tagged medical equipment assets

Looking ahead

EKHUFT is currently exploring the needed scope to introduce GS1 Global Location Numbers (GLNs), to uniquely identify sub-locations within each of the hospitals across the trust. This will allow them to make their location identification more specific, improving the accuracy of asset traceability.

Figure 3: UHF passive tags used on infusion pumps for tracking

About the author

Andy Barrow,
Head of Electronics, Medical Engineering and Radiology Maintenance,
East Kent Hospitals University NHS Foundation Trust

Andy Barrow is Head of Medical Engineering and Radiology Maintenance for 2Gether Support Solutions, a wholly owned subsidiary of East Kent Hospitals University NHS Foundation Trust.

Mr. Barrow has worked for the trust in medical device management for 30 years and across all modalities, both as a technician and as a manager. He leads a team of more than 40 technical and administrative staff who look after approximately 37,000 assets over three acute hospital sites and two smaller hospitals.

Common standard devices are managed through one of their three medical equipment libraries, using passive or active RFID tracking. Mr. Barrow's teams also look after 16,000 other devices across the community trust of East Kent, ranging from the simplest handheld devices, up to large, fixed-modality X-ray rooms, CT scanners and MRI scanners.

About the organisations

East Kent Hospitals University NHS Foundation Trust (EKHUFT) is one of the largest hospital trusts in England, with five hospitals and community clinics serving a local population of around 750,000 people. In October 2017, a wholly-owned subsidiary, 2Gether Support Solutions, was formed to provide managed equipment services to the trust.

EKHUFT provides some specialist services for a wider population, including renal services in Medway and Maidstone, and a cardiac service for all of Kent, based at William Harvey Hospital, Ashford. The trust also has a national and international reputation for delivering high-quality specialist care, particularly in urology, kidney disease and vascular services.

EKHUFT has also been ranked first in Kent for clinical research studies. As a teaching trust, it plays a vital role in the education and training of doctors, nurses and other healthcare professionals, working closely with local universities and King's College University in London.

www.ekhuft.nhs.uk

2gether Support Solutions was formed in April 2018 as a new, wholly owned subsidiary company of one of the largest NHS Foundation Trusts in the UK, East Kent Hospitals University NHS Foundation Trust. 2gether Support Solutions provides facilities, property, procurement and professional services in the South East. The company, a wholly owned subsidiary of one of the largest NHS Foundation Trust's has social values at its core.

www.2gethersupportsolutions.org

United Kingdom

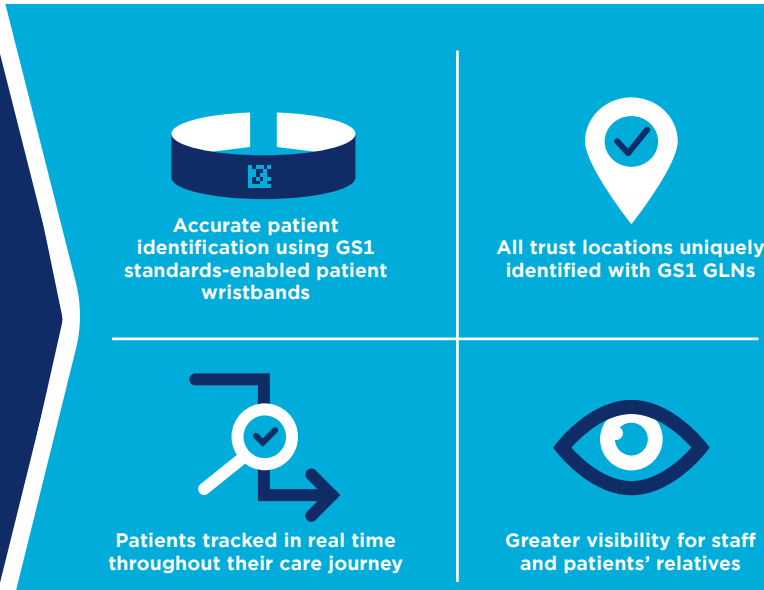
How positive patient identification can provide peace of mind for patients and their relatives

Challenge

Staff working on the breast ward at Leeds Teaching Hospitals NHS Trust (Leeds) faced numerous, daily calls from patients' relatives who wanted up-to-date care information about their loved ones. As a post-operative ward, having access to accurate information about a patient's status is invaluable for relatives. However, to get this information, staff had to call different wards and departments to check, each time an update was needed.

Approach

Using GS1 Global Service Relation Numbers (GSRNs) encoded in barcodes on patient wristbands, as well as GS1 Global Location Numbers (GLNs), staff are now able to link accurate location information for each patient to the electronic patient record (EPR). With GS1 standards, details about a patient's status can be provided in real time, making the right information easily accessible to staff when needed—and to relatives when they call.



NHS
The Leeds Teaching Hospitals
NHS Trust

For the breast post-operative ward at Leeds, being able to provide patients' relatives with accurate information is a vital part of its daily practice.

Yet, it was a significant challenge for staff members to track and trace patients as they moved around a busy hospital between wards and different departments, such as x-ray, operating theatres and recovery.

The staff didn't have access to real-time information on a patient's location, so they had to call a number of departments to get updates.

Since Leeds had already implemented GS1 standards-enabled patient wristbands and GLNs to identify locations throughout the hospital, the trust decided to use these standards along with its EPR system to provide the visibility needed by staff.

Mark Songhurst

Keeping track of patients

Surgical procedures are not only stressful times for patients, but also for their relatives. And, some surgery recovery times take longer than others, varying significantly from patient to patient. During these recovery periods, the greatest comfort that can be given by staff to a patient's relative is accurate information on how the patient is progressing through the stages of surgery and post-surgical recovery.

Unfortunately, in most of England's NHS trusts, there's no easy way to track the location of patients that doesn't involve the staff making numerous phone calls between wards and with relatives. Not only does this approach take a significant amount of time, it offers little reassurance to a patient's relatives at a very sensitive time.

Leeds wanted to change this situation. The trust decided to find a way to accurately identify and trace a patient's care journey throughout the hospital. For the staff, this would improve their visibility of a patient's progress and, in turn, allow them to communicate accurate information back to relatives in a timely manner.

Providing patient updates

Leeds staff were increasingly handling calls with queries from relatives about the status of patients. In fact, staff were spending more time tracking down patients than they were focusing on care.

For staff working on the breast surgical ward, once their patients had left the ward for pre-operative tests, procedures or surgery, staff were left with no visibility of where their patients were or when they were likely to return to the ward. Without this ability to trace a patient, they found it challenging to prepare for their eventual return.

This meant that staff had to put numerous calls into several wards and departments for updates on a patient's status—from whether "they had arrived" to if their "procedure had taken place."

Patients' relatives would frequently call the ward to receive an update on their care, but with no oversight, the staff were unable to provide them with the information they desired.

Staff needed a solution where they would have access to real-time patient and location information—a system that would allow them to track and trace their patients' journeys once they had left the ward.

Rather than limiting their ambitions to a single ward and a limited patient population, Leeds wanted to provide an organisation-wide system that would help drive digital transformation throughout the trust.

"Scan4Safety will enable 24/7 tracking of our patients and allow our endoscopy, radiology and theatre teams to be as efficient as possible. It will give clinicians the ability to manage their patients more closely and safely."

David Berridge
Deputy Chief Medical Officer and Executive Sponsor Scan4Safety
Leeds Teaching Hospitals NHS Trust and West Yorkshire Association of Acute Trusts (WYAAT)

Real-time patient care journey

As one of the six demonstrator sites in the Department of Health and Social Care's Scan4Safety initiative, Leeds was well positioned to implement a patient-traceability system as it already had GS1 standards in place. So, using GS1 identifiers encoded into barcodes, they were able to start developing their system.

The GS1 Global Service Relation Number (GSRN) was used to uniquely identify patients by encoding the identifier into a barcode on their patient wristbands, while the equivalent was done using GS1 Global Location Numbers (GLNs) for hospital locations such as the ward, bed bay or even the patient bedside.

In doing so, Leeds was in a position to be able to accurately identify its patients in combination with any of the trust-wide locations. At any point where a patient was moved to a new location, the GLN would be scanned along with the GSRN on the patient wristband to provide an accurate patient status at all times.

The breast surgical ward was chosen as the initial ward for the GS1 standards-based solution since it is a self-contained unit with its own operating theatres and recovery area. (From a trust's perspective, if the solution did not work on this ward, people could still walk around the corner and speak to each other.)

The trust decided to link the two GS1 identifiers--the GSRN for each patient and GLN for each location, and align them within the trust's EPR system. By doing this, Leeds was able to monitor the status of each patient and their movements throughout the care journey. Patients could be tracked from the ward, through to surgical preparation and recovery, and back again—all without the need to make phone calls.

To provide the necessary real-time access to patient information when needed, the trust synchronised its EPR system with the patient whiteboard at the ward's clinical station. Now, each time the individual patient record is updated with location information, the details are automatically updated in real time and uploaded directly onto the whiteboard. This provides staff with clear visibility of the information needed at a prominent location on the ward.

To take this system to other parts of the trust, the challenge has been to provide a nursing tool that could help with all situations. With this goal in mind, Leeds has been working to assign a GLN to every bed space in the hospital.

With more than 2,000 treatment locations, this has proven to be a painstaking task. Using the GLN and GLN extension AI, the trust has identified all treatment spaces in the organisation – even where there are multiple spaces in the same room.

In addition, the trust's digital and informatics teams have enabled the in-house electronic health record (EHR) and PPM+, the trust-wide hospital EPR, to read the GLN and its extension, and for the local electronic whiteboard to be updated.

The team is commencing a pilot phase with a system that will free up time for both clinical and nursing staff, allowing the same process that changes the whiteboard to update the patient administration system.

The EPR is specific to the patient's care within a single setting such as in hospital. The EHR is a larger cross-organisational record of all of the patient's care, and includes details from multiple care sectors –from the hospital, community and social care.

The GLN extension AI (application identifier) enables the identification of a physical location using a data carrier present at the location itself, AI (414) physical location or AI (254) GLN extension component.

PPM+ is Leeds' trust-wide hospital EPR which captures information into the patient record from all aspects of the patient's care, such as clinical letters, radiology results and pharmacy. It connects at regional level to the Leeds Care Record that links up with wider patient information from social care, mental health and the patient's doctor records.

"Taking the time to fully understand the potential of GLNs in the organisation (and not make rushed decisions) has allowed us to build a strong dataset that enables patient tracking in real time.

The benefits that we are exploring include:

- *Clinical staff knowing the location of their patients at all times*
- *Provision of a 'live bed state' for the organisation*
- *Ability to track patients who have been treated in the same space, at the same time*

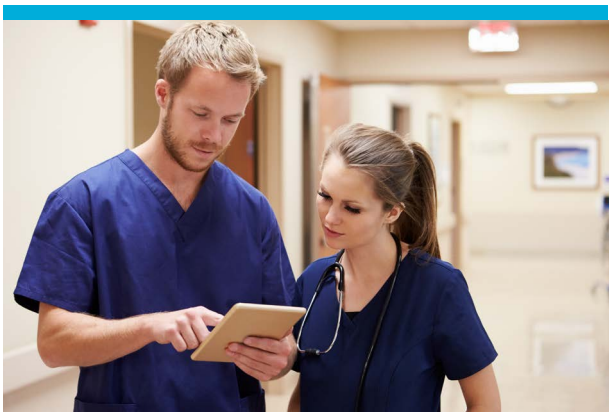
All of these have a great impact on the safety of patients. Thanks to the work of the digital and informatics team here at Leeds, we are making world-leading changes to the benefit of our staff, clinicians and, most importantly, our patients and their relatives and carers."

Mark Songhurst
Project Manager, Scan4Safety
Leeds Teaching Hospitals NHS Trust

Full visibility of the patient care journey

With patient location information readily accessible in real time, the Leeds staff now have full visibility of each patient's care journey.

In the initial weeks, they experienced a reduction in the volume of calls to the ward from relatives. And, because the staff have a better idea of the timing associated with a care journey, they are able to provide well-informed estimates as to when patients will be out of recovery, are able to take calls or when they are back on the ward. In turn, this helps to reduce the volume of internal calls between wards and departments.



The traceability provided also enables the staff to be much more equipped to prepare ahead of time for anything that patients might need for post-operative care.

While financial savings are difficult to track, patients report that they feel the staff are providing a better level of care. Nursing and theatre staff are able to be more proactive in planning. Patients' relatives are reassured when contacting the ward for updates. Now, staff at Leeds can provide the same level of exemplary care and information they give to their patients to their patients' relatives.

Operational efficiency has dramatically improved for the ward staff since they can more easily check a patient's status. And, it is this efficiency that enables them to provide patients' relatives with greater support.

Locating all patients 24/7

The trust is continuing to make improvements to the traceability system. It is rolling out the transfer of patients using the GLN, which speeds up the nursing process by combining data with care at bedside. This new process also ensures that the trust knows the location of all of its patients—a goal that is aligned with Scan4Safety's 24/7 aspiration.

Using the data provided by GS1 standards, the digital and informatics teams are rapidly building a "live bed state" for the organisation—a real-time bed status that no longer relies on manual intervention.

As knowledge of how GLNs can be used increases, Leeds is also exploring the tracking of patient data and potential sources of cross infection.

About the author

Mark Songhurst
Project Manager, Scan4Safety
Leeds Teaching Hospitals NHS Trust

Mark Songhurst has worked in England's NHS for 20 years. For the past three years, he has been a workstream leader and is currently project manager for Scan4Safety at Leeds Teaching Hospitals NHS Trust. Having worked for 13 years in the internal audit organisation, he has an in-depth understanding of the processes across the hospital that help to deliver good patient care.

Mark Songhurst is also a Future-Focused Finance Value Maker and a School of Health and Care Radicals Change Agent. He is extremely passionate when it comes to working with people and understanding how they can collaborate across the NHS to make lasting changes on services provided to patients. He was awarded the Future-Focused Finance Award by the Healthcare Financial Management Association in 2018, in recognition of his work at local, regional and national levels to improve NHS Finance.

His willingness to accept change, to walk alongside NHS staff of all levels and enabling them to engage with change and try something new, is helping drive the Scan4Safety project forward at Leeds.

