The Global Language of Business

GS1 Healthcare Reference Book 2019-2020

Stories of successful implementations of GS1 standards





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“Safer, more efficient care starts with a simple scan.”


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US

- By implementing serialisation and traceability of medicines, Johnson & Johnson Supply Chain has increased their ability to communicate transparent, real-time data across the supply chain.
- The Veterans Affairs Medical Center estimates $5,000 to $10,000 savings each month by using inventory that might otherwise have expired.



Costa Rica

- GS1 standards are brought in at the National Children's Hospital to identify 100% of their medical supplies and enable safer, more efficient care.

Chile

- The National System of Health Service in Chile introduces GS1 standards for the identification of all products in their supply chain to streamline their logistics processes.

The world implementing GS1 standards Implementation figures and benefits

Ireland

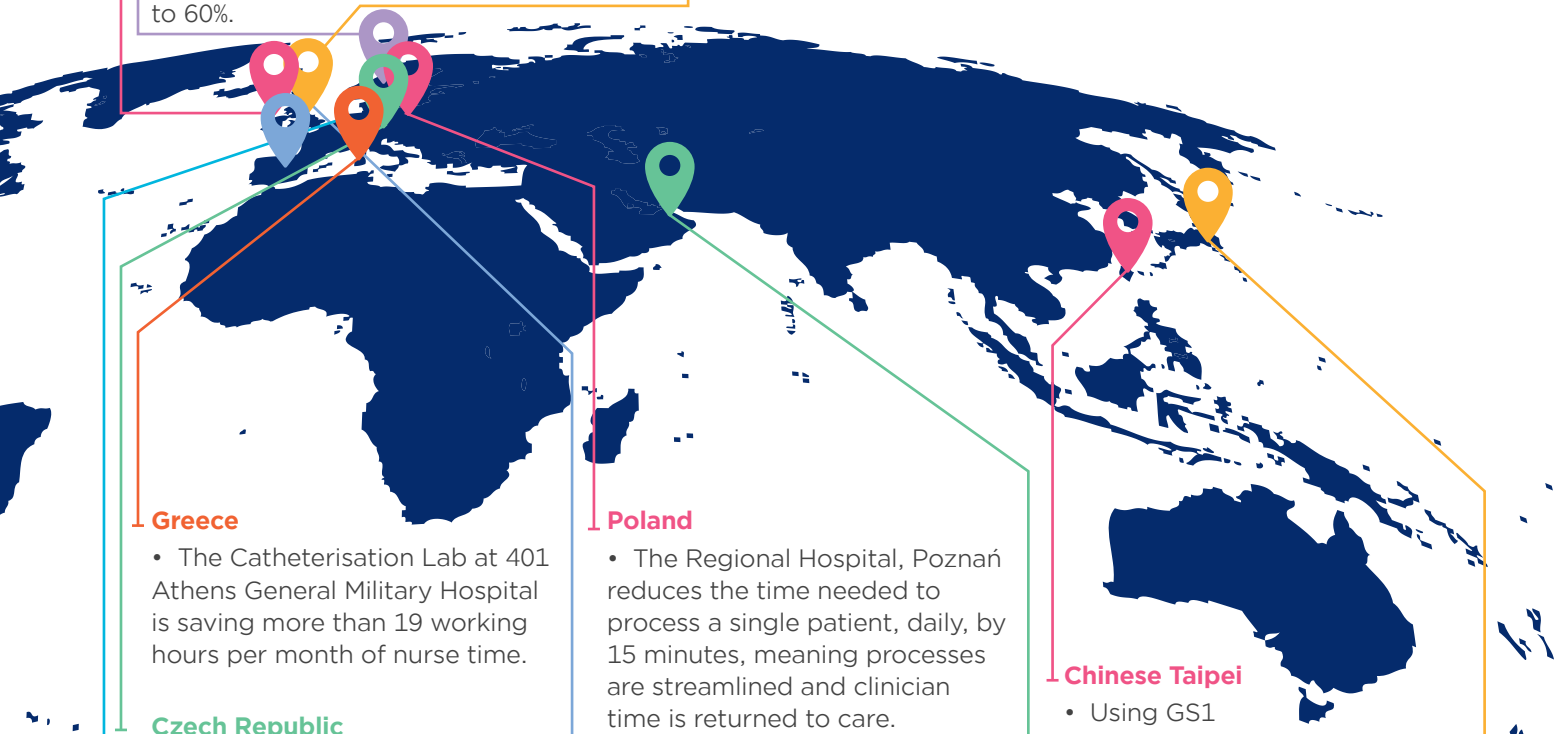
- CHI (Children's Health Ireland) at Temple Street estimate their time savings equate to half of a full-time member of staff every week, whilst also reducing waste and increasing patient safety by tracking their infant feeds with GS1 standards.

Denmark

- Introducing culture change at Rigshospitalet meant their scanning rate after six months increased from 5% to 60%.

UK

- By automating their inventory management processes, Taunton and Somerset NHS Foundation Trust have saved more than £1m, as well as more than 30 hours a week of clinical staff time.
- Royal Cornwall Hospitals NHS Trust reduces their overall dispensing error rate by 76% using GS1 standards and universal unique identifiers.
- Using GS1 standards to share vital patient information, improve patient safety and increase traceability across different healthcare providers at Royal Papworth Hospital NHS Foundation Trust saved over £50k in the first year.



Greece

- The Catheterisation Lab at 401 Athens General Military Hospital is saving more than 19 working hours per month of nurse time.

Czech Republic

- Implementing Unique Device Identification using GS1 standards helps LINET to achieve a proactive advantage.

Germany

- PHOENIX group uses GS1 standards to fulfil its FMD requirements in 17 countries for wholesale and pre-wholesale activities.

Spain

- Hospital Universitari Vall d'Hebrón ensures prostheses traceability enabling more effective recording of use, ordering, invoicing and printing implant cards.

Poland

- The Regional Hospital, Poznań reduces the time needed to process a single patient, daily, by 15 minutes, meaning processes are streamlined and clinician time is returned to care.
- At the University Clinical Centre, Gdansk, medical devices used are recorded in patient electronic health records, allowing for accurate patient contact during recall and treatment level costing.

UAE

- Dubai Health Authority sees a 96% decrease in the risk rate of medication errors through the implementation of GS1 standards to automate pharmacies.

Chinese Taipei

- Using GS1 standards to improve inventory management at Kaohsiung Armed Forces General Hospital meant a 90.1% decrease on manual work time.

Japan

- Reducing device registration time from 50 sec to 15 sec per item and enabling remote monitoring by leveraging GS1 barcodes at Tokyo Yamate Medical Centre.
- Johnson & Johnson Supply Chain's RFID pilot generates impressive outcomes: 99.96% first pass read accuracy, 80% time reduction compared to manual scanning and 70% faster exception handling.

Working together to provide the safest possible care for patients across the globe

In an increasingly complex healthcare environment, with the development of customised medical products, the need for technology and information sharing to aid decision making, the rising cost of services and treatments, and more empowered patients, one thing remains consistent – the clinicians, nurses, pharmacists, and others who are absolutely committed to ensuring every patient receives the best possible care. Across the case studies that have been submitted this year, we have seen exactly this, a need for global solutions for an increasingly global industry that enable the provision of the safest possible care. What the examples in this book demonstrate is that GS1 standards implementations work best when we all work together – that's solution providers, suppliers, wholesalers and healthcare providers. And let's not forget that the imperative is there, legislation around the world is demanding standardisation and those that are becoming compliant now are already seeing the benefits.

1 Our global healthcare industry needs global solutions

International organisations are increasingly seeing the opportunity provided by GS1 standards for unique identification of medical products and healthcare locations, automatic data capture using barcodes, and information sharing – for product data, transactions and traceability. Companies such as Johnson & Johnson (see page 87) are realising the opportunity that standards provide to ensure accuracy and consistency, and ultimately financial efficiency, in their supply chains.

The vital role of technology in the future of healthcare means that GS1 standards are becoming part of the future-proofing that's taking place in many hospitals around the world. One example is the use by Kaohsiung Armed Forces in Taiwan of artificial intelligence as part of the smart medical system being introduced at their General Hospital (see page 12).

Innovation is key to delivering the smartest and the safest care, and the adaptability of global standards means they're an important enabler to this.

2 GS1 standards are helping the healthcare industry to do its job and that's provide the safest possible care

Growing the awareness of how GS1 standards improve care has to be near the top of everyone's list of priorities when we're potentially working with tens of thousands of hospitals worldwide and many millions of staff. If those on the front line of care delivery don't know why they're scanning, it's a lot harder to integrate GS1 standards into hospital systems. That is why in Rigshospitalet in Denmark, they have a 'star scanner' (see page 24), because involving key stakeholders is proven to make the difference between seeing scanning as a new IT system versus seeing it as an opportunity to provide better care.

What many of the cases in this year's reference book prove is that it is all about patient safety, whether that's improving the safety and traceability of infant feeds at Children's Health Ireland at Temple Street University Hospital in Dublin (see page 32) or the unique identification of pharmaceutical products at the Regional Hospital, Poznań (see page 46). Every one of those implementations requires the awareness and understanding of each member of staff involved. And this doesn't just apply to the clinical application in hospitals, but also to the technology used to ensure the supply chain is accurate and that the product is appropriately identified and barcoded. This is important to ensure products in hospitals and pharmacies are available for the patient when needed.



3 It works best when we all work together

As an industry we are never working in isolation. Every time a solution is implemented that isn't part of a globally harmonised approach, it costs money and causes delays in implementation. Organisations can't benefit from speaking "one language" if they're the only one that understands it. That's why in Chile, CENABAST (Chile's Supply Central of the National System of Health Services) are working with all their suppliers to ensure they're "speaking the same language" and that after a trial period, use of GS1 standards was made mandatory (see page 94). Another example is at Royal Papworth Hospital in the UK where they're creating integrated care systems where different local healthcare providers work together to share patient records, operational information and systems to improve patient care, all using GS1 standards. Interoperability is key to successful implementation projects (see page 67).

4 The legislation imperative is already there, and those seeing the most benefits are those that are becoming compliant now

This year's reference book shows how many outstanding implementations of global standards are in progress. Whilst the benefits above are clear, they're also often driven by regulation such as the European Falsified Medicines Directive (FMD), US Unique Device Identification regulation (UDI) or national programmes such as the English National Health Service's Scan4Safety initiative, the Gulf Cooperation Council Drug Barcoding Specifications, or New Zealand's "Standard for identification and coding medical devices".

That is why it is great to be able to share the experiences of those organisations that are recognising this growing trend requiring global standardisation and are taking action. Movilitas has given us the story behind their work with the PHOENIX group towards FMD compliance (see page 83) and LINET, a medical device manufacturer with headquarters in the Czech Republic, has shared their experiences in becoming UDI compliant (see page 78).



Collaborating on a global scale, e.g. through the sharing of case studies in this Reference Book, must be part of the future of healthcare. The title of the McKinsey report "Strength in unity: The promise of global standards in healthcare"[1], emphasises this and highlights within its pages what that promise is: "implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 million to 1.4 million patient disabilities". Every person working in healthcare wants to be providing the safest possible care and every patient wants to receive it. That's why GS1 standards are vital and why safer, more efficient care starts with a simple scan.

[1] McKinsey report, "Strength in unity: The promise of global standards in healthcare", October 2012





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

Using GS1 standards to create Kaohsiung Armed Forces General Hospital's smart medical system

Challenge

Like many other hospitals in Taiwan, KAFGH had a manual process for updating their medical device and material documents.

Approach

Their UDI project introduced three changes:

1. The implementation of auto-identification for medical materials and devices.
2. Improve cost and quantity control of inventory management for medical materials and devices.
3. Introduce traceability of implanted medical devices to patients.

6.9%
lower on hospital costs

Reduce 1,829kg CO^2 emissions per year

0.9%
decrease on the error rate of medical materials by misuse

90.1%
decrease on manual work time

The implementation of auto-identification reduces the chances of human error and means that implanted medical devices can be traced to the patients that have received them. Building on existing uses of GS1's standard for implementing Unique Device Identification (UDI), Kaohsiung Armed Forces General Hospital combined it with the technology of artificial intelligence to effectively improve health quality, ensure patient safety and improve hospital management.

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Introduction/Background

Kaohsiung Armed Forces General Hospital (KAFGH) is located in Kaohsiung city, the biggest city in southern Taiwan island, and provides medical services for all residents in the area as well as emergency rescue and wartime aid. Being in such a unique position, it's been important for KAFGH to lead the way in their use of innovative technologies to better improve the management of the hospital and keep its medical service at its best.

Since 2013, following the promotion of UDI by the Taiwan Food and Drug Administration (TFDA), KAFGH has been using GS1 standards to manage their medical devices, as well as other clinical areas such as medical records. UDI using GS1 standards is also used in the administration of their inventory, distribution, pricing and supply chain.



Kaohsiung Armed Forces General Hospital
740 beds; 1,206 staff/employees

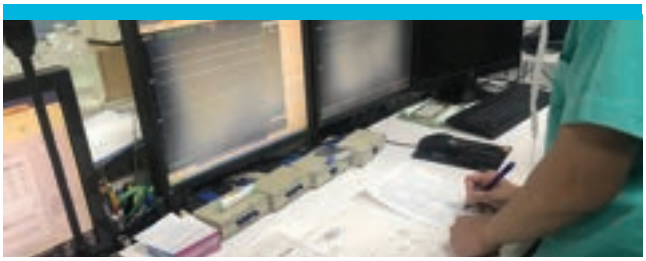
Established in 1945, including: one general hospital and four branches - General Hospital in Kaohsiung city:

- Pingtung Branch: Long term care unit
- Zuoying Branch: Simulated deep sea diving training centre
- Gangshan Branch: Aviation physiological training centre
- Kaohsiung Outpatient centre: Outpatient rehabilitation

Challenge

Like many other domestic hospitals here, KAFGH had a manual process for updating their medical device and material documents. The first aim of their UDI project was to change this in three ways:

- The implementation of auto-identification for medical materials and devices, reducing opportunities for human error and increasing patient safety.
- Improve cost and quantity control of inventory management for medical materials and devices.
- Introduce traceability of implanted medical devices to patients.



Before UDI adoption: manual record keeping



After UDI adoption: a simple scan

From the beginning, KAFGH's UDI project faced some challenges and the following points may help other hospitals that are preparing to implement UDI in the future:

- Involve key stakeholders such as clinicians, nurses, administrators and suppliers at the start of the process.
- Some suppliers will not be willing to label their products using UDI because of concerns about costs and the lack of strong enforcement of the legislation.
- Work with solution providers to enable barcode readers and data collectors to decode the barcodes correctly, so that the information provided through them is accurate. Ensure that hospital IT systems are able to read and process GS1 data. Barcode reader software available in Chinese Taipei is often not able to read GS1 standards, or product information is not being updated into hospital databases by suppliers. It can also be difficult to integrate the new IT system with capability to hold UDI information into existing databases without having to change too much. All of these aspects are worth consideration when choosing which solution providers to collaborate with.
- There can be confusion around the identification contained within the UDI, for example, according to the standards the same item but a different packaging level should have a different UDI. However sometimes the same numbering is incorrectly used for many items. This can make the identification difficult for machines and humans to read.
- The full support of senior management will help with collaboration across all departments when implementing UDI.

Further to the above, KAFGH achieved this by:

- Seeking the support and assistance of our FDA and GS1 Chinese Taipei to understand the benefits of GS1 standards and UDI implementation.
- Organising workshops and seminars for the suppliers of medical materials and devices to explain the reasons behind implementing GS1 standards following the UDI guidance, especially where there are benefits for suppliers e.g. accurate, real-time data on usage and stock from the hospital's inventory management system.
- Creating awareness, engagement and commitment around the concept of UDI in departments where implementation is taking place, providing training and a working group for staff, and inviting them to suggest any improvements they might make.

Solution

As mentioned, the main challenge for data visibility remains the ability to use UDI data throughout the whole network of the hospital's existing databases. This is why it was important to make sure that the UDI could be captured efficiently and accurately by all systems that required supply data for one purpose or another, including for interoperability purposes and for updating of the electronic patient record.

Since 2016, KAFGH has been working with XuZhen Medical Co., Ltd., which provides a GS1 standards and UDI cloud solution: Chronos®. This includes the use of Artificial Intelligence (AI), with patented algorithms and machine/deep learning, to enhance cloud computing's UDI capabilities in clinical medical environments. This allows the hospital to automatically complete the synchronisation of data feeding services, including clinical medical information system, supply chain management system, the hospital management system and the logistics system.

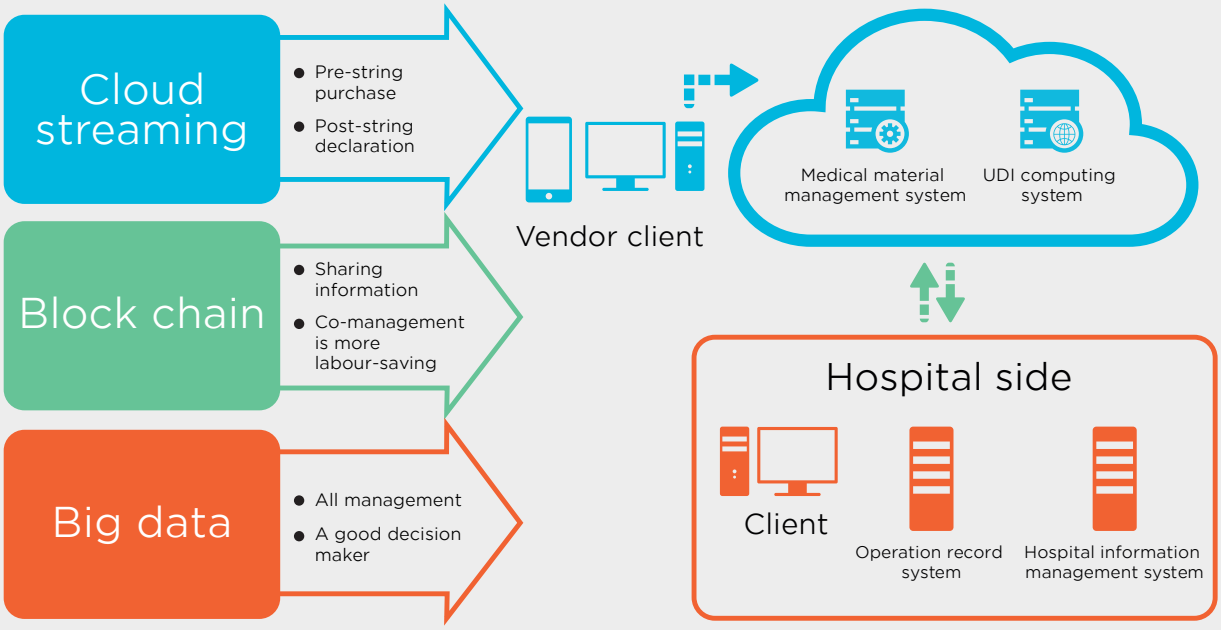
Steps

The first thing KAFGH did was to upgrade their information system to XuZhen's Chronos® so they could manage medical materials and medical devices through UDI implementation. This meant that with one scan, the management of all their clinical, and any other related processes, was automated. Chronos® is also compatible with all existing information systems in the hospital so no additional integration had to take place. Training was also provided so that hospital staff could quickly use the new tools and processes.