About the organisation

Leeds Teaching Hospitals NHS Trust is one of the largest teaching hospitals in Europe. The trust is a regional and national centre for specialist treatment, a world-renowned biomedical research facility, a leading clinical trials research unit, and also the local hospital for the Leeds community.

It is one of the largest and busiest acute hospital trusts in the UK and is also one of the largest employers in the Leeds region with over 18,000 staff. The work they do serves to support the health and well-being of the community by playing a leading role in research, education and innovation.

The trust operates on a budget of £1.3b, providing local and specialist services to its immediate population of 770,000 and regional specialist care for up to 5.4m people.

www.leedsth.nhs.uk

United States

Fulfiling a vision of digital transformation with GS1 standards

Challenge

The Franciscan Missionaries of Our Lady Health System (FMOLHS) is a non-profit healthcare system serving more than half of Louisiana's population. As a Catholic ministry, FMOLHS provides $39 million yearly in non-reimbursed care and community support for the underprivileged. Challenged by the rising costs and growing complexity of delivering quality healthcare, FMOLHS needed to improve its operational efficiencies, control costs and remain focused on what mattered most—the safety and care of its patients.

Approach

To help drive the digital transformation of its critical processes, FMOLHS took the strategic step to implement GS1 standards. Working closely with its suppliers and GS1 Healthcare US® Initiative solution providers, the health system laid a firm standards-based foundation that integrated with its software-based systems, to manage and control product inventory and location information.

85%

of implants that come into the warehouse are uniquely identified with Global Trade Item Numbers

Improved inventory management, providing just-in-time delivery of products to warehouse locations

Increased patient safety with barcodes scanned in operating rooms to capture detailed data about products used in procedures

Better outcomes based on information about the cost per case analysed by physicians about products and procedures

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM

The Franciscan Missionaries of Our Lady Health System is a healthcare innovator, with hospitals, clinics and physicians located throughout Louisiana —making it the state's largest health system. In 2012, the Vice President of Supply Chain led the strategic decision to implement GS1 standards to support the automation of the health system's supply chain and clinical processes. Since then, implementing GS1 standards has proven to be a multi-year undertaking, involving all five hospitals, their subsidiaries and affiliate organisations and several community hospitals.

"With unique identification in place, we explained [to suppliers] how we could all benefit, especially our patients. By using the GTIN, we confidently pull the right product, for use in the right procedure, for the right patient, and at the right time."

Sandi Michel
System Director, Supply Chain Strategy, Data Standards & Interoperability
FMOLHS

Sandi Michel

A strategic decision for patient safety

As a health system focused on patient safety and outcomes—from blood banks to physicians' practices to imaging centres— and with a state-wide footprint from Baton Rouge to Bogalusa and from Lafayette to Lake Charles—FMOLHS has made GS1 standards an important pillar of the institution.

"By implementing global standards, our primary goal has been to improve patient care and safety," says Sandi Michel, System Director of Supply Chain Strategy at FMOLHS. "To do this, we are focused on significantly increasing the efficiency of our operations and the control we have over the products we use."

Starting with standards for automation

FMOLHS commenced to lay the foundation of GS1 standards by working with its suppliers. Early on, the hospital brought together about 80 representatives from its manufacturers and group purchasing organisation to review its standardisation vision and strategy.

"We requested that they start using the GS1 Global Trade Item Number® (GTIN®) encoded in a barcode to uniquely identify each of their products," advises Ms. Michel. "With unique identification in place, we explained [to suppliers] how we could all benefit, especially our patients. By using the GTIN, we confidently pull the right product, for use in the right procedure, for the right patient, and at the right time. We told them: 'We want to be 100 percent driven by GS1 standards and this strategy requires that you are, too.'"

Since this initial meeting, FMOLHS continues to work with its suppliers to implement GTINs encoded in GS1 two-dimensional (2D) GS1 DataMatrix barcodes. The health system has also conducted pilots with seven manufacturers to share product data (based on GTINs) for purchasing transactions.

"We soon moved to a GS1-certified data pool and started sharing product data (i.e., GTINs and other valuable information) with our suppliers via the Global Data Synchronisation Network™ (GDSN®)," says Ms. Michel. "Our plan has been to standardise on the use of the GTIN for all items purchased and used inside our system. While we are always looking for the best products to use for our patients, standardising on one, two, or even three products gives us the advantage of having accurate and complete data for comparison purposes and, ultimately, for making the best buying decisions."

As FMOLHS has become increasingly committed to standardisation, it has also become committed to working only with manufacturers that use the GS1 system of standards.

Office of data standards and interoperability

FMOLHS took an unprecedented step to establish a separate group to drive the implementation of GS1 standards—the Office of Data Standards and Interoperability. The group includes Sandi Michel and five managers who were charged with taking GS1 standards "as deep into the FMOLHS system as possible."

"Rather than 'adding on' the standards implementation responsibility to a person's existing job, we decided that a dedicated team was needed to drive the desired change," says Ms. Michel. "We worked across the health system with operations professionals, supply chain specialists, clinicians and nurses to transform processes with standards."

Executive support is also critical for the team's success. "Our Vice President updates the CFO, CEO and all of the hospitals' CEOs about our progress," explains Ms. Michel. "We could not have achieved all that we have without this high-level support."

After six years of accomplishments—progressing through each phase of implementing GTINs, GLNs, the GDSN and clinical integration—the five managers moved into positions in other supply chain organisations, such as Supply Chain Strategy, MMIS and Resource Utilisation and Value Analysis, where today they continue to influence the use of GS1 standards throughout the health system.

"Today, approximately 85% of implants that come into our warehouse are uniquely identified with GTINs," says Ms. Michel. "We have evolved to the point where the use of GS1 standards is now a requirement for manufacturers that supply products to our health system. It's that important to us."

Another building block of the GS1 standards foundation is the GS1 Global Location Number (GLN) that uniquely identifies each location within the FMOLHS health system. Today, all FMOLHS locations have each been assigned their own GLN.

"Today, approximately 85% of implants that come into our warehouse are uniquely identified with GTINs. We have evolved to the point where the use of GS1 standards is now a requirement for manufacturers that supply products to our health system. It's that important to us."

Sandi Michel
System Director, Supply Chain Strategy, Data Standards & Interoperability
FMOLHS

"We created a hierarchy of locations—from the five large hospitals to the smaller hospitals and the physician clinics, all the procedure areas and other facilities, such as imaging or tissue banks," says Ms. Michel. "We assigned GLNs to places where products are stored, like a cart in the 'med-surge' area, a closet in a given department, or even a shelf in a closet on a certain floor. This precise level of identification is needed to better manage inventory and ultimately, deliver outstanding patient care."

Supporting the best unit of measure

The use of GTINs, GLNs and GDSN has enabled FMOLHS to better manage its inventory and provide just-in-time delivery of needed products. "By using GTINs, we know exactly what products we have and how many," Ms. Michel says. "And the GLNs tell us specifically where they are."

Using GS1 standards and its warehouse management system provided by Tecsys, a GS1 Healthcare US Initiative member, FMOLHS can now track the locations of products throughout the system with a few keystrokes.

In fact, FMOLHS is using GS1 standards to provide the "best unit of measure" to any location in its system identified by a GLN. Whether a case, box or single unit, the best unit of measure—and in the requested quantity—is ready for just-in-time delivery. For instance, if an FMOLHS clinic needs just three items out of a case of 24, the warehouse is able to divide the order, scan the items' barcodes to capture the product data, and then put the three items in a tote headed for the clinic, with the rest divided among other facilities.

L to R: James Phillips, Supply Chain Client Services Manager; **Brittney Sprague,** Supply Chain Client Services Manager; **Sandi Michel,** System Director of Supply Chain Strategy; **Emmett Robbins,** Supply Chain Client Services Manager; **Michelle Keller,** Supply Chain Client Services Manager; **Lakisha Bowie,** Strategic Sourcing Manager

"Each item or 'unit' is labeled with a GTIN encoded in the GS1 DataMatrix barcode so that we can scan, track and manage the movement of the single unit," advises Ms. Michel. "We expect to realise cost savings by eliminating over-ordering. If we have too many of an item in a location, we can move it to another location that needs it. We can run inventory reports on what products we've purchased and where they are, using the GTINs and GLNs."

"Our UDITracker system can download and report on implantable product information—stored in the Epic EHR system—by patient record. That includes the implant's size, serial number, batch/lot number and expiration date, to name a few. If a product is recalled, we can easily run a report to identify each patient who received that implant."

Sandi Michel
System Director, Supply Chain Strategy, Data Standards & Interoperability
FMOLHS

Taking standards to the OR and EHR

As products are used in the FMOLHS operating rooms (ORs), nurses scan their barcodes to capture data about the products used in patient procedures and for the Epic EHR system. "By scanning barcodes, we are using virtually a foolproof method to capture crucial medical information and populate each of our patient's health record," says Ms. Michel.

Scanning barcodes directly into patients' healthcare records eliminates mistakes when capturing and recording the correct GTIN, expiration date, batch/lot number, and serial number since there is no human intervention, i.e., mistyped, transposed or omitted numbers.

Before scanning, a product's digits or alphanumerics could be transposed when typed into a patient's records. The error would go undetected unless the record was accessed for an explant, a recall or other reason. "This is very risky to the patient receiving implantable life sustaining and life supporting devices," advises Ms. Michel. "Now, scanning in the operating room eliminates or mitigates that risk."

Scanning barcodes also updates inventory records in the Tecsys warehouse management system and in FMOLHS' medical device management system called UDITracker®, provided by Champion Healthcare Technologies, a GS1 Healthcare US Initiative member.

"Our UDITracker system can download and report on implantable product information—stored in the Epic EHR system—by patient record," explains Ms. Michel. "That includes the implant's size, serial number, batch/lot number, and expiration date, to name a few. If a product is recalled, we can easily run a report to identify each patient who received that implant."

"Because nurses scan tissue product barcodes, we can monitor the tissue on hand by expiration date, removing those that are about to expire to prevent using them in error," continues Ms. Michel.

In the event of a recall, each location can be alerted to pull the products from inventory within minutes—a patient safety measure that may have taken days or even weeks before GS1 standards were implemented.

"If the item is sitting on the shelf, we access the automated inventory management system and go right to the shelf to pull the product," says Ms. Michel. "If the product is an implantable device, we can search in the system and locate the serial number, patient's account, and notify the surgeon. The surgeon would then notify the patient."

Send clinician back to patient care

If Joint Commission International (JCI)[1]—the hospital accreditation organisation—conducts an audit, FMOLHS has a complete and accurate picture of inventory labeled with GS1 standards, throughout the system. By using GTINs linked to case numbers—rather than individual patient names— FMOLHS can stay within the confines of Health Insurance Portability and Accountable Act[2] (HIPAA) rules.

1 For more information about JCI, see www.jointcommissioninternational.org.
2 For more information about HIPAA, see www.hhs.gov/hipaa/index.html.

Educating nurses about scanning barcodes

"Our nurses were very receptive to scanning barcodes versus manually entering the product data into our systems," says Ms. Michel. "It saves them a significant amount of time and is much more accurate since inputting a string of digits can be prone to errors."

Ms. Michel and her team have worked with nurses to educate them about "which barcode" to scan on packages when multiple barcodes are present.

"They [nurses] have become so familiar with us that they still call to ask questions and save packages with barcodes that produce errors," Ms. Michel explains. "We investigate why the barcode didn't properly scan and fix the problem with the supplier, so that it doesn't happen again. It takes time, but it's worth the effort since our nurses will save time in the future and the information captured will be accurate in our patients' records."

As FMOLHS has gained more and more experience with scanning barcodes, they have been able to provide valuable feedback to manufacturers. With small tubes where conventional scanning proved difficult, for example, manufacturers found that the GS1 DataMatrix barcode was needed.[3] The 2D GS1 DataMatrix is a robust barcoding solution for products with limited space since it holds a significant amount of information within a small footprint.

FMOLHS also found barcodes printed on reflective material could be difficult to scan, so they developed workarounds, while sharing this finding with manufacturers.

The analysis included the cost per case, by procedure, by physician and by products used. Today, patient outcomes are also considered as well as other types of information like labour costs, time in the OR, facility overhead and reimbursements.

"Without standards and the traceability they enable, this level of evaluation would be difficult, if not impossible," says Ms. Michel. "By using GS1 standards, our surgeons can now see what it costs for a procedure, the anticipated patient outcome, the length of recovery time—all the pieces of information invaluable to informed healthcare."

"We initially thought that physicians would not want to share this kind of information, but we were wrong," continues Ms. Michel. "They are not only proud of their work and successes, they also want to share and learn from each other."

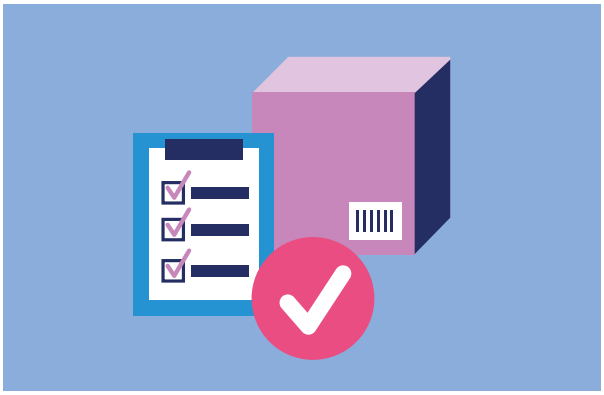
Detailed reporting is going to continue at FMOLHS, with the information going back to the CMO who collects data on the right products, the right physicians, the right facilities and the cost associated with every piece of patient care. The system is even considering analyses of reimbursements from insurance companies based on its detailed data.

"We're not really worried about the cost itself, but we want to be responsible to FMOLHS to say we are buying the right product by getting a 100% accurate picture," Ms. Michel says. "We're not interested in the cheapest. We're looking for the best."

Ms. Michel offers the recent introduction of a new product. Based on visibility about the cost and corresponding effectiveness of the product used in procedures, the CMO can now take this insightful information back to the physicians for further analysis or decision about whether to continue to use it.

"By using GS1 standards, our surgeons can now see what it costs for a procedure, the anticipated patient outcome, the length of recovery time— all the pieces of information invaluable to informed healthcare."