At the same time, KAFGH also worked with suppliers to highlight the benefits of implementing GS1 standards and UDI labeling guidelines for them, including the real-time online consignment stock management interface that is specially designed for suppliers by XuZhen's Chronos®.

Lastly, XuZhen's Chronos® connected internally to each system of the different departments in the hospital, so that they'd get the right data as they need it, and also to provide the required information needed for the public database, owned by the TFDA, for product authentication.

UDI system architecture



What is achieved above is an intelligent management system with three supportive ICT features:
1. cloud streaming **2.** block chain technology **3.** opportunity for big data analysis

Material inventory

Smart capability managing general medical supplies, consumables, high-value implants

Reduce the managing burden of administration personnel

Clear and simple accounting

Less procurement process

Less expired inventory in hospital

Clinical utilisation

One scan and easy use

Significantly reduce the problems of out-of-stock

Lower the cost

Healthcare practitioners

Improve the accuracy of health insurance declaration

Reduce medical loss of hospital

Provide complete Electronic Medical Records (EMRs)

Suppliers

Precise reconciliation

Prediction of inventory replenishment

Logistics information of product delivery

At this stage, KAFGH has already implemented UDI-based information systems for all existing 16 surgical operation rooms from different divisions across the whole hospital.

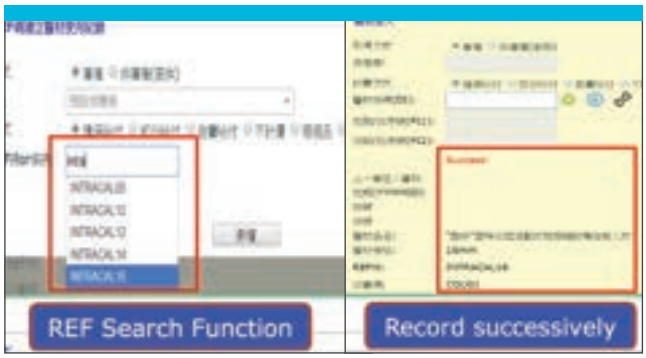
As a result of their work so far, more than 90% of medical materials and devices can be identified by scanning their UDI barcodes; less than 10% could not be identified. In those instances, the system can retrieve the correct product data from the cloud using the reference number shown on the box. Both marking/labeling can be read by the readers so the patient record can be updated. The software provides a constant link to the TFDA database of product permits which every medical product must apply for and be registered before launching to the Chinese Taipei market. There is still a small percentage of bulk medical materials without UDI, such as cotton buds, gauze, bandages etc. Here, KAFGH would use the GTIN in the EAN-13 barcode to identify them.

The three areas that need to be considered when implementing UDI are:

1. Products without UDI labels



Use reference number when UDI not available



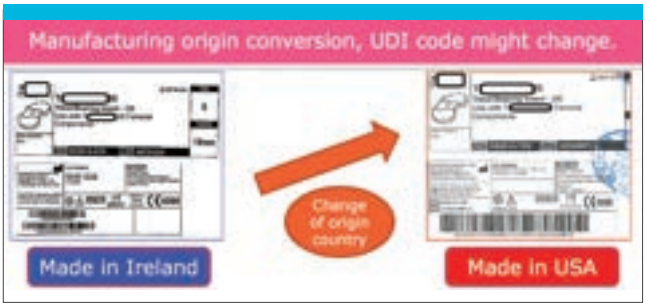
Solution system screens using reference number to check

2. Same product items but with a different package level

Package type	Package level	DI code
Single package	0	04711234560012
Two in package	0	04711234560029
10 in package	0	04711234560036
A box of 48 groups of 2 into the packaging	1	14711234560026
A box of 48 groups of 10 into the pack-aging	1	14711234560033

Same product items but UDI changes, which are identified as same product grouping by Chronos® Artificial Intelligence

3. Same product items show same company brand but different origin of production (different country code)



Same product items but UDI changes, which are identified as same product grouping by Chronos® Artificial Intelligence

Products without a match in the system are suspended as suspicious products and technicians then confirm whether a warning notice to the company or to TFDA is needed. That's another way the new system provides such control, improving protection against counterfeiting for hospitals and for patients.



Benefits

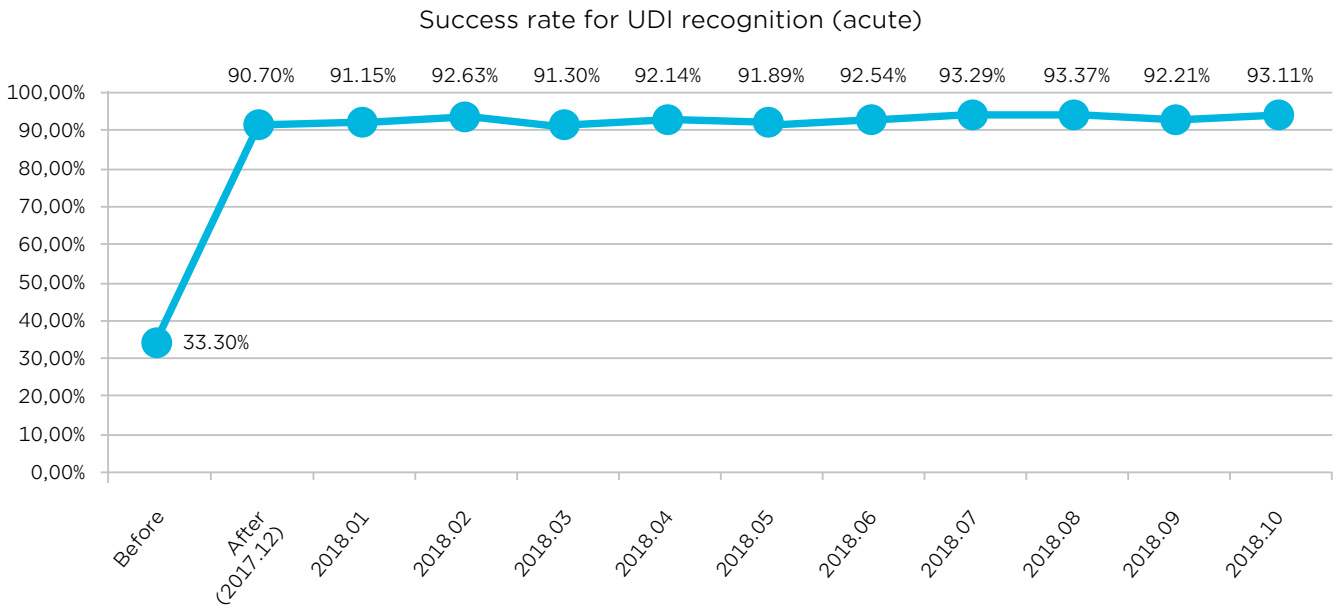
All stakeholders in the healthcare supply chain have benefitted from KAFGH's experience of UDI implementation. Above all, the automation has released healthcare professionals' time back to care, where they previously would have been busy with traditional manual administration and management. The system's traceability has enhanced patient safety by using GS1 standards and UDI to correctly identify products with a simple scan of barcode.

Moreover, UDI helps showcase all levels of inventory information for both the hospital and all suppliers. This prevents issues around undersupplying or oversupplying products by offering a clear, real-time picture of patients' (or surgeons' / physicians') usage, so as to ensure a seamless supply.



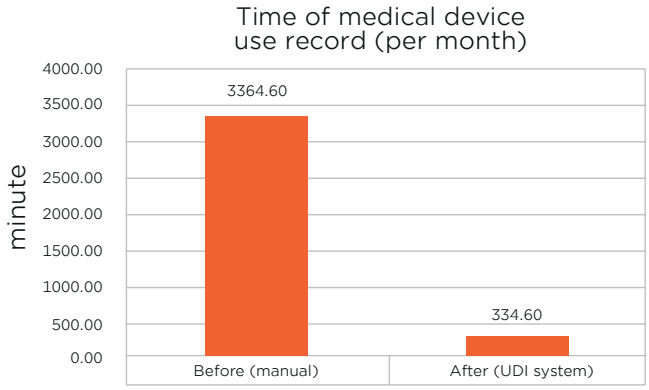
Quantitative indicators:

1. Above 90% success rate on UDI recognition right after solution implementation



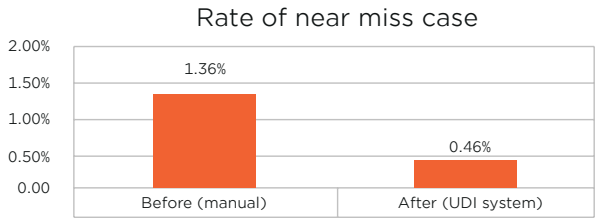
Category	2017.12	2018.01	2018.02	2018.03	2018.04	2018.05	2018.06	2018.07	2018.08	2018.09
Item number (should be identified)	140	192	285	437	369	518	456	462	377	398
Class 1 medical device	0	4	5	12	10	4	12	12	9	1
Human donation organisation	0	2	0	1	2	0	0	0	0	0
Drug	2	3	5	6	2	4	1	5	4	1
No UDI label (suppliers don't supply)	2	4	5	12	10	30	21	14	10	22
UDI system error	9	4	6	7	5	0	0	0	2	7
Item number (successfully identified)	127	175	264	399	340	480	422	431	352	367
Success rate for UDI recognition (%)	**90.7**	**91.2**	**92.6**	**91.3**	**91.1**	**91.9**	**92.5**	**93.3**	**93.4**	**92.2**

2. 90.1% decrease on manual work time (including administration management man-hours and medical recording man-hours)



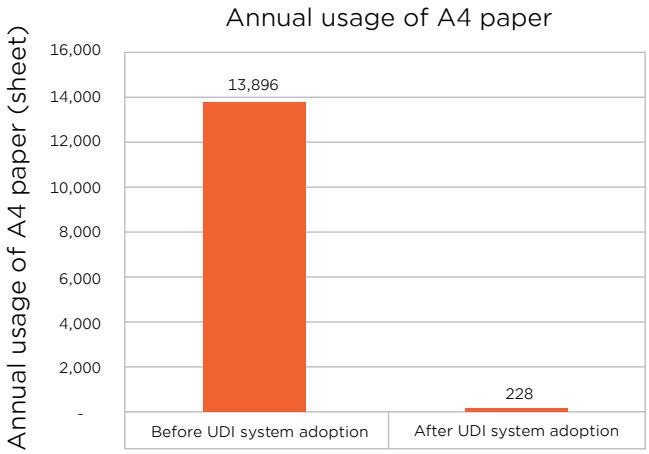
90.1% decrease (3364.60 minutes down to 334.60 minutes.)

3. 0.9% decrease on the error rate of medical materials by misuse



0.9% decrease (From 1.36% down to 0.46%)

4. Save 13,668 A4 papers ($) and reduce 1,829kg co_2 emission per year



Save 13,668 A4 papers
(From 13,896 sheets down to 228 sheets)

5. 6.9% lower on hospital cost

Paper cost down	273.44 USD per year
Salary cost down	4734.61 USD per year
Near miss cost down	3891.05 USD per year
Patient safety cost	Incalculable and priceless

Qualitative benefits:

- The product transparency after implementation reduces the issues and problems of consignment products.
- Lessen the number of administrative tasks for clinicians and nurses, leaving them to focus on the care of patients.
- Ensure full traceability of medical devices and products to patients.
- Improve internal data sharing between information systems and databases so as to advance hospital management.

Conclusion

Today, hospitals in Chinese Taipei are using multiple information systems, each designed for the different needs of each department. The challenge for IT departments, therefore, is to enable the use of product IDs across this complicated infrastructure. UDI offers a unique chance to capitalise on a standard used all the way through to the patient and beyond.

KAFGH's UDI project is an incredible achievement in Taiwan as it finally standardises documentation processing and reporting throughout a hospital, with data captured efficiently and accurately by UDI and used by all their existing systems. Following on from this success, the next stage for KAFGH will be to apply unique identification to the full life cycle of drug dispensing, using barcodes like the GS1 DataMatrix, in their hospital.

The key to success remains the ability to leverage UDI throughout the healthcare supply chain. Once implemented, KAFGH have seen benefits such as:

1. Improved inventory management

Once all medical devices have a scanable barcode, inventory management is no longer an arduous process, susceptible to human error. It provides real-time, online analytics regarding cost, recalls and waste. This empowers healthcare providers to reduce waste significantly, audit inventory easily, and stock their facilities effectively.

2. More time with patients

Instead of manually filling out device information on forms or trying to hunt down the model of a medical device, the scanable and readable UDI label makes this information readily available. The automation of the process on data entry and electronic medical records releases more time to physicians and nurses to focus on their patients.

3. More informed patient treatment

UDI ensures that all information regarding an implanted medical device is retained. This enhances the analysis of devices on the market by providing a standard and clear way to document the device use in electronic health records, clinical information systems, claim data sources and registries. It helps doctors to better respond to a patient's unique needs by retrieving more detailed information accordingly.

4. Better assessment of device performance

A UDI solution like KAFGH's provides a lot of trackable data for medical devices, which doctors can use to assess medical implants by looking at the health outcomes by the model of device, the hospital where it was implanted, and in some cases the physician who performed the surgery. Through more accurate reporting, reviewing and analysing of adverse event reports, problem devices can be identified and corrected more quickly. Additionally, a more robust post-market surveillance system can be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.

5. Reduction in medical errors

Scanning a UDI barcode makes it easy for healthcare professionals to rapidly and precisely identify a device and obtain important information concerning the characteristics of the device. This helps the reduction of medical errors by enabling an additional level of verification before a medical device is used or implanted in a patient. This extra authentication helps prevent mix-ups, which can have harmful or even deadly consequences.

6. Faster recalls

The UDI system eliminates all guesswork by providing data transparency that allows manufacturers, distributors and healthcare facilities to effectively manage medical device recalls. Using a simple scan, medical professionals can quickly see if medical devices in their facilities are included in a recall, and remove those devices from use.

7. Reduction in counterfeiting

UDI barcodes lock a medical device into a chain of custody process. With UDI, medical devices are controlled from the manufacturer to the distributor, to the healthcare provider, and all the way to patient use. This means medical devices are checked at multiple points, especially for KAFGH, where the UDI solution provides powerful features to screen suspicious products or forgeries. This greatly reduces the possibility of a counterfeit device entering clinical usage.



About the authors



Dr. Chou-Yuan Ko
Superindendent
Kaohsiung Armed Forces General Hospital

General Ko is currently the superintendent of Kaohsiung Armed Forces General Hospital. He makes sure KAFGH pass strict requirements of patient safety and spares no effort to continue promoting the hospital's quality improvement work.
He is also one of the most important decision makers of KAFGH's UDI technology promotion.



Dr. Shih-Chung Huang
Physician of cardiology
Kaohsiung Armed Forces General Hospital

Dr. Huang is currently the attending physician of cardiology and the chief of the Teaching and Research Centre in Kaohsiung Armed Forces General Hospital. One of his responsibilities is to encourage his team members to cooperate with other departments to achieve the best results.



Dr. Kingsley Huang
Postdoctoral research fellow of the Institute of Clinical Medicine
National Yang-Ming University

Dr. Huang is a postdoctoral research fellow of the Institute of Clinical Medicine, National Yang-Ming University in Chinese Taipei. Meanwhile, he is also a chief technology officer of XuZhen Medical Company Limited, which helps integrate clinical systems with UDI concepts using his innovative solutions to medical merchandise management.



Major YI-Liang Shih
Medical material supply officer
Kaohsiung Armed Forces General Hospital

Major Shih is currently not only the medical material supply officer of Kaohsiung Armed Forces General Hospital, but also is a pharmacist. Since 2014, he has been responsible for the development and promotion of UDI technology in KAFGH. He's also one of KAFGH's key implementers of technology promotion.

About the organisation

XuZhen Chronos®
A GS1 standards and UDI oriented cloud solution developed by Xu Zhen Medical Co., Ltd. the start-up company with strong strengths and worldwide ambitions aiming to provide IoT, blockchain and cloud technologies as a solution to empower the outstanding medical services in major medical institutions. www.xuzhen.com.tw



Costa Rica

National Children's Hospital uses GS1 standards to improve efficiency in patient care

Challenge

The inventory the National Children's Hospital were working with was identified in a variety of ways and their data was not being used efficiently. It was also being looked after by medical personnel who did not have training in the management of logistics processes.

Approach

Working with GS1 Costa Rica, the National Children's hospital implemented GS1 standards and better logistical practices to bring innovation to their way of managing medical supplies and to initiate the automation of processes.

100%

of medical supplies in the warehouse identified by GS1 standards

Employees trained about GS1 standards and best logistics practices

Planning system for care management defined allowing necessary supplies to be available for the timely care of patients

Cleansing of the warehouse to remove expired products

The National Children's Hospital Costa Rica was inaugurated on May 4, 1964 with the mission to "contribute to improving the health of the child population of the country by providing specialised and emergency care through comprehensive quality services, effectively, efficiently, with equality of opportunity". Since then, this noble institution has become the national standard for children's care and backs this with ongoing research into how they can better the health of Costa Rican children and become more efficient in delivering patient care. As part of this, the Integral Care Unit for Burns (UCINQ), in the year 2018-2019, began implementation of automated management of inventory control for the medical supplies in their warehouse.

Olga Arguedas

Greater efficiency in resource management

Improving the management of medical supplies in UCINQ was the challenge, so that they could provide better quality service and greater patient safety through efficient resource management. The inventory they were working with was identified in a variety of ways and their data was not being used efficiently. It was also being looked after by medical personnel who did not have training in the management of logistics processes. Inaccurate controls and poor visibility of inventory caused problems such as shortages and expiration of products at all levels of medical care. This made it impossible for the unit to make timely decisions or to optimise the allocated budget.

The medical staff was dedicating a lot of time to completing administrative tasks inefficiently, which reduced the time available for patient care.

Manual processes that generated patient risks:

Expired / discontinued	34%
Without standard identification	20%

Note: Today the whole inventory is identified and suitable to be used.

"GS1 standards and their integration with technology are our best ally in carrying out our philosophy of contributing to the improvement of the health of the child population in our country, through providing comprehensive quality services, effectively, efficiently, and for everybody."

Dr. Jaime Cortés Ojeda
Head of the surgery
National Children's Hospital

Automating safer processes using GS1 standards

GS1 Costa Rica, through its advisory service, recommended the implementation of GS1 standards and better logistical practices to bring innovation to their way of managing medical supplies and to initiate the automation of processes. The project was carried out in UCINQ, using the GS1 128 and GS1 DataMatrix data carriers as the foundations of the implementation.

The first step was documenting the technical requirements and the existing basic procedures, so that they could visualise the adjustments needed in the daily routines at UCINQ. Once this first step was agreed upon, support and training was provided by GS1 Costa Rica in order to build on the understanding of GS1 standards and their applications, within each of the new processes developed. In parallel to this, UCINQ worked with a software provider to roll out the recommendations agreed with GS1 and they were able to achieve automated management in the following processes:

1. Product identification.
2. Control of income, outputs, and physical inventory takings.
3. Control by lot number, expiration date, and purchase order.

The composition of the identification of products through the data carriers GS1-128 and GS1 DataMatrix was as follows:

DATA	AI
Product identification	01
Lot number	10
Expiration date	17
Purchase order	400

"At the Children's Hospital, we are pioneers in innovation at a whole country level. Now we have a process that helps us in our administrative day-to-day, but the most important thing is that it assures us of the safety of the patient: we know we have the right patient, the right medication, the right dose, and the right method of administration at the right time."