Sandi Michel
System Director, Supply Chain Strategy, Data Standards & Interoperability
FMOLHS



3 Centers for Disease Control and Prevention. (2018). Scanning Two-Dimensional Barcodes Enhances Vaccine Clinical Practice. Retrieved from https://www.gs1us.org/industries/healthcare/standards-in-use/cdc.

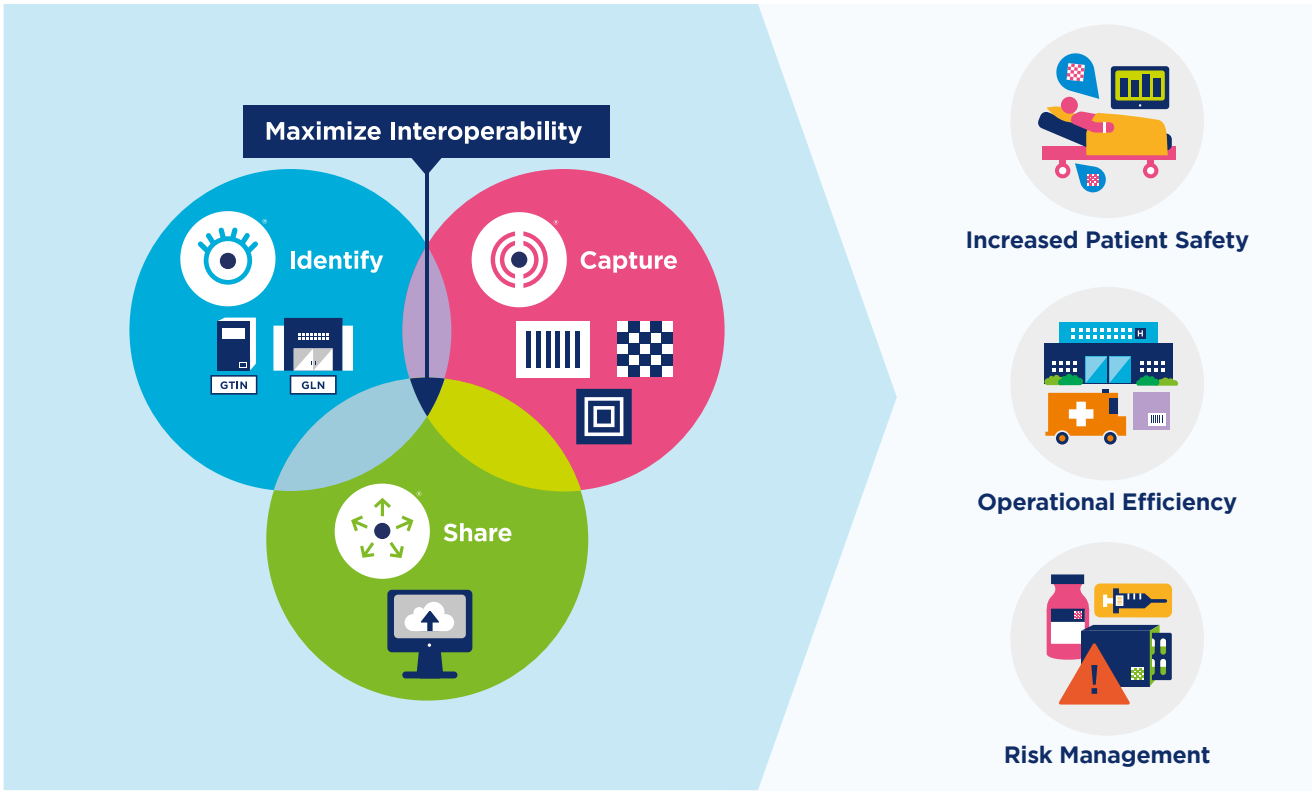


Figure 1: GS1 standards for identifying, capturing and sharing information—about products, business locations and more—make it possible to follow prescription drugs and medical devices from the point of manufacture through to the point of care; improving inventory management, increasing patient safety and delivering better outcomes.

Collaborating for multiple wins

Ms. Michel recommends to "just get started" and work with GS1 US to learn about implementation best practices.

The FMOLHS system-wide use of GS1 standards is truly one of the most comprehensive examples in a healthcare environment.

"Using GS1 standards and standardisation is a win-win in automating our business and clinical processes. It's a win for the patient in increased safety, it's a win for the nurses and clinicians in time-savings, accuracy and tracking. It's a win for the physicians that information is captured in a patient's record and they can match outcomes to products and procedures. It's a win for hospital management because data helps shape policies and protocols."

Sandi Michel
System Director, Supply Chain Strategy, Data Standards & Interoperability
FMOLHS

They have chosen to fully leverage global standards to realize widespread efficiencies, cost- and time-savings, as well as delivering patient safety practices to a greater degree than was once possible.

About the author

Sandi Michel
System Director of Supply Chain Strategy, Data Standards & Interoperability
Franciscan Missionaries of Our Lady Health System

Sandi Michel has worked with FMOLHS for ten years. Mrs. Michel brings 30 years' experience in operations and technology with AT&T. She held senior level leadership positions as Vice President of Technology and Operations and Director for US Voice & Data Network Services for two of the largest Communications companies in the US. Ms. Michel earned a Master's Certification in Project Management through Steven's Institute of Technology and AT&T Bell Laboratories, and a Lean Six Sigma Black Belt. She has a Bachelor of Science Degree in Business Administration.
Ms. Michel served on the GS1 US Executive Leadership Committee for 2015-2016 & 2019-2020 and is a member of the GS1 US Industry Sponsor Group, and Provider Advisory Groups. She was the founder and director of the FMOLHS Office of Data Standards and Interoperability featuring GS1 Data Standards. In January 2019, Ms. Michel joined the Healthcare Transformation Group (HTG) representing FMOLHS. She has served on numerous AHRMM Committees and other advisory groups.

About the organisation

As a nonprofit, mission-focused Catholic healthcare ministry, the **Franciscan Missionaries of Our Lady Health System** gives special attention to citizens who are most in need. During the most recent fiscal year, FMOLHS provided more than $39 million in unreimbursed care and community support to the underprivileged.

FMOLHS brings together outstanding clinicians, the most advanced technology and leading research to ensure that patients receive the highest quality and safest care possible. This commitment is grounded in a history that is more than 100-years-old, but reflected today by a strategic vision of transforming healthcare through superior performance and excellent patient care.

fmolhs.org


RB1
RB2

Suppliers

Responsible for the medicines and medical devices needed at all levels of patient care, manufacturers need to make sure they are doing this as safely and accurately as possible. Using GS1 standards helps to ensure they know where products have come from, where they're going, and that they are safe for use. Take a look at the following case studies to see how they're doing this.

Brazil

Aché Laboratories successfully implements GS1 standards to ensure traceability

Challenge

With a growing global demand for drug traceability, Laboratories (Aché) needed to implement a traceability system that would help it track and trace its pharmaceuticals throughout the supply chain—from production to healthcare providers.

Approach

Even though Brazilian regulation helped to define "what and how" traceability should be implemented, Aché found that to be compliant, it would need to start the project from "scratch." Patient safety was Aché's top priority as the company implemented a traceability system, enabled by GS1 standards and aligned with the needs of consumers and the requirements of government.

100%

of secondary and tertiary packages have GS1 barcodes

aligned with national and most international traceability regulations

Applying global identification and barcode standards

180 million

drug packages are labelled with GS1 DataMatrix barcodes

aché
mais vida para você

Every company that is part of the healthcare supply chain prioritises offering its patients and consumers the best products and services, always focusing on patient and consumer safety. In today's healthcare industry, it is essential for companies to remain competitive. With this in mind, Aché Laboratories considers innovation to be an important part of its growth strategy—one that is consistently executed.

Aché's decision to implement the drug traceability project at its laboratory in 2018 was based on Brazilian regulatory requirements and the growing global demand from consumer markets. And considering the opportunity to innovate, Aché accepted this challenge.

Why was implementing traceability a challenge?

First, there had not been a similar drug traceability regulation in Brazil before, so benchmarking results were not available to help the company better understand the magnitude of the implementation. Rather, Aché had to start from "zero"—creating internal processes, developing production-line coding equipment, working to involve and integrate several departments of the company, training the team and much more.

Márcio Reis Freitas

About Aché

Aché Laboratories is a 100% Brazilian-owned corporation that has been in operation for 53 years. It has one of the largest marketing and sales organisations in the Brazilian market, which gives it extensive reach for publicising its products, disseminating scientific knowledge to health professionals, and providing consumers with access to a complete portfolio of quality products.

With nearly 4,900 employees, Aché is focused on diversity and its benefits for the business. More than 2,500 employees are dedicated to maintaining relationships with healthcare professionals and points of sale. The company has a broad and diversified portfolio with 327 brands. There are 145 therapeutic classes for 18 medical specialities available via multiple channels—trade, institutional, public and private.

In 2018, Aché pharmaceutical products were sold at 72,027 points of sale and 2,067 private institutions. Its products are also distributed throughout 26 countries covered by licensing agreements, such as Mexico, Nicaragua, El Salvador, Guatemala, Honduras, Venezuela, Panama, Chile, Algeria, Ukrain, Saudi Arabia, Kuwait, Arabic Emirates, Japan and many more.

Taking on a challenging project

When Aché decided to implement its traceability system, the company knew it would be a challenge. The company would need to make structural changes in the factory where any mistake—large or small—would have a major impact on production. Secondly, at that time, the Brazilian traceability regulation was in its "draft" stage and subject to change, making the company's "return on investment" uncertain and risky.

Implementing standards on production lines

Beginning in 2018, Aché started implementing GS1 standards for use in the company's factory located in Guarulhos, São Paulo.

Based on requirements published by ANVISA (the Brazilian health regulatory agency), a Global Trade Item Number® (GTIN®), the ANVISA registry number, serial number, expiry date and lot number are all encoded in the GS1 DataMatrix barcode, printed on labels and applied on pharmaceutical secondary packages—deployed on 23 production lines in the factory.

Later in 2018, the company expanded the project to its newly opened factory located in Cabo de Santo Agostinho-Pernambuco in Northeastern Brazil, with seven additional production lines applying GS1 standards-enabled labels. At the same time, logistics units were each uniquely identified with the GS1 Serial Shipping Container Code (SSCC) encoded in GS1 barcodes. This level of identification met the ANVISA's drug traceability regulation requirements to ensure traceability up to the tertiary packaging level.

Today, Aché Laboratories has 32 lines producing approximately 180 million packages, labelled with GS1 identifiers and attributes encoded in GS1 DataMatrix barcodes. The company's initial investment was approximately €4 million.

The next phase planned is to implement GS1 standards in the logistics department to enable the integration of production with shipments to customers.

Worth the investment

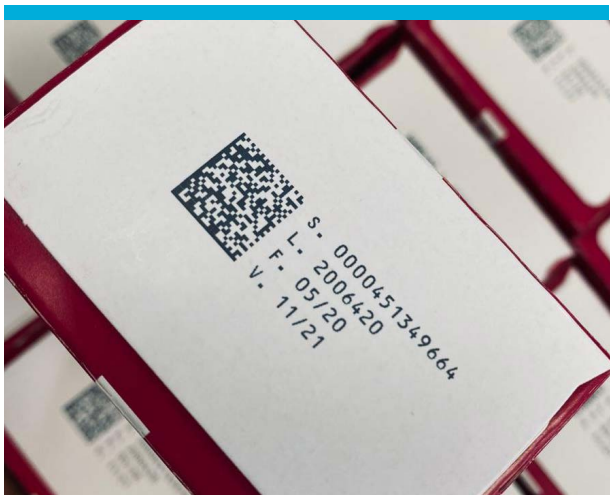
Aché advises that GS1 standards has provided the company, its healthcare providers and consumers with a wealth of benefits and a solid return on the initial investment. The company's traceability system now includes 100% of secondary and tertiary packages produced in São Paulo and Recife factories.

Aché has developed an app for consumers so that they can access valuable information about their Aché medicines. By using global GS1 standards, the pharmaceutical manufacturer is aligned with national regulations and the vast majority of global traceability regulations. The foundation of standards has given Aché the ability to serve multiple markets that require drug traceability, thus, allowing it to expand into new markets.

Lessons learned

The implementation of the traceability project was a strategic decision for Aché Laboratories. The company seized the challenge of implementing GS1 standards, giving itself enough time to implement standards on its production lines, and to correct any mistakes. It was also the opportunity to create a "lessons learned" database that can provide best practices and a benchmark, for Aché itself and for other companies.

Aché Laboratories is currently prepared to export to international markets requiring drug traceability and can now ensure high-quality service to customers and consumers.



About the author

Márcio Reis Freitas
Industrial Director
Aché Laboratories

Márcio Reis Freitas is Industrial Director of Aché Laboratories with 29 years of experience in pharmaceutical industrial environments. With a degree in Industrial Chemistry, Mr. Freitas specialises in Six Sigma "Black Belt" methodology with a masters degree in Business Management from Fundação Getulio Vargas (FGV). He has extensive knowledge in the areas of Production, Industrial Engineering, Industrial Excellence, Industrial Projects and Quality Assurance. Mr. Freitas has been at Aché Laboratories since 2005, where he is responsible for five sites in the areas of Production, Industrial Engineering, Projects and Operational Excellence.

About the organisation

Achê Laboratórios Farmacêuticos S.A. is a Brazilian-owned corporation. For more than 50 years, the company has been in operation and is, today, one of the largest pharmaceutical companies in Brazil.

www.ache.com.br

Colombia

Traceability: The key for driving efficiencies in the supply chain

Challenge

Alexion needed to create a traceability system that would address Colombia's pilot specifications.. Working with multiple stakeholders across the company's supply chain, Alexion led the way to implement GS1 standards, align processes, integrate systems and manage the necessary change for full traceability.

Approach

Alexion chose GS1 standards to uniquely identify, barcode and label packages and individual units of Soliris, a medicine selected for the traceability pilot. As the packages of Soliris traveled throughout the supply chain, employees and caregivers scanned the GS1 DataMatrix barcodes to capture and share information with all stakeholders.