Dr. Cinthya Mora
Head of the reconstructive surgery service
National Children's Hospital



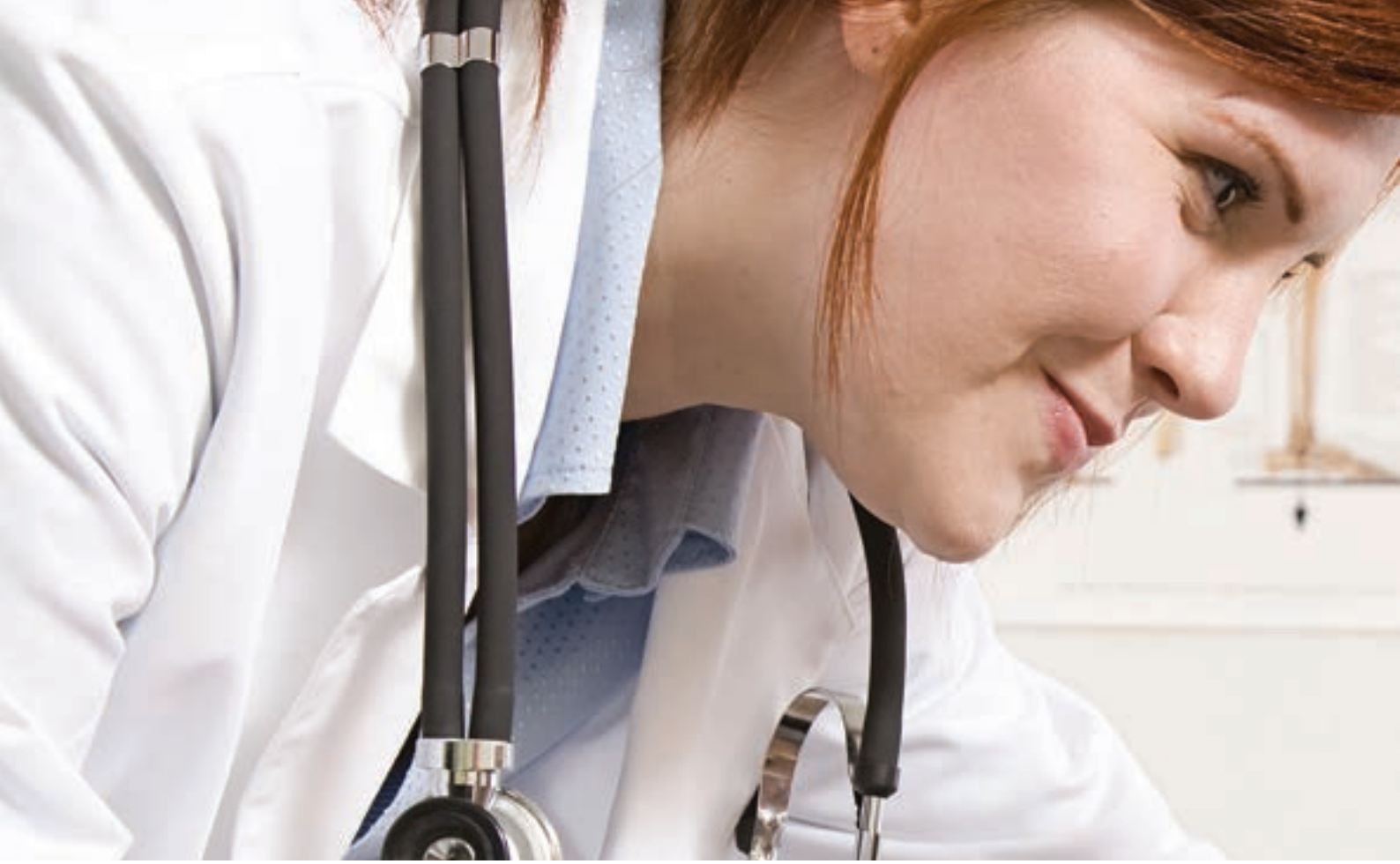
GS1-128



GS1 DataMatrix

Benefits so far

- The inclusion of GS1 identification standards to 100% of the medical supplies in the warehouse.
- Definition of policies and work standards based on the management of the entry and exit of articles.
- Cleansing of the warehouse. This involved donating products that were not being used to other institutions, and a large number of expired items was discarded. Currently, 100% of the inventory of the warehouse consists of active medical supplies.
- Incorporation into the warehouse of technological devices (printer for labeling, computer, and telephone, etc.), and warehouse management software to perform tasks, and inventory entries and exits.
- Products stored in the warehouse that did not have identification were tagged and were adjusted to GS1 standards (internal work and with suppliers).
- Use and revenue policies restricted to the warehouse were established.
- A planning system for care management was defined, which allows the necessary supplies to be available, and more quickly, for the timely care of patients.



- Workers are trained in GS1 standards and best logistics practices for warehouses, as well as in the use of the information system. This allows for greater and more effective use of the data. Now there is logistic staff responsible with the guidance from nursing staff.
- At a general level, a culture was created focused on planning, policy compliance, maximisation of resources and use of technology. This provides greater patient safety by avoiding errors, and greater efficiency of the equipment, allowing the medical staff to focus on the direct care of patients.

Project scope at Integral Care Unit for Burns (UCINQ)



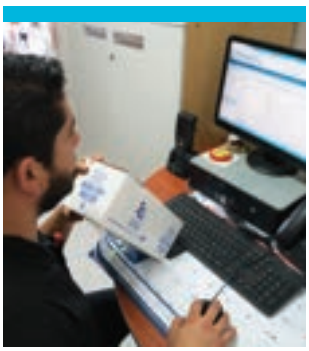
Next steps

Work at the hospital continues to be exhaustive and is a daily challenge for all the personnel involved. Doctors, nurses, and administrative staff focus on meeting the five requirements for patient safety: correct product at the right time, in the right patient, by the right professional, by the correct route and in the correct dose.

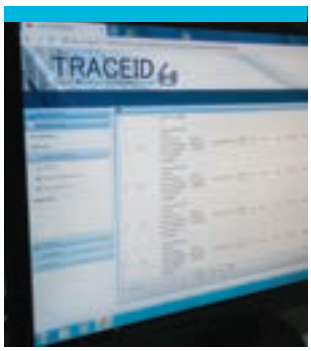
Next steps in 2019 include:

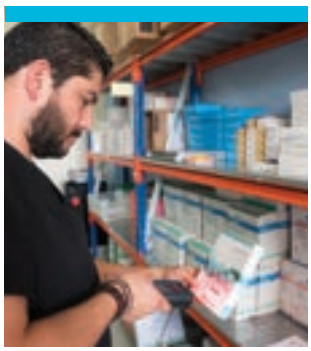
- The generation of statistics and data that allows strategic decisions to be made.
- Visualisation of care costs per patient.
- Development of new approaches to personalized services.

In the medium term, the authorities intend to make a formal contract to replicate the model in all the warehouses of the hospital, starting with the stores of general surgery, anesthesiology, orthopedics, and odontology.











About the author



Olga Arguedas
M.D. PhD. General director
National Children's Hospital

Dr. Olga Arguedas is the General Director of the National Children's Hospital in San José, Costa Rica. She received her medical degree from University of Costa Rica, Faculty of Medicine and her training in Paediatrics at the National Children's Hospital in Costa Rica. Then she obtained a Masters and a PhD degree in Paediatric Immunology at the University of Gothemburg in Sweden, with post-doctoral studies at the Gaslini Institute in Genova, Italy. She also did studies in Hospital Management at the National University of Distance Education in Costa Rica. Dr. Arguedas has been in practice for more than 30 years.

She is a Professor in Paediatrics at the University of Costa Rica, and has been the author of several articles and chapters in books. She has been the Director of the Department of Paediatric of the University of Costa Rica, and the Executive Director of the Center for Strategic Development, Research and Education of the Costa Rican Social Security System.

About the organisation

The National Children's Hospital Costa Rica was inaugurated on May 4, 1964 with the mission to "contribute to improving the health of the child population of the country by providing specialized and emergency care through comprehensive quality services, effectively, efficiently, with equality of opportunity". Since then, this noble institution has become the national standard for children's care and backs this with ongoing research into how they can better the health of Costa Rican children and become more effiencient in delivering patient care. https://www.ccss.sa.cr/hospitales?v=21

Denmark

Bedside scanning requires cultural change

Challenge

Despite the fact that scanners were present in the Righospitalet dispensary, barcodes were present on 99% of the secondary packs and on 84% of the primary packs, the nurses only used the scanners for approx. 5% of the dispensations.

Approach

Barcode scanning needed to be higher on the agenda and nurses needed to see the benefits for both patients and themselves. In collaboration with GS1 Denmark, the clinic held a staff meeting with the focus on patient safety and how scanning in the dispensary helps to prevent unintended events. Cultural change was needed to ensure everyone involved saw the value of scanning.

The nurses now have a positive attitude towards the new workflow

The clinic held a staff meetings with the focus on patient safety and how scanning in the dispensary helps to prevent unintended events

The clinic works to ensure that all medicines are marked with scannable barcodes

60%

Scanning rate after six months increased from 5% to 60%

Rigshospitalet is a University Hospital in the Capital Region of Denmark. It is a highly specialised hospital, which covers almost all medical areas. Annually 85,000 inpatients and around 1 million outpatients are treated at the hospital, which covers 1,200 beds. The Department of Paediatric Surgery is a clinic at Rigshospitalet, which handles the treatment of children and adolescents with acute and chronic conditions. It is a clinic with complex patient pathways and an everyday life that has many different tasks.

Trine Spiegelhauer

In 2010, scanners were installed in the dispensary, as it became a requirement in the Capital Region of Denmark that medicine should be scanned to ensure that the right drug is dispensed. Despite the fact that scanners were present in the dispensary, and that barcodes were present on 99% of the secondary packs and on 84% of the primary packs, nurses only used the scanners for approx. 5% of the dispensations. “This is proof that requirements and technology alone do not provide patient safety”, states Trine Spiegelhauer, who at that time was nursing director at the Department of Paediatric Surgery.