100%

end-to-end traceability—from factory to patient bedside

Visibility of medicines across the supply chain

Traceability information successfully captured and accessed by all stakeholders

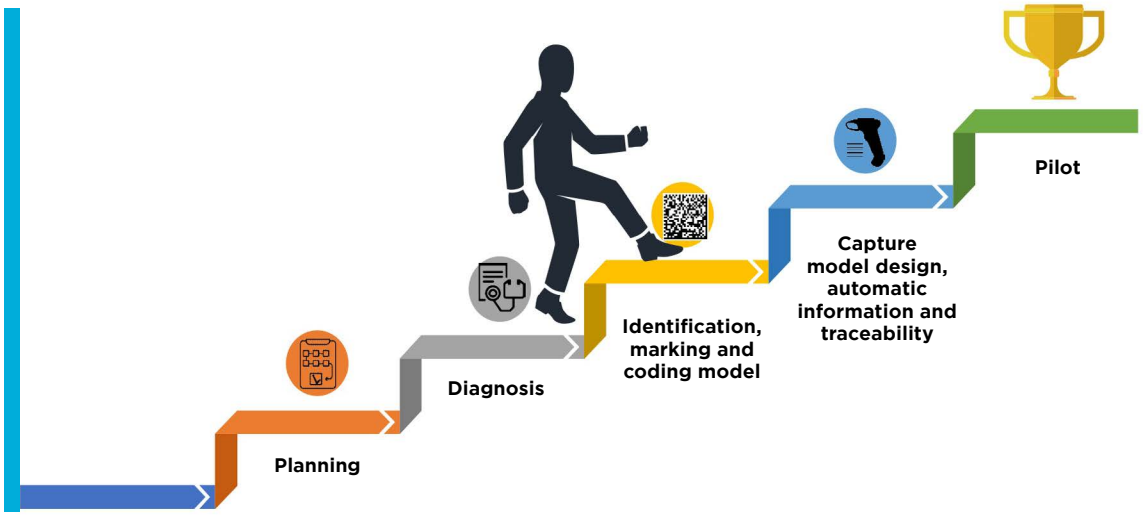
Collaboration between all stakeholders for fully integrated system in compliance with the Colombian pilot requirements regulation

Sponsored by Alexion, the medicine traceability project established a model to capture information using GS1 standards and guidelines. The purpose of the project was to increase the visibility of the medicine, Soliris, throughout the supply chain.

By ensuring pharmaceutical traceability with GS1 identification and barcodes, Alexion aimed to minimise, and even eliminate, the falsification of medicines in its supply chain.

Alexion, in collaboration with its partner, Audifarma, sponsored a project to establish a traceability system that would capture information and enable the visibility and traceability of pharmaceuticals thoughout the supply chain. The project initially focused on the medicine, Soliris. Five phases were executed: planning, diagnosis, implementation of GS1 standards for medicine identification, and development of the scanning methodology to capture information about the medicine as it traveled from the factory to patients.

Giovanny Cruz



Every part of the supply chain

The scope of the project's trial encompassed every part of the supply chain. At its headquarters in Bogotá, Alexion assigned a Global Trade Item Number® (GTIN®) to uniquely identify the Soliris product. The GTIN and other information—lot number, serial number and expiration date—were encoded in a GS1 DataMatrix barcode, printed on a label and applied to the medicine's individual unit of dosage as well as packages. These packages were then shipped to the company's distribution centre. Two major wholesalers in Bogotá and Barranquilla ordered packages of Soliris and distributed them to two healthcare providers for dispensing and administration to patients.

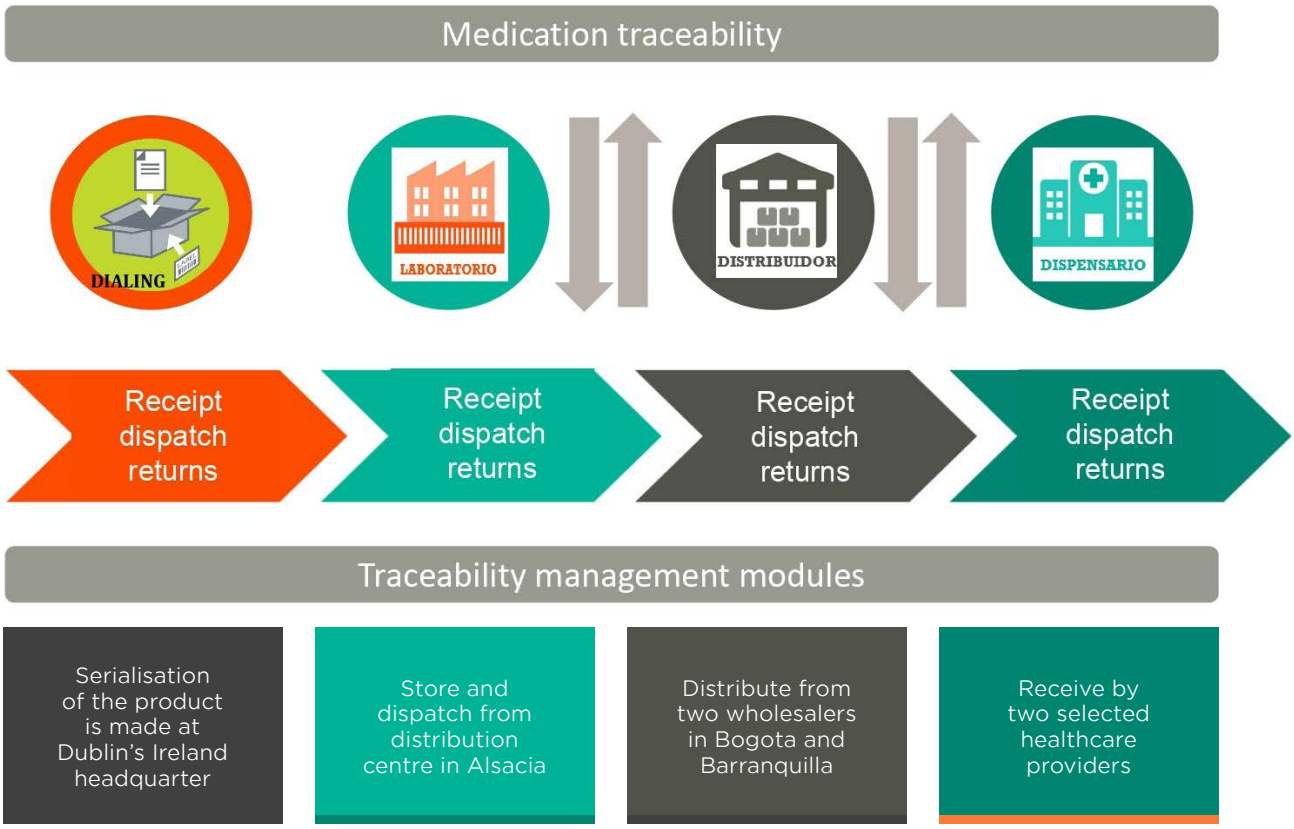
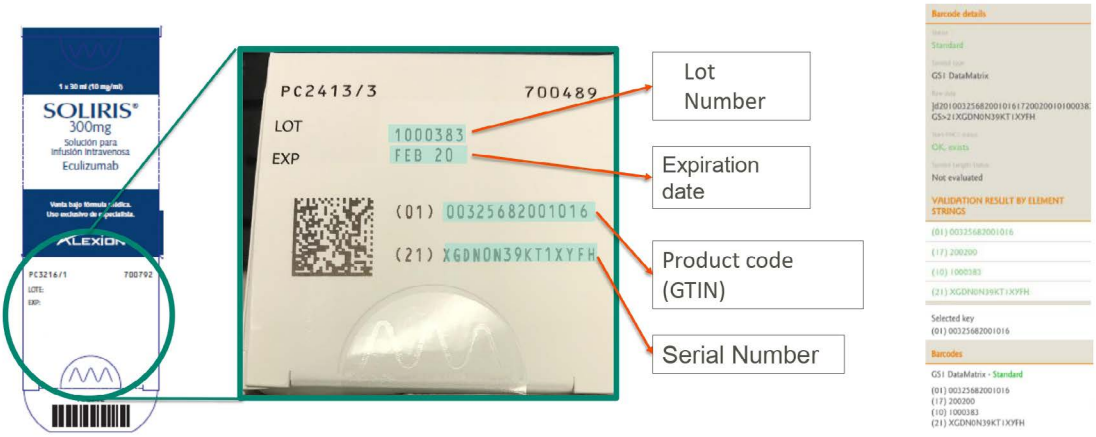


Figure 1: Traceability management modules

Each step of the way, GS1 DataMatrix barcodes on Soliris packages, and then individual dosage units, were scanned to capture information about the medicine throughout the supply chain. The GS1 system of standards was chosen since it offered a global standardised way to uniquely identify and barcode pharmaceuticals. The GS1 DataMatrix barcode was especially important since it is small enough to fit on individual dosage units, yet can hold a large amount of information that can be captured with a single scan.

The project has demonstrated how a medicine like Soliris can be tracked to the patient bedside where it is administered, and then traced back to the factory where it originated. This traceability system, enabled by GS1 standards, confirms Alexion's compliance with Colombia's pilot specifications and improves patient safety each step of the journey.



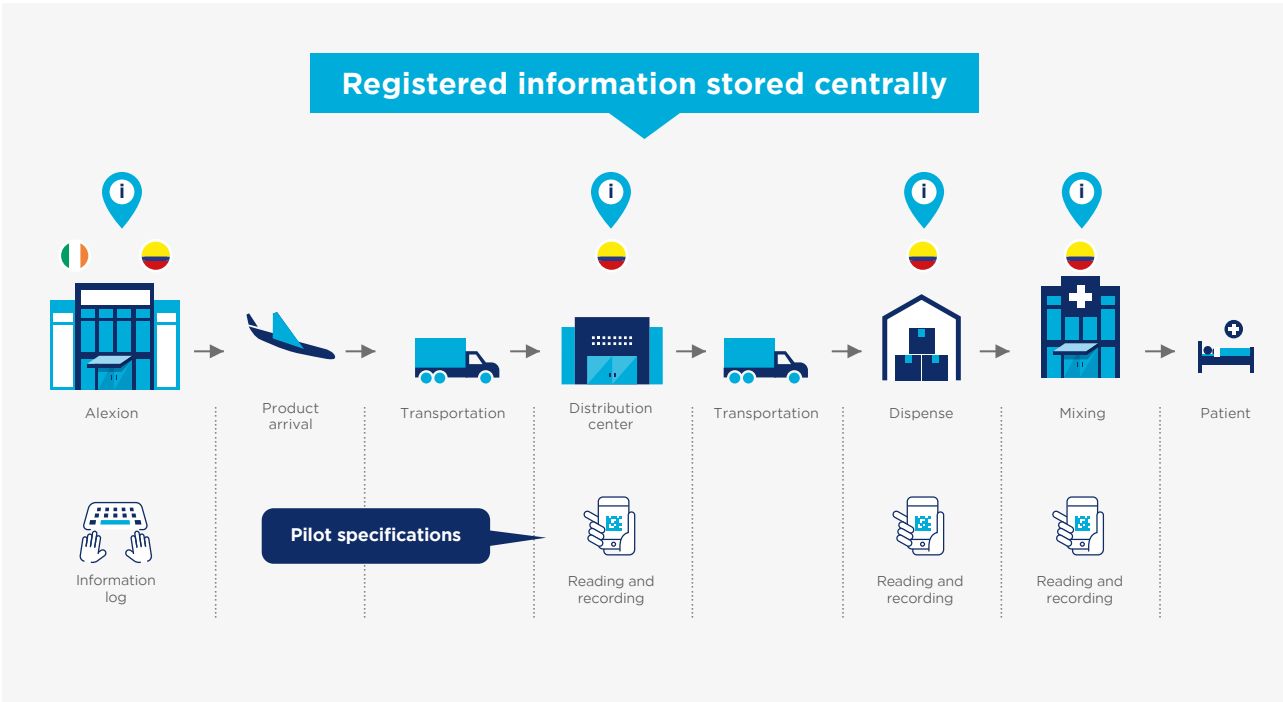


Figure 2: Traceability platform

Systems integration

To gain visibility of the medicine, it was necessary for the various stakeholders' systems to be integrated so that all could have access to the medicine's information—its status and location throughout the supply chain.

By working together in a collaborative way, the project stakeholders understood and realised the value of integration and applied strategies for the success and sustainability of the traceability system.

About the author

Giovanny Cruz
Product Logistics Specialist
Alexion Pharmaceuticals

Giovanny Cruz is an industrial engineer and specialist in International Logistics Management with 20 years of experience in the Pharmaceutical sector. He joined Alexion Pharmaceuticals in 2012 as leader of the company's logistics process. Currently, Mr. Cruz is the manager of the traceability project that addresses high-cost medicines for the Colombia supply chain.

About the organisation

Alexion is a worldwide pharmaceutical company that is dedicated to an understanding of rare diseases, which began with its pioneering work in complementary biology. This knowledge allows the company to innovate and evolve into new areas, where there is great unmet need and opportunity to help patients and families fully live their best lives. Alexion has delivered transformative medicines for people with PNH, aHUS, AQP4, NMOSD, gMG and HPP.

alexion.com

Germany

Bionorica ensures compliance with Russian serialisation law ahead of official deadline

Challenge

Bionorica had to ensure compliance with the Russian serialisation law before the 1 July 2020 deadline.

Approach

Movilitas' fully compliant set of services and solutions helped Bionorica handle the complex serialisation requirements. An integration of the company's SAP ® Advanced Track and Trace for Pharmaceuticals (ATTP) solution with the Russian Order Management System (OMS) was established to enable the request of required crypto codes. Additionally, a direct integration from Bionorica's SAP ATTP solution to the Russian Drug Circulation Monitoring System (MDLP) was created using Movilitas.Cloud for monitoring and legal reporting of all transactions. GS1 standards provided the foundation for the traceability system.

"By 2024, the unified national track & trace digital system will cover all industries, from cigarettes and medications, to clothing and child nutrition." [1]

30%
faster reporting process through automation

52%
reduction in implementation costs since all involved systems are based on GS1 standards

Compliance would not have been possible without GS1 standards

Bionorica®

movilitas

Bionorica is one of the world's leading manufacturers of scientifically researched herbal medicines. As the premier supplier for the phytomedicine market in Russia, the company faced the country's regulatory deadline of 1 July 2020. All new medications released must comply with Russia's Federal Law No. 425-FZ, which dictates the requirements of drug serialisation that manufacturers must meet. The goal of this regulation, as with others in the EU and around the globe, is to reduce the occurrence of counterfeit medications that could negatively impact patient health. Bionorica needed to ensure compliance with the pending regulation and tight timeframe to maintain its current supply levels.

Marco Steinkamp

Track and trace in Russia

The Chestny ZNAK is a national track and trace system created by the Centre for Research in Perspective Technologies (CRPT) in Russia. The system's purpose is to protect customers from fake goods, including medicines, by ensuring authenticity and declared quality. "By 2024, the unified national track and trace digital system will cover all industries, from cigarettes and medications, to clothing and child nutrition."[1]

Five steps cover the product journey—from a manufacturer assigning a digital code, to a store scanning the item before placing it on the shelf, to a customer scanning the code on the mobile app. This process creates a record of the entire value chain and helps prevent counterfeit goods from getting into the hands of consumers, which ultimately protects consumers' health and rights. Additionally, full product traceability supports businesses with optimising their supply chain processes and reducing costs, while increasing revenue and competitive advantage.

1 Source: https://chestnyznak.ru/en/business/#footer-link-two

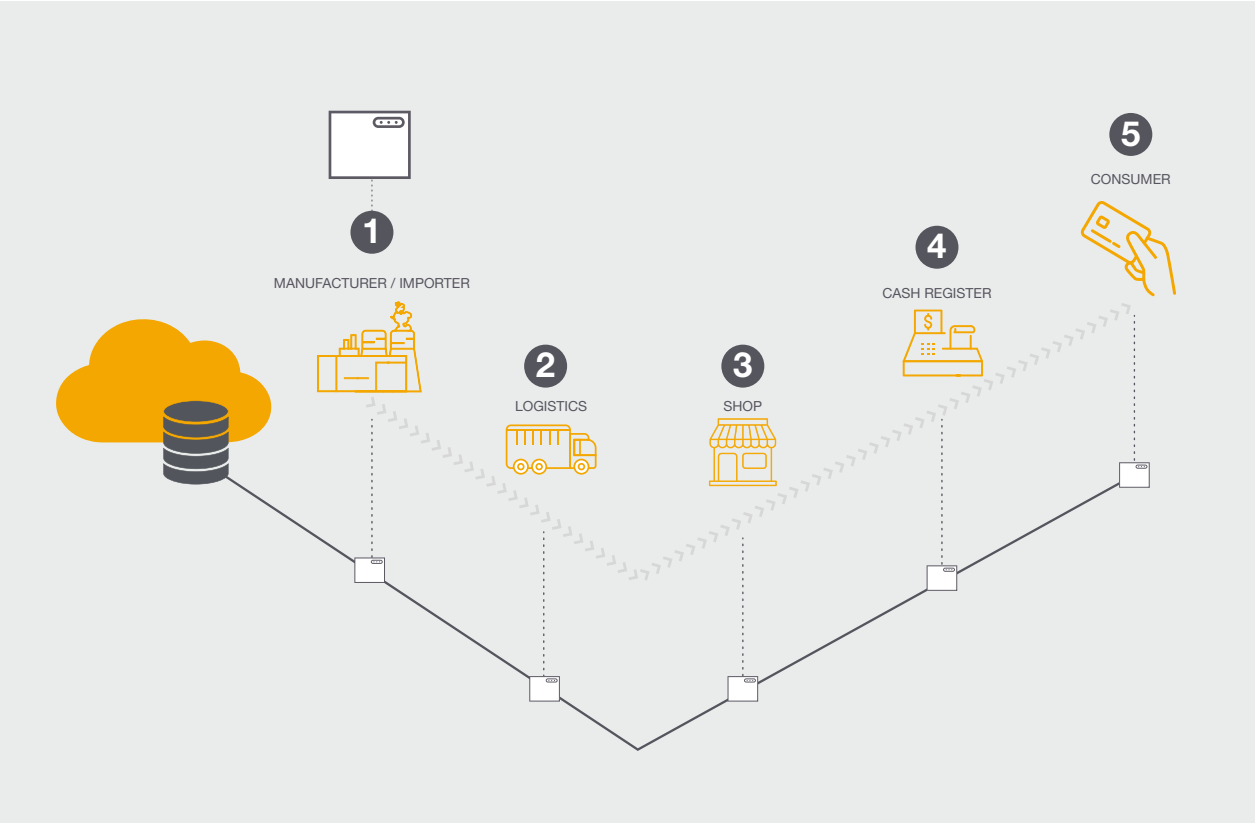


Figure 1: Track and trace in Russia covers the complete product journey - from production to consumption - Source: chestnyznak.ru

Serialisation and traceability for medicine in Russia

After a federal law was enacted in April 2010, Russia developed a dedicated track and trace information system called IS MDLP to monitor pharmaceutical products. In February 2017, an experiment was initiated to implement and monitor the identification of specific pharmaceutical products. In December 2017, Federal Law No. 425-FZ passed, amending the original law. It specified a deadline of 1 January 2020, which was later extended until 1 July 2020, and states the requirements of drug serialisation that manufacturers and other pharmaceutical stakeholders—such as distributors, pharmacies and healthcare providers—must meet.

Bionorica required a solution that established a direct connection to the Russion Order Management System and automated the reporting process, while taking its needs as a global manufacturer of herbal medicines into account.

The challenge

The pharmaceutical industry has found the Russian serialisation regulation difficult to meet based on its complex requirements. Meeting the regulation requires a different approach to the technology solutions implemented for the EU Falsified Medicines Directive (FMD) and other countries' regulations.

In order to be compliant, healthcare stakeholders must gather additional key data and communicate with the Russian systems. In addition to a two-dimensional (2D) barcode and randomised serial numbers, the regulation requires a cryptographic key that is requested

from the Russian Order Management System for each order. Therefore, technology used in compliance solutions must be able to handle the longer codes from data exchange to aggregation.

Additionally, the law specifies that more than 50 transactions must be monitored and reported, from manufacturing to dispensary. The reports, which must be encrypted and signed, are uploaded to the MDLP. This process is manual, which is resource intensive and can have a higher risk of errors. Thus, Bionorica required a solution that established a direct connection to the OMS and automated the reporting process, while taking its needs as a global manufacturer of herbal medicines into account.

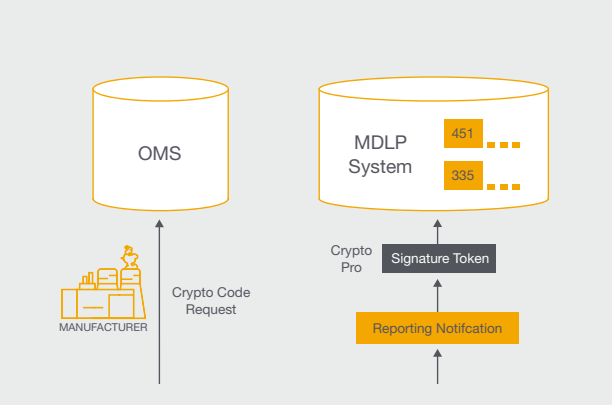


Figure 2: A cryptographic key is requested from the Russian Order Management System (OMS) for each order. The reports, which must be encrypted and signed, are manually uploaded to the MDLP.

How Bionorica ensured compliance with the Russian serialisation law

To ensure compliance with Russia's serialisation law before the deadline, Bionorica needed a direct connection between its SAP ATTP solution and the Russian OMS to be able to request crypto codes. The company also required the solution to automate the extensive reporting process.

By taking advantage of the Movilitas fully compliant set of services and solutions, Bionorica was able to handle the complex serialisation requirements. Based on its successful technical expertise, extensive traceability experience and detailed understanding of Russia's Federal Law No. 425-FZ, Movilitas, a GS1 Solution Partner, was selected by Bionorica to tackle the complexity of the regulation.

To automate the reporting process, it was necessary to implement a communication bridge that would help streamline the bidirectional flow of information, including up to 50 reports that are required of the marketing authorisation holders (MAHs) and contract manufacturing organisations (CMOs).

Only by taking advantage of Movilitas' fully compliant set of services and solutions, Bionorica was able to handle the complex serialisation requirements.

Using Movilitas.Cloud for monitoring and the legal reporting of all transactions, a direct integration from Bionorica's SAP ATTP solution to the Russian MDLP system was created.

Movilitas.Cloud was easily implemented, because it did not require local installations or modifications to the production line. It is a GAMP 5 validated software-as-a-service (SaaS) solution that streamlines compliance by enabling communication between SAP ATTP and the Russian MDLP system for message processing and retention. Movilitas.Cloud provides both foreign and domestic connections in accordance with industry best practices.

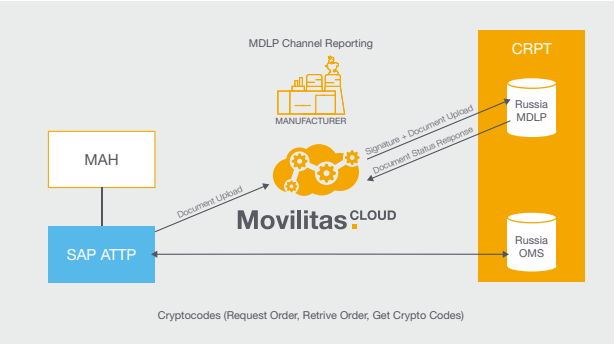


Figure 3: The integration of SAP ATTP and OMS enables the request of crypto codes. The reporting process is automated through the direct connection of SAP ATTP and MDLP using Movilitas.Cloud.

Bionorica requested and managed the cryptocodes through the direct integration of SAP ATTP with the Russian OMS. In the automated reporting process, the necessary documents are generated in SAP ATTP, uploaded to Movilitas.Cloud via Bionorica's own middleware and exchanged with Russia's MDLP system via the latter. With Movilitas.Cloud, Bionorica tracked and managed the status of reports.

The role of GS1 standards

Global GS1 standards provide the needed foundation for such an authentication and traceability system. They are an integral part of national regulations like Russia's Federal Law No. 425-FZ, significantly improving the integrity and visibility of local and global healthcare supply chains. Bionorica's case shows that global GS1 standards are crucial when securing a global supply chain and tackling national serialisation regulations, thereby preventing counterfeiting, the resale of medicines and the sale of expired medicines, as well as reducing drug shortages.

Bionorica was able to increase its patients' safety while maintaining compliance, because all systems involved in the project (the Russian OMS and MDLP, SAP ATTP, Movilitas.Cloud) adhere to GS1 standards and, therefore, are interoperable.

This facilitated a 30% faster reporting process as the standards allow for an easier exchange of information. Bionorica was also able to reduce the adjustment and implementation costs by 52% and to achieve compliance with a go-live date ahead of the deadline.

Bionorica's case shows that global GS1 standards are crucial when securing a global supply chain and tackling national serialisation regulations, thereby preventing counterfeiting, the resale of medicines and the sale of expired medicines, as well as reducing drug shortages.

Bionorica was able to increase its patients' safety while maintaining compliance, because all systems involved in the project (the Russian OMS and MDLP, SAP ATTP, Movilitas.Cloud) adhere to GS1 standards and, therefore, are interoperable.

About the author

Marco Steinkamp
European Sales Director
Movilitas

Marco Steinkamp studied Logistics at the Fontys University of Applied Science in Venlo (NL). In 2005, he joined British American Tobacco (BAT). During his 10+ years with BAT, he held several positions and was a member of BAT's local and global supply chain organisation. For more than four years, Marco also supported BAT's Global Track & Trace Program as Senior Project Manager in logistics as well as manufacturing environments. With this end-to-end supply chain track & trace experience and expertise, he joined Movilitas as the European Sales Director for Track & Trace in May 2015. After moving into the role of the Global Sales Director for Track & Trace in 2017, Marco became European Sales Director in December 2019.

About the organisations

Movilitas is a technology leader delivering the next generation of solutions and consulting services across multiple industries to advance smart supply chain ecosystems. We are recognized as a trusted SAP partner for digital supply chain transformation. We help businesses realize new growth opportunities, adapt to today's on-demand economy and maintain compliance. Through services, such as Movilitas.Cloud, or extensions and accelerators for SAP solutions, our clients unlock data to realize greater efficiencies and new revenue streams.
movilitas.com

Bionorica, located in Neumarkt, Bavaria, is one of the world's leading manufacturers of scientifically researched herbal medicines. Doctors, pharmacists and patients in more than 40 countries trust in Bionorica's products. In 2019, the Bionorica Group achieved sales of EUR 333 million. Based on the "phytoneering" strategy, Bionorica decodes the extensive active ingredient potential of plants (phytos) using cutting-edge research and technology (engineering). The result: highly effective medicines with few side effects. Bionorica's research and development priorities involve the treatment of symptoms in the respiratory tract, urinary tract, women's health and the immune system.

bionorica.de

Jordan

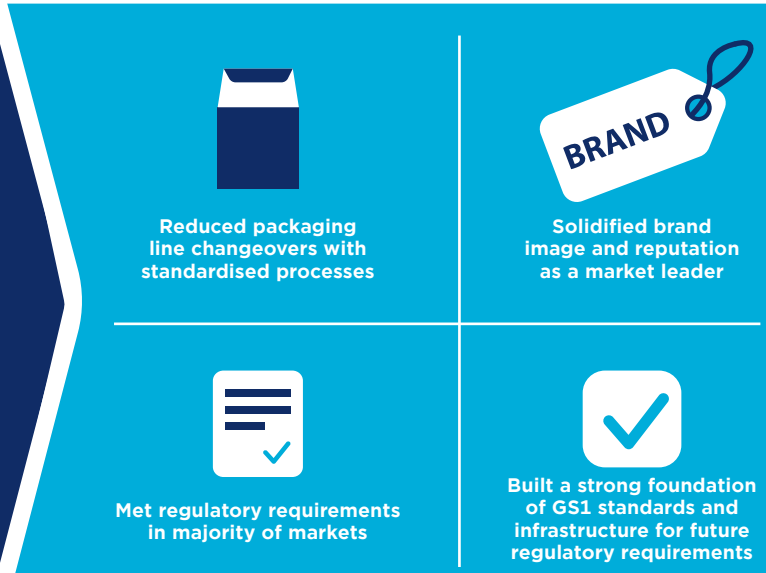
Hikma Pharmaceuticals adopts GS1 standards for regulatory compliance and traceability

Challenge

Hikma Pharmaceuticals (Hikma) needed to put in place a track and trace system for its full line of pharmaceuticals. The company wanted a system that would easily scale across its three global regions in response to emerging regulatory requirements.