Methods of change

In other words, barcode scanning should be higher on the agenda, and Trine made plans for methods of change. “Basically, all nurses must see the benefits for both patients and themselves. Specifically, how barcode scanning prevents adverse events”, says Trine. In collaboration with GS1 Denmark, the clinic held a staff meeting with the focus on patient safety and how scanning in the dispensary helps to prevent unintended events. “It can promote implementation and, in some cases, strengthen the legitimacy of the purpose of a project when several stakeholders work together. In this specific project concerning the scanning of medicines in the dispensing process, it was important for us to invite GS1 Denmark as a partner”, says Trine.

Before the process started one of the barriers for scanning was that some barcodes could not be scanned. To get an overview of the percentage of scannable barcodes, GS1 Denmark conducted a survey. The result was that the scanners in the dispensary were not able to scan 2D barcodes. Subsequently, the scanners and software were updated and configurated, and afterwards all barcode types could be scanned, which also was a great driver for the process.

To ensure continuity in daily routines, the following was implemented:

- Two nurses were appointed as ambassadors for the purpose of creating a good atmosphere around barcode scanning.
- Software and hardware were updated to avoid technical barriers.
- Scanning was discussed at the weekly clinic meeting.
- Each week, based on data for the use of the scanner, a 'Star Scanner' was announced.

Monitoring the staff – the reaction

The first couple of months, 'The Star Scanner' put a sensitive issue on the agenda, namely monitoring and privacy:

"When it became clear to the nurses that in the IT system we could monitor behaviour right down to person level, some were a little scared. But through open dialogue about the purpose and by establishing the benefits for the nurses, this was no longer an issue. However, it is a fact that the human aspect in a process of change must not be underestimated – otherwise the change can go backwards", says Trine.

Results

Trine's plan for cultural change has created visible results. The nurses have a positive attitude towards the new workflow and now take action when they encounter packages that cannot be scanned or that do not have a barcode. It creates an important feedback link to the suppliers, and in collaboration with the hospital pharmacy of the capital region and GS1 Denmark, the clinic works to ensure that all medicines in the clinic are marked with scannable barcodes. Missing barcodes are a barrier that results in inconsistent workflows, thereby increasing the risk of errors.

% By focusing on scanning, the scanning rate after six months increased from **5%** to **60%** (for both inpatients and outpatients), and scanning has become a natural part of workflow.

Deployment at several clinics

In 2018, Trine became nursing director of the Clinic for Children and Adolescents with Surgical Diseases, which includes five other specialties in addition to the Department of Paediatric Surgery.

The new clinic has not yet focused on scanning, and it is Trine's goal to achieve the same results for barcode scanning in this clinic. But how?



"To a large extent I will transfer the implementation methods that we used in the Department of Paediatric Surgery - it worked", says Trine. However, there are some differences between the clinics to consider.

"Staff turnover has generally increased in the nursing profession over the past 10 years. This underlines the importance of having barcode scanning as part of the training for new employees to ensure good scanning habits from the start", believes Trine. In addition, Trine will involve the internal improvement secretariat of the hospital and share her experiences with management colleagues in other departments:

"In this way, our learnings can benefit others and hopefully inspire other departments to focus on barcode scanning and culture," hopes Trine.

The change process: the importance of the leader

Creating behavioural and attitude change in a staff group is a classic example of a change project - and a major task for the responsible leader. Trine has gained a lot of experience, and her advice is:

- "It is very important to be a clear leader and show the way, but it is equally important to have strong nurses on the floor as ambassadors to help pave the way".

"A cultural change must make sense for the individual nurse in order to succeed. Therefore, the process must be done with small steps forward, so that everyone can participate and see ongoing results. Then it makes sense for the individual nurse."

Trine Spiegelhauer
Nursing director
The Clinic for Children and Adolescents with Surgical Diseases

- "Implementing barcode scanning is not something you do overnight. It is a process that needs to be kept in focus. If you think of it as a project that can be implemented in a limited period and then left alone, it will not be a success - not a lasting one, at least".

Barriers to cultural change

When implementing barcode scanning as a new work routine, some barriers are important to keep in mind. If the new routines are not maintained, there is a risk of falling back to the old work routines. The risk of "relapses" increases if IT equipment such as scanners do not function optimally, or are placed in an impractical location with regard to the nurses' routines. Cooperation with your local IT department is therefore crucial. Also, to be able to get the statistics that can document progress and share the progress with the nurses.

A watchful eye for opponents of change is also necessary, and emphasises the importance of having positive ambassadors in the staff group:

"The most efficient way to deal with opponents is dialogue, and no one can disagree that we should do everything possible to increase patient safety", concludes Trine.

About the author



Trine Spiegelhauer
Nursing director
The Clinic for Children and Adolescents with Surgical Diseases

Qualified as a Registered Nurse in 1997 from Rigshospitalet Nursing School, Copenhagen. She holds a master's degree in Public Governance from Copenhagen Business School. Trine has been function manager at the Department of Paediatric Surgery since 2004, and in January 2018 she became nursing director for the Clinic for Children and Adolescents with Surgical Diseases.

About the organisation

The clinic consists of four departments that treat children and adolescents with acute and chronic diseases of the gastrointestinal tract, kidney urinary tract, liver, genitals, face, bones and joints. Many of the diseases are complex, and the clinic therefore deals with children and adolescents from all over Denmark, as well as Greenland and the Faroe Islands.

There is a total of 41 beds in the 4 sections, and approximately 55 nurses are responsible for the daily care of children and adolescents. Annually, over 3,000 inpatients and almost 10,000 outpatients are treated in the clinic.
www.rigshospitalet.dk



Greece

The impact of GS1 standards on operating room efficiency at the 401 Athens General Military Hospital

Challenge

Lack of standardisation for the hospital's inventory made it very difficult to have a clear view of operating room stock and the medical devices used during surgeries. Moreover, the hospital's Enterprise Resource Planning (ERP) did not allow accurate traceability of high-risk items such as implants.

Approach

Using GS1 standards, the hospital can now unambiguously identify inbound materials and medical devices used for each patient, not only in the OR but also in the Cardiac Catheterisation Laboratory and the Interventional Radiology Department.

Expiration dates are checked automatically before devices are used

Using GS1 standards the hospital can now unambiguously identify inbound materials and medical devices used for each patient

19h

Savings in nurse time are more than 19 working hours per month

€ 21,000

net return on investment in 2018

In army supply chain processes, it's imperative to achieve fast and accurate operations. 401 Athens General Military Hospital, the largest army hospital in Greece, wanted to provide its patients with the same level of operational efficiency. Lack of a standardised coding and naming scheme for the hospital's inventory made it very difficult to have a clear and precise view of operating room (OR) stock and the medical devices used during surgeries.

Sotirios Tsiafos-Tsiaras

Moreover, the hospital's Enterprise Resource Planning (ERP) did not allow accurate traceability of high-risk items such as implants. Manual registration of medical devices in the hospital's Electronic Patient Records was time-consuming and in many cases error prone. Using GS1 standards, the hospital can now unambiguously identify inbound materials and medical devices used for each patient, not only in the OR but also in the Cardiac Catheterisation Laboratory and the Interventional Radiology Department. This implementation has already offered faster item registration in the OR, improved traceability and remarkable stock effectiveness. GS1 standards are invaluable to the hospital's internal supply chain and they have already created a pipeline of future projects that will offer a better, more efficient caregiving experience for its patients.

The Athens General Military Hospital was founded in 1904 (renamed as "401 Athens General Military Hospital" in 1970) and is the largest of all the Hellenic Army's hospitals. It is also one of the largest healthcare institutions in Greece. Apart from its historical importance, the hospital is a base for scientific knowledge with engagement in research and training educational activities. It is this institution that trains Hellenic Army doctors and nurses (who are considered as high-level professionals in the Greek healthcare industry) and civil doctors who have been accredited by the Hellenic Ministry of Health. Moreover, it performs clinical and laboratory research projects and maintains a great medical scientific library. The hospital is also a member of the web community named "IMIHO - Interconnection of Military Hospitals" which has as its core purpose medical information exchange among South Eastern Europe military hospitals that specialise in challenging military and humanitarian activity.



Poor data accuracy, unreliable processes

In such a demanding healthcare environment, the problems that were arising from having a non-standardised medical device coding and naming scheme were multiple.

First, there was not an accurate view of the OR's stock. Before the implementation of GS1 standards, there was no clear monitoring of what had been used on each patient during surgery, as well as on-the-shelf stock levels. This was a clear threat to the adequacy of management of everything needed for operations. Enquires from medical staff prompted a thorough but time-consuming search and the answers were sometimes inaccurate.

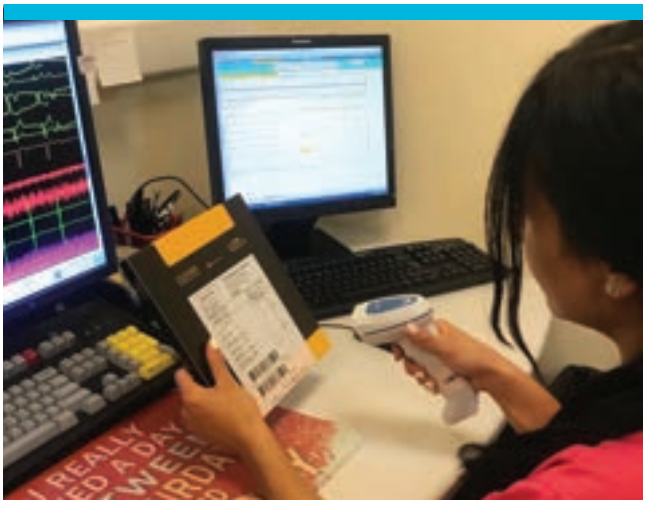
Moreover, the hospital's ERP did not support the recording of crucial item quality information such as batch/lot numbers, serial numbers, and expiration dates. The absence of this information made it difficult to locate items near their expiration date, or recalled or expired items. It also made it hard to plan an effective budgeting and procurement strategy.

Furthermore, recording of items used in surgeries was administered manually. Before GS1 standards, nurses in the OR were searching for item information (usually by reference number) in catalogues (spreadsheets) with a high risk of mistakes during the process. They first had to locate the item reference number and then manually register it in the hospital's ERP system. Expiration dates and other data for each item, were briefly cross-checked by the personnel and marked, if required, in paper documents for internal circulation. This practice included high-risk items such as implants, stents, and pacemakers, etc. Also, the nursing staff had to dedicate even more time to rechecking the records afterwards and, most of the time, items (such as surgical sutures and other general use items) that had been used in operations were not recorded at all.

Therefore, stock and surgery cost information wasn't reliable. The whole process was extremely time-consuming, resulting in a defective, bureaucratic process for hospital staff. In addition to these challenges, and most importantly, staff couldn't focus completely on their main duty – patient care.

The demand was clear. Reliable, accurate data needed to be captured, registered in the system and used for tracking and tracing high-risk materials. This required a major upgrade in hospital processes, focused on automation. The most difficult part was the engagement of staff in the ultimate vision: implementing GS1 standards and using them as a reliable, trusted tool in their daily routine.

The hospital, based on the previous and successful Hellenic Army Medical Supplies Centre GS1 standards implementation project (GS1 Healthcare Reference Book 2016-2017), decided that they could successfully adapt to this challenge by upgrading the hospital's internal system to use GS1 standards.



A new era of automated, secured and reliable data begins

The first step was easily decided upon. There should be unique identification and highly accurate automated data capture of invasive, high risk and high cost materials (specifically medical devices) used in the OR, the Catheterisation Laboratory and the Interventional Radiology Department.

Beginning in September 2017, the project started as a pilot for certain operating rooms and classes of items. It officially ended on October 2018 but continues as an ongoing project, aiming to include all operating rooms and all categories of medical devices. Full implementation in the Catheterisation Lab started in January 2018 and in August 2018 for the Interventional Radiology Department.

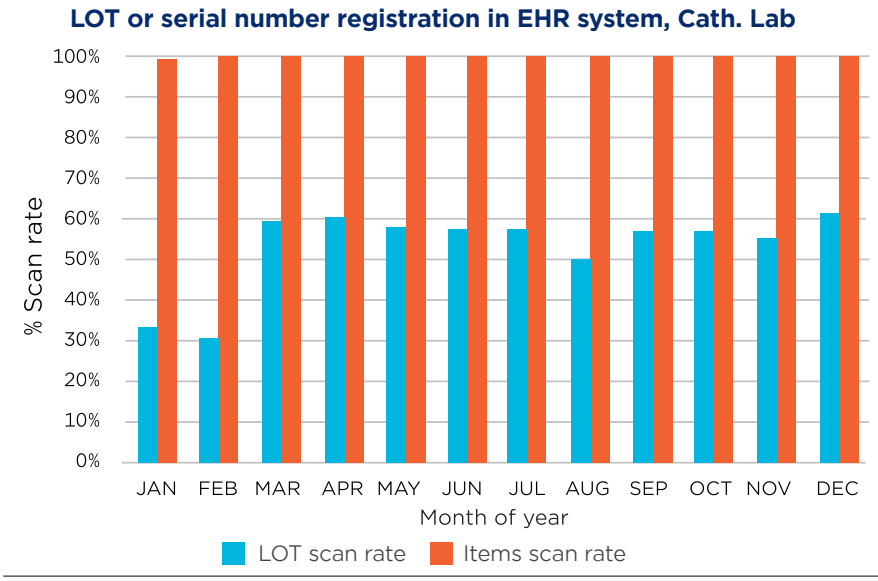
The hospital decided to use several components from the GS1 standards family. Firstly, the GTIN offers unambiguous and transparent identification for primary and secondary packaging of trade items received from suppliers. Then, in terms of automatic identification and data capture processes, the hospital's system registers data primarily through scanning GS1 barcodes like GS1 DataMatrix, GS1-128, EAN-13 without being limited to only these GS1 barcode symbols. GTINs and barcode scanning have been implemented for item identification for all inventory movements and the registration of medical devices into patient records. GS1 Application Identifiers are a vital tool for registering important quality information like batch/lot, expiry, serial etc. By using GS1 standards, the hospital utilises the interoperability already available in most of the registered items from their local and international suppliers. In terms of ensuring conformance with the new processes, the hospital provided clear notification to suppliers about these new specifications and immediately received a positive response which is ongoing and very encouraging.

Capitalising on the benefits of a global system of standards

The GS1 system of standards has, from the initial project implementation, proven its potential. During its implementation journey, the hospital has, for the first time, seen unpreceded business benefits both tangible and intangible.

1. Enhanced patient safety: expiration dates are checked automatically before medical devices are used in the OR, thus alerting nurses to expired items. Also, through GS1 barcodes and GS1 Application Identifiers, accurate product identification plus registration of batch/lot numbers and serial numbers in patient records is available, as well as the easy recall of implants if needed. During the implementation in 2018, at the Catheterisation Laboratory, more than 570 different GTINs were associated to 732 medical procedures. Moreover, 165 serial numbers of high-risk medical devices were registered to 165 patients. Finally, more than 55% of high-risk medical devices, such as stents and pacemakers, were registered with their lot/batch information during every operation at the Catheterisation Laboratory.

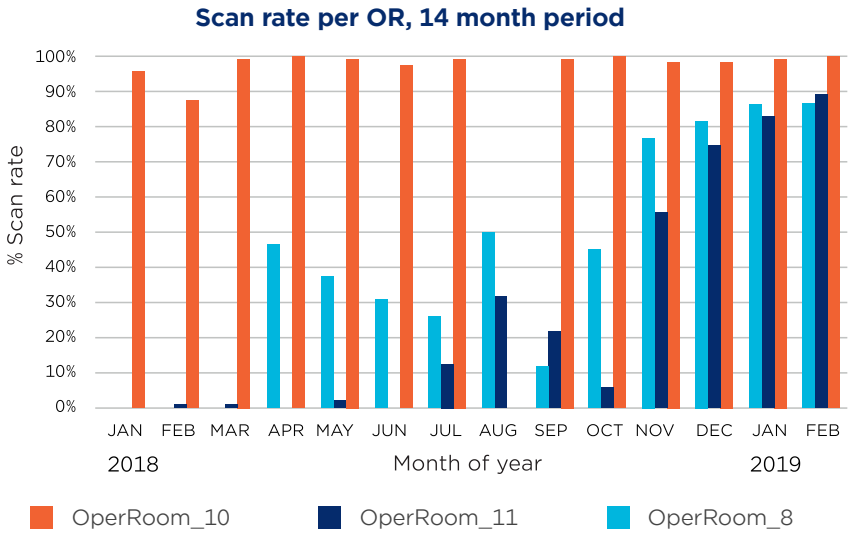
In the following figure, the consistent rate of registering batch/lot (or serial numbers) in the Catheterisation Laboratory throughout the year is visible:







In the ORs, there has been continuous improvement in the scan rate of registered items. Below is the scan rate for the three active operating rooms:



2. More efficient and reliable supply chain procedures: the hospital's departments can now manage their stock more easily, as well as tracking consignment items.
3. Reliable information for strategic supply planning: accurate consumption data, produced in the Catheterisation Lab during 2018, made it possible for the finance department to form a specific supply strategy for the 2019 fiscal year.
4. Significant gains in the time needed for certain procedures: times for routine procedures have vastly improved through GS1 standards deployment. At the Catheterisation Lab, the time needed for stock counting is now more than 85% less than the time needed for doing the same job manually (plus it is now 100% accurate). In the Anesthesia Department, the time needed to register anesthesia sets for a patient is 80% less through barcoding than manually entering item codes using the hospital's software. It is calculated that savings in nurse time are more than 19 working hours per month.
5. Nursing staff engagement: perhaps the most important success factor of the project is the great interest from nursing staff in the new way of working. Medical and nursing staff have shown a very positive attitude towards the use of GS1 barcodes. Even though the pilot project started in the OR, it quickly moved successfully to other departments (e.g. the Catheterisation Lab) because of the interest and engagement of the nurses. GS1 standards have literally transformed the way the hospital's personnel work.
6. Return on investment: the initial capital investment of around 10,000 euros was used for hardware purchase only and not for software development as this was implemented in-house. Nevertheless, the amount spent has been recouped in a year and it was calculated that there was a net return on investment of around 21,000 euros in the fiscal year of 2018 from items that were returned to suppliers and replaced due to short expiry dates.

GS1 global standards are the future of Hellenic Army's hospitals

GS1 standards implementation now has a proven record of success, with significant operational and financial impact in the 401 Athens General Military Hospital. It has therefore become an ongoing project that steadily develops through the hospital's different departments. The management has decided that GS1 standards will lead the hospital's process automation vision, and the future includes:

1. Stock management of items in consignment (mostly orthopedic implants such as plates, screws etc.) during Q1 of 2019.
2. Implementation of specialised software for the traceability of cytostatic medicines (preparation in the laboratory and administration to the patient using bed-side scanning). The project is scheduled in two distinct phases: the first includes Cytostatic Lab software implementation, based on GS1 standards, during Q1 of 2019. The second phase includes bedside scanning for treated patients and is planned for Q2 of 2019.
3. Pilot installation of an SLS (Safety Labeling System) for high-risk anesthesia drugs used in the OR, planned for Q1 of 2019.
4. Copying the current success story, implementation of GS1 standards in the Catheterisation Laboratory and Operating Rooms at the second largest Army Hospital in Thessaloniki.
5. Patient identification using wristbands on which the patient data are presented both in human-readable format and in a GS1 DataMatrix. The specific project implementation is scheduled for Q1 2019 and is considered a top priority by the hospital's management.