Approach

The company implemented GS1 standards to uniquely identify its medicines at the individual dosage level. These GS1 identifiers were encoded in GS1 DataMatrix barcodes for application on packages. By scanning these barcodes, Hikma can now easily capture information in its IT systems for traceability—from its plants to healthcare providers, and ultimately, to patient bedsides.



hikma.

Founded more than 40 years ago, Hikma's purpose is to provide high-quality, affordable medicines to the people who need them. As a global pharmaceutical generics market player, Hikma has always strived to be a leader in adopting the latest technologies to enhance product quality and ensure patient safety. In 2019, the company's revenue exceeded US $2.2 billion, including Middle East and North Africa (MENA), US and Europe for injectables, generics and branded businesses.

Khalid Abughoush

Responding to regulation

With ever-increasing global regulatory demands, Hikma had to comply with new regulatory requirements demanding the implementation of track and trace systems. As of 2020, more than 80% of Hikma's global markets are requiring the use of GS1 standards for traceability, as a requirement for drug manufacturers.

Hikma started the implementation of GS1 standards to enable the track and trace system in many of its facilities across MENA, Europe and US. This meant assigning each medicine a serialised Global Trade Item Number® (GTIN®) that was encoded in a 2D GS1 DataMatrix barcode, printed on a label and applied to the medicine's package.

With GS1 standards in place, Hikma had the necessary foundation to enable a traceability system that would enable it to securely track products throughout its supply chain, thus protecting healthcare providers and patients against counterfeit products.

As an early adopter of GS1 standards, Hikma had already installed machines and upgraded its IT infrastructure for traceability when regulations were more flexible—actions taken in order to secure its position in the company's target markets. This provided Hikma with a head start and ease of implementation for countries that had recently required GS1 standards' implementation.

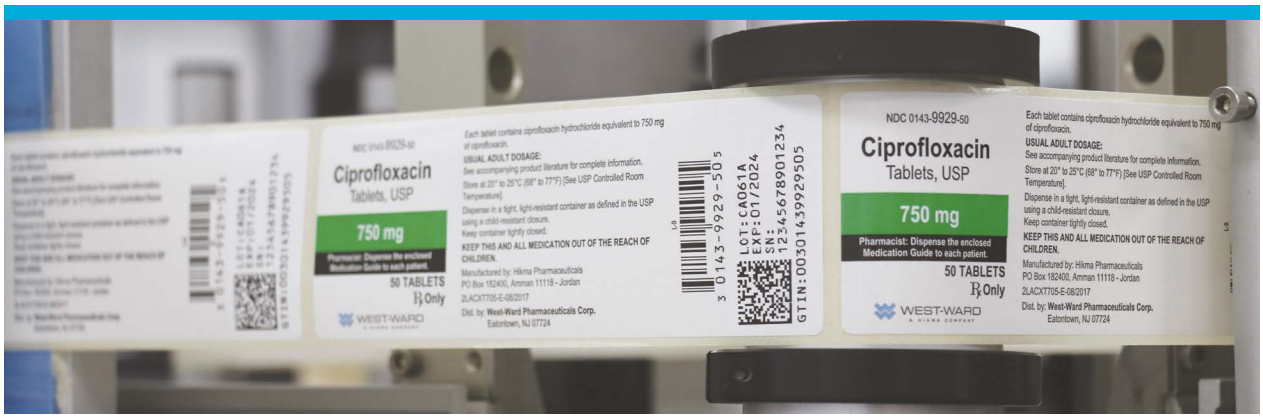
These are the main Hikma markets that have adopted GS1 standards as a mandatory requirement for regulatory compliance and shipping.

1. US
2. Jordan
3. Egypt
4. Saudi Arabia
5. Oman
6. Qatar
7. Bahrain
8. Lebanon
9. Slovakia

Becoming an early adopter

When implementing GS1 standards, Hikma invested millions of dollars in new packaging machinery capable of serialising bottles and cartons. The company also upgraded its IT infrastructure and internal procedures for quality assurance so that products are properly encoded with the correct GS1 standards.

By implementing GS1 standards, Hikma is paving the way for the next steps in creating its track and trace system. This foundation of standards will also help to enhance quality control systems in final packaged products. Newly installed machines along with new capabilities and standardised process parameters have streamlined setup procedures for packaging machines and provide real-time productivity reports.



Experiencing early benefits

While Hikma's track and trace system has not been completed for all manufacturing sites, the benefits of using GS1 standards are already being realised on the shop floor level with the installation of new machines and the ability to track every product.

By implementing GS1 standards, Hikma has achieved the following benefits:

1. Reduced packaging line changeovers based on standardised process parameters and enhanced technology implemented for serialisation.
2. Solidified brand image and reputation as a market leader with the highest quality and technology standards.
3. Met regulatory requirements needed in the majority of Hikma's target markets.
4. Built a strong infrastructure, knowledge of GS1 standards and serialisation best practices—all needed as prerequisites for aggregation. Aggregation will be the new requirement by all countries that currently need serialisation as a regulatory requirement.

Securing a leadership position with standards

As of April 2020, aggregation will be mandatory for all shipped pharmaceutical products to Saudi Arabia. Saudi Arabia is considered one of the main markets in the MENA region and has three manufacturing plants—General Formulation, Cephalosporin and Penicillin.

Since Hikma has used GS1 standards for many years and has the proper infrastructure for its track and trace system, the implementation for aggregation of the Saudi Arabian sites has been flawless without any major challenges. After implementing the aggregation and synchronisation of data with the Saudi Food and Drug Administration (FDA), whole chain traceability will be achievable for all batches shipped to Saudi Arabia, starting with the manufacturing site and ending with the patient.

Hikma has always strived to achieve the highest quality in drug manufacturing capabilities to ensure the safety of its patients globally. The company will always adopt the latest technologies for this purpose. By using GS1 standards, Hikma will continue to secure its global position across its main target markets and enhance its manufacturing capabilities.

About the author

Khalid Abughoush
Packaging Manager, General Formulation Plant
Hikma Jordan

Khalid Abughoush is the Packaging Manager of Hikma Jordan's General Formulation plant. He has completed his dual degree from Queen's University, Canada in Chemical Engineering and Biochemistry, and completed his graduate degree from Harvard University, US in Strategic Management through correspondence. He is currently leading the implementation of GS1 standards for Hikma Jordan plants and has five years of experience in the healthcare industry.

About the organisation

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, Hikma has been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, Hikma is a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe. The company uses its unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. Hikma is committed to its customers, and the people they care for. By thinking creatively and acting practically, the company provides them with a broad range of branded and non-branded generic medicines. Together, Hikma's 8,400 colleagues are helping to shape a healthier world that enriches all our communities. Hikma is a leading licensing partner, and through its venture capital arm, is helping bring innovative health technologies to people around the world.

hikma.com

United States

Driving Unique Device Identification compliance puts focus on patient safety

Challenge

With a focus on improving patient safety, the US Food and Drug Administration (FDA) recognised the potential risks of not being able to accurately identify each medical device out in the world. As a result, Unique Device Identification (UDI) was introduced. Additional countries have also enacted regulations. For UDI to be effective, it necessitates a harmonised and consistent approach.

Approach

Johnson & Johnson Supply Chain (JJSC) has a comprehensive UDI program enabling it to meet compliance milestones. Collaboration, data management and product identification are key components. JJSC supports the use of GS1 standards and assigns Global Trade Item Numbers (GTINs) to Johnson & Johnson company medical devices.

Complying with UDI regulations puts the focus on patient safety

75,000

device records submitted to FDA's GUDID by J&J companies

84%

of records submitted to GUDID utilised GS1 as issuing agency

Universal adoption allows healthcare providers to use UDI data

Patient Safety

UDI regulations being introduced around the world have resulted in key benefits focused on patient safety and hospital effectiveness. Common components of these regulations include labelling, a publicly accessible data repository and direct marking on reusable medical devices.

Johnson & Johnson Supply Chain embraces product identification and traceability as it has numerous benefits for patients, customers and the industry. JJSC has enterprise, supply chain product identification and traceability programmes and a comprehensive UDI programme, enabling it to meet compliance milestones. Collaboration, data management and product identification are key components.

Tom Jones

"Guided by Our Credo, we put the needs and well-being of the people we serve first. Complying with UDI regulations puts the focus on patient safety. Widespread adoption of GS1 standards to support UDI requirements aids the industry and protects the patient," says Vivek Nadadur, Senior Director of Digital Identification & Traceability.

Collaboration

In 2013, when the US FDA published its UDI regulation establishing a common, worldwide system for product identification for all medical devices sold in the United States, the JJSC dedicated UDI team, along with multiple functions, created an approach that would meet compliance milestones and could be leveraged to meet future regulations from around the globe. Compliance requires collaboration across multiple functions. Given the typical regulatory components of data submission, labelling and direct marking, there must

be a coordinated effort with participation from Regulatory Affairs, Information Technology, Quality, Supply Chain and engagement of the commercial organisation for that market.

JJSC's first objective was to review and interpret the regulations on what it means to be compliant. Next, the team developed the data submission infrastructure, enabling all Johnson & Johnson companies to consolidate and submit their device records to the health authority in a consistent manner. Working closely with the company's medical devices, consumer health, and pharmaceuticals segments ensured a consistent interpretation of the regulation. Segment leaders worked with their respective companies to execute the appropriate actions, including the significant efforts associated with data collection, evaluation and, where appropriate, remediation of barcodes and labels, and similar activities associated with direct marking requirements.

It Takes a Unified Effort

Regulatory Affairs
Interpretation of regulations
Primary conduit to Health Authorities

Information Technology
Apply technology to meet requirements
Develop the data submission infrastructure

Quality
Establish policies and procedures to sustain compliance

Supply Chain
Execute data collection, evaluation and remediation of barcodes and labels

Commercial
Provide customer perspective as we pursue compliance

Operating Companies
Execute strategy labels, direct markings, data

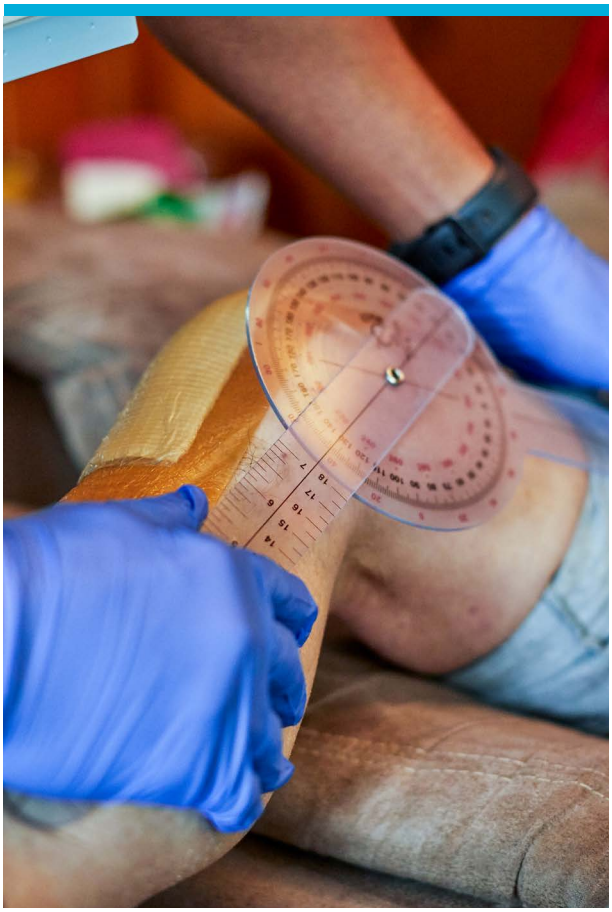
"Guided by Our Credo, we put the needs and well-being of the people we serve first. Complying with UDI regulations puts the focus on patient safety. Widespread adoption of GS1 standards to support UDI requirements aids the industry and protects the patient."

Vivek Nadadur
Senior Director of Digital Identification & Traceability
Johnson & Johnson Supply Chain

Data management

The data management effort was significant, especially since prior to the US FDA's UDI regulation, many associates typically did not think of their products in terms of device class.

By creating an organisational working structure in 2013 to interpret and collect the required data, JJSC was able to leverage that network to comply with the requirements of subsequent regulations. Many of the data fields required by regulations from European Union, Korea, China and Saudi Arabia were similar, if not exact, to the fields submitted to the US FDA's Global Unique Device Identification Database (GUDID).



Product identification

Johnson & Johnson companies support the use of GS1 standards and have adopted the GS1 standard for their barcodes. Global Trade Item Numbers (GTINs) have been assigned to medical devices and are labelled with GS1 barcodes. The popularity of GS1 as an issuing agency is evident from the submissions to GUDID. A recent search of the GUDID suggests that over 84% of the records submitted utilised GS1 as the issuing agency.

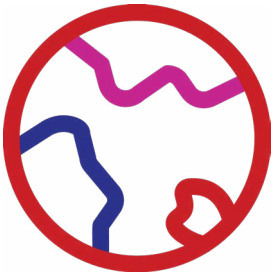
Patients, customers and the industry benefit from using GS1 standards.

- **GS1 standards help to more accurately identify medical devices that are received, dispensed and recorded in patient records.**
- **The GS1 barcode is accepted by all countries with UDI regulations, and manufacturers have more flexibility in distributing the same product to multiple markets.**
- **Universal adoption allows healthcare providers to use UDI data in their procurement systems, inventory management systems, electronic health record systems and implant registries.**
- **Product availability is enhanced with the ability to leverage inventory across multiple markets. It's easier to avoid stockouts and ensure that the appropriate device is available, when needed.**
- **GTINs across multiple regions enable device manufacturers to more easily identify products and batch numbers in the event of any product concerns.**

Lessons learned

A comprehensive UDI strategy, a collaborative multi-functional team and the adoption of GS1 standards help to enable successful regulatory compliance. UDI helps healthcare professionals identify products in a consistent manner.

Most importantly, the implementation of UDI improves patient safety, ensuring the right product is at the right place, for the right patient. With GS1 standards, JJSC is ready to enhance product identification and improve patient safety around the world.



Initially UDI commenced in 2013 in the United States. It's now grown to approximately 40 countries.

About the author

Tom Jones
Digital Identification & Traceability Director
Johnson & Johnson Supply Chain

Tom Jones is a Digital Identification & Traceability Director for Johnson & Johnson Supply Chain. He leads the enterprise efforts for unique device identification and serialisation. Mr. Jones worked in information technology, business intelligence, and supply chain at the company, and has held multiple programme leadership roles at Ethicon Endo-Surgery, LLC, the DePuy Synthes Companies, and within the supply chain organisation.

About the organisation

Johnson & Johnson Supply Chain includes three business sector supply chains—Consumer Health, Medical Devices and Pharmaceuticals—that cover planning, sourcing, internal and external manufacturing, as well as the Supply Chain Strategy, Innovation & Deployment organisation and the Deliver organisation, which manages distribution and customer service. Additional enterprise-wide functions that are part of the Johnson & Johnson Supply Chain include Quality & Compliance, Environmental Health, Safety & Sustainability and Engineering & Property Services, and Procurement.

www.jnj.com

United States

Barcode readability for DSCSA 2023 interoperability

Challenge
For the third consecutive year in 2019, AmerisourceBergen and McKesson conducted barcode assessments to gain an up-to-date view of industry's progress in implementing serialisation requirements of the 2013 Drug Supply Chain Security Act (DSCSA). Cardinal Health conducted its own barcode assessment of homogeneous cases from pharmaceutical manufacturers. All three assessments were supported by GS1 Healthcare US.

Approach
Taking a consistent, year-over-year approach, the teams from AmerisourceBergen and McKesson with collaboration from GS1 Healthcare US scanned 2D barcodes on product packages, capturing data to measure the percentage of readable 2D barcodes encoding an NDC, serial number, lot number and expiration date.

Readable 2D GS1 DataMatrix barcodes with all 4 DSCSA data elements

Specialty Products
71.9%
scanned at AmerisoureBergen

Rx Products
71%
scanned at McKesson

Homogeneous Cases
78.7%
scanned at Cardinal Health with 2D (GS1 DataMatrix) barcodes

Homogeneous Cases
73.3%
scanned at Cardinal Health with linear (GS1-128) barcodes

AmerisourceBergen

CardinalHealth

McKESSON

In the summer 2019 and for the third consecutive year, AmerisourceBergen Corporation (AmerisourceBergen) and McKesson Pharmaceutical (McKesson) in collaboration with GS1 Healthcare US®, assessed the barcodes of packages "lowest saleable unit" in their distribution facilities to obtain a view of industry's progress in implementing serialisation requirements of the 2013 DSCSA.[1] During this same timeframe, Cardinal Health conducted its own barcode assessment of homogeneous cases from pharmaceutical manufacturers, with support from GS1 Healthcare US.

Ameer Ali, Quentin Dittman & Scott Mooney

Conducting assessments

The DSCSA defines the requirements for an interoperable, electronic system to identify and trace pharmaceutical products throughout their distribution in the United States.[2] As part of the requirements, pharmaceutical products must be marked with a National Drug Code (NDC), serial number, lot number and expiration date.[3] (When using GS1 standards, the NDC is represented by a GS1 Global Trade Item Number® or GTIN®.)

1 Drug Supply Chain Security Act, Pub. Law No. 113-54, 127 Stat 599 (2013).
2 United States. Department of Health and Human Services. Food and Drug Administration (FDA) (n.d.). "Drug Supply Chain Security Act." Accessed September 14, 2018 at: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ DrugSupplyChainSecurityAct/default.htm
3 Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(b)(2)(A), 127 Stat 599, 609 (2013).

The DSCSA also specifies that packages (known as "lowest saleable units" in industry) must be marked with a two-dimensional (2D) barcode (e.g., GS1 DataMatrix barcode), and homogeneous cases with either a 2D barcode or linear barcode (e.g., GS1-128 barcode).[4]

Assessment results offer an indicator of how many packages and cases in the market today are marked with a serialised readable barcode containing the four DSCSA-required data elements.

It is critical that barcodes are applied in a standardised way to facilitate accurate movement of product across the healthcare supply chain and to associate the physical product markings with the serialised electronic data exchange that will occur on or before 27 November 2023.

The 2019 barcode assessments expanded the scope of analysis to include the 27 November 2023 interoperable requirements and quantify impacts of readiness in these areas. GS1 Healthcare US and the Big 3 wholesalers are participating in the U.S. Food and Drug Administration (FDA) Pilot Project Program under the Drug Supply Chain Security Act, Docket No. FDA-2016-N-0407 for the scanning, data collection, analysis and reporting of the barcode testing pilot.

Previous barcode assessment studies were conducted by AmerisourceBergen and McKesson in 2017, and again in 2018 with the addition of Cardinal Health, each year facilitated by GS1 Healthcare US. These studies identified issues with lack of adherence to industry barcode standards and placement— problems that can result in serious consequences, such as improper identification of products, mis-shipments, reduced operational efficiency and product availability issues.

With results from the 2019 assessments, AmerisourceBergen, Cardinal Health and McKesson are now able to follow up and share results with their individual supplier manufacturers and repackagers so that they can continue to make any course corrections, as needed.

Data management

Taking a consistent, year-over-year approach, the teams from AmerisourceBergen and McKesson with collaboration from GS1 Healthcare US once again scanned 2D barcodes on product packages, capturing data to measure the percentage of readable 2D barcodes encoding an NDC, serial number, lot number and expiration date.

Both wholesalers scanned package barcodes in the same distribution centres, assessing the same types of products. AmerisourceBergen assessed specialty medications and McKesson focused on prescription pharmaceuticals.

The AmerisourceBergen team took a different scanning approach than in previous years by using a mobile application. "We created a mobile app that enables us to capture the data encoded in barcodes as well as note specific issues, analyse barcodes for specific criteria and take photos of the issues that we find—all within the same entry. We can then share the analysis and pictures with manufacturers, giving

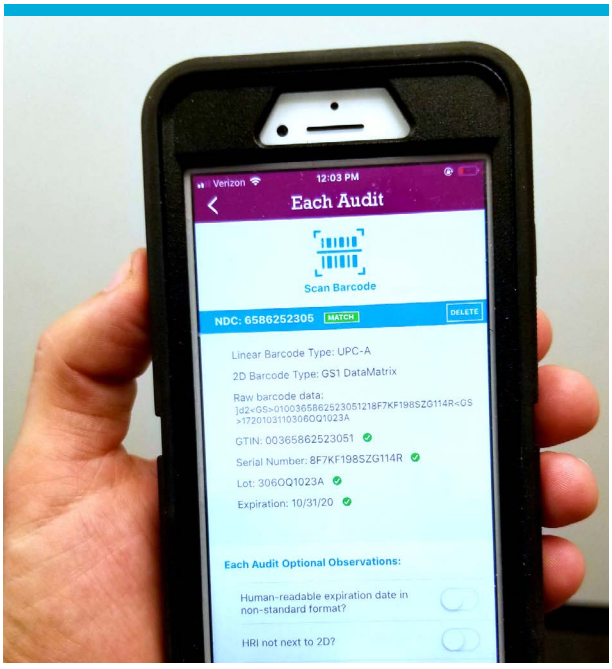


Photo courtesy of AmerisourceBergen. Mobile app displayed.

4 Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(a)(9)[A], 127 Stat 599, 608 (2013).

them constructive feedback," explains Ameer Ali, Senior Manager of Secure Supply Chain & Manufacturer Operations, AmerisourceBergen.

In 2019, the sample sizes for both AmerisourceBergen and McKesson included:

- AmerisourceBergen scanned 1,545 packages representing 270 manufacturers and 100% of on-hand specialty products. The new mobile application enabled AmerisourceBergen team members to work individually and capture all information in one place—a significant boost to productivity.
- McKesson scanned 16,314 packages representing 477 manufacturers. A team comprised of McKesson personnel scanned barcodes using production scanners, and captured scanned information in McKesson's own production system.
- At both AmerisourceBergen and McKesson distribution centres, the GS1 Healthcare US team scanned more than 3,700 packages to provide an independent audit of the results. The analysis from the packages scanned by AmerisourceBergen, McKesson and GS1 Healthcare US teams revealed a 99.9% accuracy of the audited items.

Ali with AmerisourceBergen says, "Conducting the audit in conjunction with the GS1 US assessment ensures that the information is reflective of the entire industry and measured against agreed upon standards."

"We created a mobile app that enables us to capture the data encoded in barcodes as well as note specific issues, analyse barcodes for specific criteria, and take photos of the issues that we find-all within the same entry. We can then share the analysis and pictures with manufacturers, giving them constructive feedback."

Ameer Ali
Senior Manager, Manufacturer Operations
AmerisourceBergen

Specialty Products at AmerisourceBergen

1,545
packages scanned
representing 270 manufacturers

Homogeneous Cases at Cardinal Health

19,444
barcodes scanned
2D and linear barcodes on 7,996 cases from 177 manufacturers

Rx Products at McKesson

16,314
packages scanned
representing 477 manufacturers

Cardinal Health focused on homogeneous case-level barcodes on pharmaceutical products in its Groveport, Ohio National Logistics Centre.

"This year, we wanted to see if there was an improvement year-over-year," says Quentin Dittman, Director of Operations Technology at Cardinal Health. "After last year's assessment, we really dug into the data. We started talking with our suppliers, reaching out to understand any issues. This understanding was really crucial for us in order to push for the highest level of compliance. Bad barcodes mean bad problems for the supply chain."

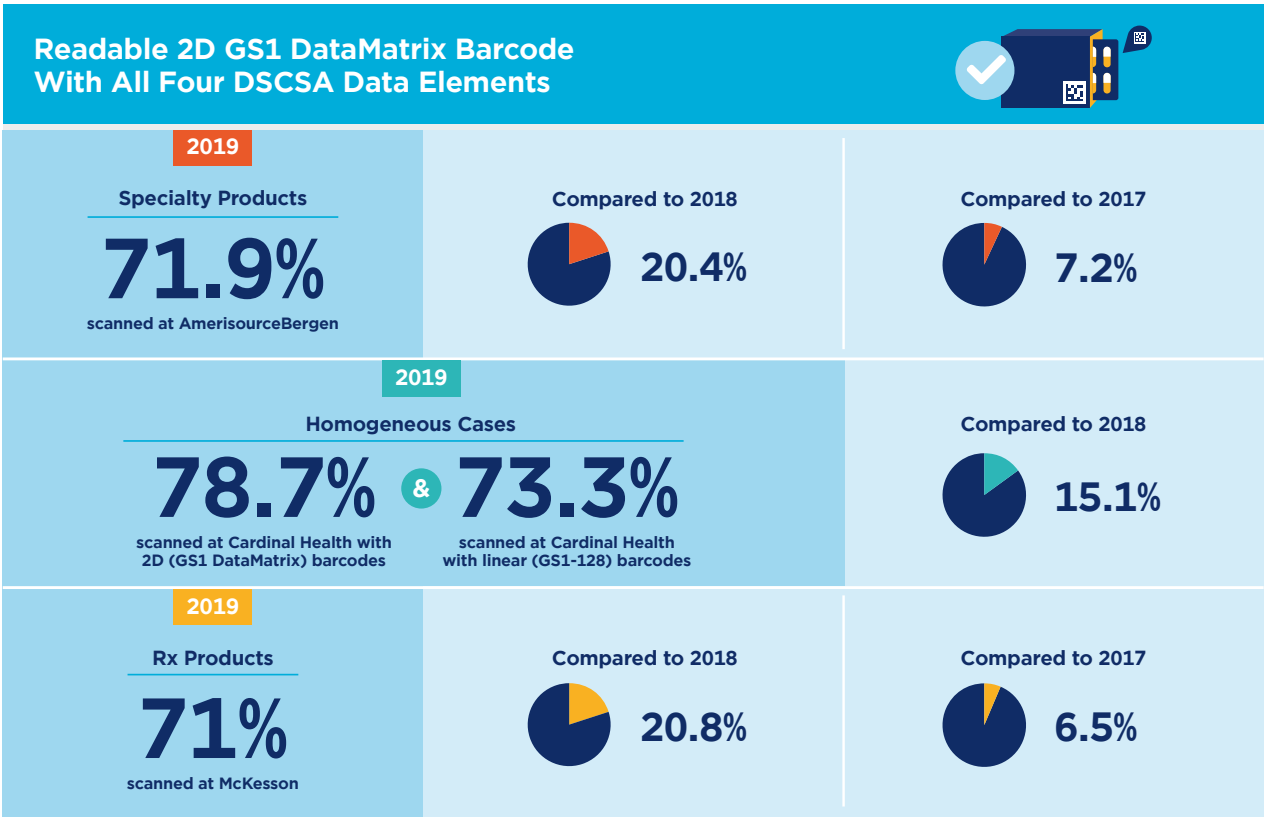
The HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain recommend that manufacturers use two linear barcodes with the NDC (GTIN) and serial number in one, and the lot number and expiration date in the other, or one 2D barcode encoding all four data elements.[5] The Cardinal Health assessment encompassed both approaches.

A new addition to Cardinal Health's scanning process was its own internal tool to conduct the analysis and validation of product data. "We call it the 'barcode validator' and it's going to be used for our production going forward when we're evaluating all of our suppliers' barcodes," says Mr. Dittman. "We thought it was really important for us to have an in-house tool and system."

- Cardinal Health scanned 19,444 2D and linear barcodes on 7,996 cases from 177 manufacturers. This included both faster- and slower-moving ambient products from their racks, plus cold chain products stored in the refrigerator.
- At Cardinal Health, the GS1 Healthcare US team scanned 4,120 2D and linear barcodes on 1,548 cases.

"In my opinion, having GS1 US be part of the assessment by auditing the data was critical since they provide a third-party perspective on the quality of the data and process. They ensured that any data captured was verified, lending an extra layer of credibility to the results."

Quentin Dittman
Director of Operations Technology
Cardinal Health



5 HDA (2017). HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain. Retrieved September 14, 2018 from https://www.healthcaredistribution.org/resources/hda-guidelines-for-bar-coding-in-the-pharmaceutical-supply-chain

Exceeding expectations

The results from the AmerisourceBergen and McKesson assessments showed a significantly higher year-over-year increase of nearly 52 percentage points when compared to the 2018 assessment, and 66 percentage points when compared to 2017.

In fact, all wholesalers were very pleased that suppliers exceeded their expectations of 50 percent to 60 percent.

- Of the specialty products at AmerisourceBergen, 71.9% of all packages had a readable 2D GS1 DataMatrix barcode with all four DSCSA-required data elements (compared to 20.4% in 2018, and 7.2% in 2017).
- Similarly, the prescription products at McKesson, 71% had a readable 2D GS1 DataMatrix barcode with all four DSCSA-required data elements (compared to 20.8% in 2018, and 6.5% in 2017).
- At Cardinal Health, 78.7% of homogeneous cases with 2D (GS1 DataMatrix) barcodes and 73.3% with linear barcodes had all four data elements (compared to 15.1% in 2018).

"The results just blew me away," says Scott Mooney, Vice President of Distribution Operations, Supply Chain Assurance, McKesson. "It was fantastic to see the percentage increase so high. Now, we just have to fill the gap to get to 100 percent."

Mr. Dittman agrees, "The results are very exciting; they exceeded my expectations. And as we process more and more inventory, I expect to see the compliance reach up to 90 percent or even 100 percent."

"The grandfathering allowance from the FDA was helpful to assure that supply chains remained stocked with inventory, and patients could get the proper medications that they needed, when they needed them. I think that there were far fewer manufacturers selling grandfathered product than might have been expected—given that we also saw such a high percentage of product with the 2D barcode."

Scott Mooney
Vice President of Distribution Operations, Supply Chain Assurance
McKesson Corporation

An additional year-over-year significant change was experienced with the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. This could be a reflection of an industry build of inventory last year with lot-only based products, and in 2019, older inventory was consumed prior to the conversion of serialised packages.

Top observations

As part of the assessments, AmerisourceBergen, McKesson and Cardinal Health noted the following observations:

High levels of serialised inventory

US FDA issued a draft guidance, informing industry that it was delaying enforcement of the DSCSA requirements until November 2018, to provide manufacturers additional time and avoid supply disruptions.[6]

The AmerisourceBergen and McKesson assessments were conducted in May and July, respectively—at least six months after the November 2018 deadline.

"Of course, the compliance deadline really drove suppliers' actions toward serialisation," says Mr. Ali. "We recently started seeing significantly more serialised products in our warehouse distribution network. So, the serialised inventory in the supply chain is steadily increasing as expected, with grandfathered inventory expected to continue to decrease over the next several months."

Mr. Dittman adds, "Our manufacturing partners are burning through the backlog of inventory that they had produced when preparing to meet their 2018 serialisation requirements. We're getting to a point where all the products will soon be serialised as we're seeing the expiration dates slide."

Mr. Mooney from McKesson says, "The grandfathering allowance from the FDA was helpful to assure that supply chains remained stocked with inventory, and patients could get the proper medications that they needed, when they needed them. I think that there were far fewer manufacturers selling grandfathered product than might have been expected—given that we also saw such a high percentage of product with the 2D barcode."

6 United States. Department of Health and Human Services. FDA (June 2017). "FDA Issues Draft Guidance: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy." Accessed September 14, 2018 at: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm

Mr. Mooney points to the impressive effort by suppliers when making this change. While many of the suppliers may have a small number of products, many of them have 100-150 products that are manufactured in 10-12 different product facilities. “Our experience is that suppliers are not lagging behind,” explains Mr. Mooney. “A supplier that is not 100% may just have a facility that is delayed in getting the conversion completed to handle the 2D barcodes.”

Mr. Ali confirms that AmerisourceBergen saw that some manufacturers had a mixture of good and bad labels, most likely due to a variation of packaging locations and contract manufacturers.

Improved expiration date

AmerisourceBergen and McKesson also note the significant improvement of properly encoding the barcode with the expiration date—previously an issue in 2017 and 2018.

In previous assessment years, the wholesalers saw suppliers use “00” as the day in the expiration date. A secondary problem was that the day in the expiration date was not being included in the human readable, even when it was encoded in the barcode.

“Out of the 16,300 packages that we scanned, only 183 of these had expiration date issues,” advises Mr. Mooney from McKesson. “This was a huge, positive change and will be especially important when we start exchanging data as trading partners.”

Mr. Mooney suspects that guidelines like the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability*, helped suppliers make this shift.

Mr. Ali with AmerisourceBergen still warns about the impact on the supply chain when expiration dates are not encoded accurately, or human readable information is not labelled according to the guidelines. “Pharmacies, for example, that rely on human readable expiration dates may have difficulty accurately reading the information when dispensing pharmaceuticals to patients,” says Mr. Ali. “This could have a real impact on patient health, in addition to the supply chain.”

An additional year-over-year significant change was experienced with the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. This could be a reflection of an industry build of inventory last year with lot-only based products, and in 2019, older inventory was consumed prior to the conversion of serialised packages.

Better barcode quality

Another area of improvement was the legibility of barcodes.

In 2017 and 2018, AmerisourceBergen and McKesson could not scan certain barcodes since they were applied on shiny surfaces or were printed in inappropriate colours.

“These kinds of problems were nearly absent this year,” says Mr. Mooney. “To the best of my knowledge, we had only two instances where we experienced barcodes in difficult-to-read colors or surfaces. With the quality barcodes, we were able to scan noticeably quicker.”

Mr. Dittman with Cardinal Health agrees that barcode quality improved, considering the amount of time required to make those changes. At the same time, he advises it’s not quite where it needs to be. “I’d like to see everybody following the standard. Although there is a marked improvement, it’s not where it should be from a supply chain or downstream perspective.”

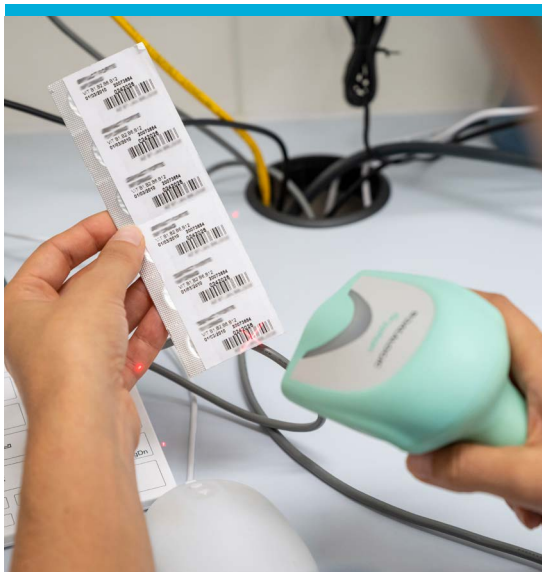
Cardinal Health, McKesson and AmerisourceBergen are all reaching out to their suppliers, providing one-on-one feedback on areas where improvements can be made.

"As we move more towards the data exchange of 2023, I think our ability to leverage the information available today becomes more acute. It's making sure that we have the right pieces in place until we get to 2023 when we can then all unlock the complete value that's promised today."

Quentin Dittman
Director of Operations Technology
Cardinal Health

"When all products have readable 2D barcodes, we can begin truly looking at the exchange of data and the incorporation of that data into our processes. We will be 'marrying' the physical product with its digital twin. In other words, every product will have a dual state—a digital version and physical version—that we will be able to match between our respective platforms. That's what we are required to do in 2023."

Scott Mooney
Vice President of Distribution Operations,
Supply Chain Assurance
McKesson Corporation



Business benefits

As suppliers "close the gap" for 100% readability, the next big step for wholesalers and suppliers alike will be using the data for more efficient processes.

"We begin using the data this November (2019) when we start doing saleable returns verification, confirming what's encoded in the barcode against the data that manufacturers have kept on file," says Mr. Mooney. "Many suppliers in the industry are working on getting the data organised and presentable for their verification returns program."

Other process benefits for wholesalers include scanning barcodes to determine if a product's expiration date is within acceptable limits, providing healthcare providers with the "go/no go" when dispensing of the product. "Today, we check for recalls manually by referring to the human readable on the package," explains Mr. Mooney. "Now, with readable barcodes, we can harvest the data for increased efficiencies inside our distribution centre."

Mr. Dittman from Cardinal Health also references the potential for increased efficiencies in Cardinal's distribution centre as data is increasingly accessed from readable barcodes. "It starts at our front door when the product arrives in receiving. Barcodes help save us time, effort and ultimately, labour costs. There's also a quality impact since we're limiting (or eliminating altogether) manual intervention where there's a propensity for error."

"As we move from more than 70% to 100% readable barcodes, we will continue to lay the foundation for exchanging data as part of the 2023 requirement."

Industry value

Perhaps the most exciting results will be realised in 2023—just three short years away. “When all products have readable 2D barcodes, we can begin truly looking at the exchange of data and the incorporation of that data into our processes,” says Mr. Mooney. “We will be ‘marrying’ the physical product with its digital twin. In other words, every product will have a dual state—a digital version and physical version—that we will be able to match between our respective platforms. That’s what we are required to do in 2023.”

“I think the dilemma we will face is that there’s a strong appetite to quickly use this data,” continues Mr. Mooney. “But from a process perspective, we need to take the time required to move as an industry—one step at a time. We can start to test the exchange of serialised data, but ultimately, the entire industry will need to have data flowing back and forth between all trading partners. We’re looking at ‘how and when’ this becomes possible.”

Mr. Dittman says, “As we move more towards the data exchange of 2023, I think our ability to leverage the information available today becomes more acute. It’s making sure that we have the right pieces in place until we get to 2023 when we can then all unlock the complete value that’s promised today.”

Mr. Ali adds, “With full traceability planned for 2023, the ability to track and communicate across the supply chain will be down to the unique lowest saleable unit. This has never been available before and will unlock value and increase accuracy and specificity to new levels. Until then, the objective is to work to eliminate physical and data exceptions, and add the processes and equipment necessary to enable the capture, verification and exchange of this information between stakeholders.”

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Ameer Ali
Senior Manager, Manufacturer Operations
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About the authors

Ameer Ali
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Ameer Ali is Senior Manager, Manufacturer Operations at AmerisourceBergen, a Fortune 25 company and a leading pharmaceutical distributor. He brings 16 years of Supply Chain experience in various industries. He's involved with DSCSA implementation at AmerisourceBergen as well as optimising data exchange processes and packaging compliance. Mr. Ali participates in many industry initiatives including the GS1 US assessment of DSCSA barcodes in the pharmaceutical supply chain, the GS1 US Rx Secure Supply Chain Workgroup and project advisory board of the Healthcare Distribution Alliance Research Foundation. He also co-chaired the GS1 US Healthcare GLN Advisory Workgroup.

Quentin Dittman
Director of Operations Technology
Cardinal Health

Quentin Dittman is a Director, Deployment Leader at Cardinal Health, a position he has held since November 2019. He is responsible for Lean Six Sigma activities in the Pharmaceutical Segment in the East Deployment Area. Prior to this role, Mr. Dittman was Director of Sustain and Track & Trace at Cardinal Health. In this role, he is responsible for transforming the Pharmaceutical segment by leveraging technology and lean processes to deliver agility and flexibility in an ever changing environment. Quentin is also responsible for optimising the Pharmaceutical Distribution supply chain in response to the Federal Drug Supply Chain Security Act of 2013 (DSCSA).

Scott Mooney
Vice President of Distribution Operations, Supply Chain Assurance
McKesson Corporation

Scott Mooney is Vice President of Distribution Operations, Supply Chain Assurance at McKesson Corporation. His primary responsibilities are assuring product integrity through regulatory compliance and traceability. Mr. Mooney leads McKesson's Traceability Team working on Drug Supply Chain Security Act implementation across McKesson's various business units.

He joined McKesson in 1987 and had previous roles in Finance, Distribution Center Management and as a Regional Vice President of Distribution Operations. Mr. Mooney is active in Healthcare Distribution Alliance's (HDA) Traceability Workgroup in addition to serving on the HDA Industry Relations Council and participating in several committees including the Federal and State Government Affairs Councils and Regulatory Affairs Council.

He is a current Tri-Chair of the GS1 Global Healthcare Leadership Team having been on the team as a member for the past five years. Scott participates in the GS1 US Rx Secure Supply Chain Workgroup and was previously a member of the GSMP Process Oversight Committee.

About the organisations

AmerisourceBergen Corporation is one of the world's largest pharmaceutical services companies, serving global markets with a focus on the pharmaceutical supply chain. Servicing pharmacies, providers and pharmaceutical manufacturers, the company provides global product sourcing and distribution and related solutions designed to improve product access, increase supply chain efficiency and enhance patient care.

www.amerisourcebergen.com

Headquartered in Dublin, Ohio, **Cardinal Health, Inc**. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, health systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company provides clinically-proven medical products and pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Backed by nearly 100 years of experience, with approximately 50,000 employees in nearly 60 countries, Cardinal Health ranks among the top 25 on the Fortune 500.

www.cardinalhealth.com

McKesson Corp. is a global health services and information technology company, which provides medicines, pharmaceutical and care management products. It operates through the McKesson Distribution Solutions and McKesson Technology Solutions segments. The McKesson Distribution Solutions, which includes McKesson US Pharmaceutical, distributes ethical and proprietary drugs, medical-surgical supplies and equipment and health and beauty care products throughout North America. This segment also provides specialty pharmaceutical solutions for biotech and pharmaceutical manufacturers, provides financial, operational and clinical solutions for pharmacies.

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About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

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. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefits to all stakeholders. Global members of GS1 Healthcare members include more than 120 leading healthcare organisations worldwide.

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