The impact of adopting a global system of standards has led to improved patient safety, and interoperability internally within departments and externally with suppliers. Fast and accurate data capture, and full tracking and traceability of high risk and upscale materials, is a strategic priority for Greece's largest military hospital, particularly now that the healthcare spending in general has severely been affected by budget cuts. The estimated tangible and intangible business benefits from the adoption of this system are vital.

About the author

Sotirios Tsiafos-Tsiaras
OR traceability project manager
401 Athens General Military Hospital

Sotiris Tsiafos-Tsiaras is a military pharmacist with more than 20 years of experience in the healthcare supply chain. He is the person leading the implementation of GS1 standards in the Greek Army's Healthcare sector. He has been a logistics manager at the Greek Army Medical Supplies Centre and is credited with the design and implementation of the Centre's WMS based on the GS1 system. Currently he is the OR traceability project manager at 401 Athens General Military Hospital, where GS1 standards are utilized for tracking medical devices and materials used in the Operating Rooms, in the Cardiac Catheterisation Lab and the Interventional Radiology Department. Mr Tsiafos-Tsiaras holds a Bachelor of Science in Pharmacy and a Master of Science in Logistics and Supply Chain Management. He also holds a Diploma in Information Systems Management and Database Programming.



About the organisation

Athens General Army Hospital was founded in 1904 (renamed as 401 Athens General Army Hospital in 1970) and it is the largest of all Hellenic Army's hospitals. It is, as well, one of the largest Healthcare Institutions in Greece. Apart from its' historical importance, the hospital is a cradle of scientific knowledge engaging in research and training educational activities. It is the institution that trains the Hellenic Army doctors and nurses (who are considered as top notch professionals in the Greek Healthcare Industry) and also civil doctors who have been accredited by the Hellenic Ministry of Health to be trained at the hospital. Moreover, it performs clinical and laboratory research projects and also maintains a great medical scientific library. The hospital is also a member of the web community named "IMIHO - Interconnection of Military Hospitals" which has as core purpose the medical information exchange among South Eastern Europe military hospitals that are specialised in challenging military and humanitarian activities. https://401gsn.army.gr

Ireland

Best practice patient safety and traceability of infant feeds at CHI (Children's Health Ireland) at Temple Street

Challenge
In 2016 the hospital was audited by the Food Safety Professionals Association (FSPA). One of the findings of the audit was that the hospital was unable to track feeds to patients.

Approach
The hospital implemented a standards-based traceability database, barcode labelling and a scanning system that could capture the critical data about each product (expiry date or best before date, batch number, location within the hospital e.g. store or ward, the staff member that delivered or prepared the feed and ultimately the patient that received it).

- **Patient safety benefits from the additional controls and full traceability of feeds**
- **Estimated time savings equate to 0.5 full time staff per week**
- **Reports/audits at the touch of a button**
- **Electronic batch recall now possible (from hours to seconds)**

The Special Feeds Unit (SFU) at CHI at Temple Street looks after the storing, preparation and delivery of prescribed feeds to infants with special dietary needs. In 2016 the hospital was audited by the Food Safety Professionals Association (FSPA). One of the findings of the audit was that there was a necessity to track feeds to the patient in the hospital for the purposes of patient safety and in case of product recall. It was agreed, as a matter of urgency, that a modern, time-efficient computerised traceability system based on standards was required by the unit.

Sinead Moran

Background

CHI at Temple Street is a 135 bed children's hospital in Dublin. The hospital cares for all types of patients and some require very specific care, such as metabolic patients. These patients need their weight, blood sugar and cholesterol levels monitored carefully to ensure better quality of life and to reduce the risk of a heart attack or stroke. It is vitally important that these patients receive the correct feeds. As a result, the Special Feeds Unit prepares and dispatches up to 400 patient feeds per day. The Special Feeds Unit also hold emergency feeds in a freezer for such patients, even when they are not an in-patient in the hospital, and these feeds must be checked and counted every day.

The challenge: product recall

Following an audit conducted by the FSPA in 2016 it was recommended that the hospital implement an electronic traceability system for special feeds. The previous process was paper-based and time consuming. If the hospital received a recall notice from a supplier, they had to manually hunt through paper records from the last six months to identify what patients had received that batch as well as to locate the tins of product with that batch number so that no further product could be distributed. This information was often difficult to locate on the product and hard to read. Additionally, staff had to find all the recalled product within the hospital and there were no physical controls in place to automatically ensure that recalled product was not subsequently issued to patients.

Project objectives

The purpose of the new electronic traceability system was to ensure complete, real-time visibility of each special feed across the hospital; in stores; in the feed preparation area; on the ward, right to the patient. The critical information for traceability and recall purposes includes product name, product barcode/GTIN, best before or expiry date, batch number and patient ID. Instant access to this information provides full visibility of stock at all times for patient safety, inventory and financial purposes, and fully complies with the legal requirements for food traceability and recall. To be effective the new system needed to be quick, efficient and accurate and not hinder the day-to-day work of healthcare staff in any way.

Preparing the business case – going paperless to improve patient safety

The manager and staff of the SFU formed a cross-departmental team that included; the hospital facilities manager, Catering, Procurement and ICT. The SFU manager also attended regular meetings with the dieticians and nursing staff to ensure they were fully briefed and included in the process. The team worked together to define the flow of product from Goods In, through the SFU and to the patient in the ward. (Scanning at the patient bedside is planned for phase two). A system specification was drawn up outlining the needs for a standards-based traceability database, barcode labelling and a scanning system that could capture the critical data about each product (expiry date or best before date, batch number, location within the hospital e.g. store or ward, the staff member that delivered or prepared the feed and ultimately the patient that received it).

Following a tender process in early 2018 and consultations with three solution providers, the hospital began work with the standards organisation GS1 Ireland for the software, and the hospital's ICT team procured the necessary hardware.



Fig. 1 Feed preparation area with wall mounted touch screen PCs and Scanners displaying the GS1 scanning app

The need for unique identifiers

Every member of staff, patient and ward within the hospital was assigned its own unique identifier. It was agreed that the hospital would follow industry best practice in assigning globally unique identifiers for the following purposes:

Product identification (Global Trade Item Number (GS1 GTIN)) - products already had GTINs assigned to all levels of product packaging by the manufacturer and these are used throughout the traceability process.

Location identification (Global Location Number (GS1 GLN)) – each location to which goods are dispatched or stored are assigned a GLN e.g. ward.

Staff identification (Global Service Relation Number (GS1 GSRN)) - the staff number is embedded in a GS1 identifier.

Patient identification – the existing non-GS1 barcode is scanned today but this may change to a GS1 barcode in the future.

System go live

Commencing April 2018, the new traceability software, GS1 scanning app was installed on PCs and wall-mounted tablets, together with barcode scanners, in key hospital locations; Goods In, SFU stores and in the feed preparation area. Phase one was completed in June 2018. Additional modules to manage the daily inventory count for the freezer feeds and heat-treated feeds were added in March 2019 and this further supported the objective of the SFU manager to achieve a fully paperless process.

The barcode

While all the products being purchased by the hospital had a unique identifier (GTIN) encoded in a barcode it was discovered that this information was not held in the hospital's product file. Before the SFU team could start to label and track the products, they needed to import their product file and capture the GTINs. The GS1 scanning app has a "product setup module" which made it very easy to create the links between the product GTIN, the case GTIN and the existing product data held on file. This step is fundamental to the set-up of the scanning process as it means that when a barcode is scanned the system knows what product it is and whether it is a single unit or a case with multiple units. The data also offers great insight into the full range of products carried by the hospital, by type and supplier.

Scanning of this product barcode is used as a trigger to generate the GS1 serialised barcode applied to the individual cases of product at Goods Receiving. The purpose of adding this barcode is two-fold to add:

1. The information on the packaging in human readable form (such as the batch number and use by date or best before date) in a barcode to make it scannable.
2. A serial number to enable unique identification and tracking of each individual instance of the product.

The addition of the serial number is crucial to provide unique identification of each instance of a feed container, for the following reasons:

- When a container is opened, the expiry date is limited to one month from the date of opening, so each container must be tracked individually throughout the hospital processes.
- If individual items are deemed to be opened, damaged, or otherwise compromised, they can be flagged accordingly and the system can then prevent their subsequent use.
- To prevent double-counting or over-counting of stock inventory. Serialisation allows the system to 'link' individual instances of a product with individual patients.
- Serialisation also allows the system to record if an item which was 'linked' to an individual patient was not subsequently fed to that patient (i.e. if it is returned to stock).



All of the above information is encoded according to GS1 standards using GS1 Application Identifiers.

The work required to barcode label and serialise each product at Goods In replaced an existing manual activity to add the expiry date. This meant that while the new process initially added some time at Goods Receiving, ultimately there is a significant time and paper saving overall, as it has removed the need to manually record batch information on multiple records as products move throughout the hospital.

> "The new system has proven its efficiency credentials. It now takes us less time to prepare feeds as the date and batch data does not need to be handwritten. There's less chance of making a mistake and it cuts down on our paper work."
>
> **Cherrylyn Panganiban**
> Healthcare assistant
> CHI (Children's Health Ireland) at Temple Street

Common industry practices



Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
5391234560008	5391234560015	5391234560022

The new process

Goods In

When products arrive from suppliers they are recorded, labelled and added to stock. This is done by scanning the outer case barcode (Fig. 2) which usually includes the key traceability information (product ID, expiry or best before date and batch number). Where this information is not available in a barcode it is manually entered into the system by SFU staff. Where information is entered manually, the system always requires it to be entered twice as a critical control point.

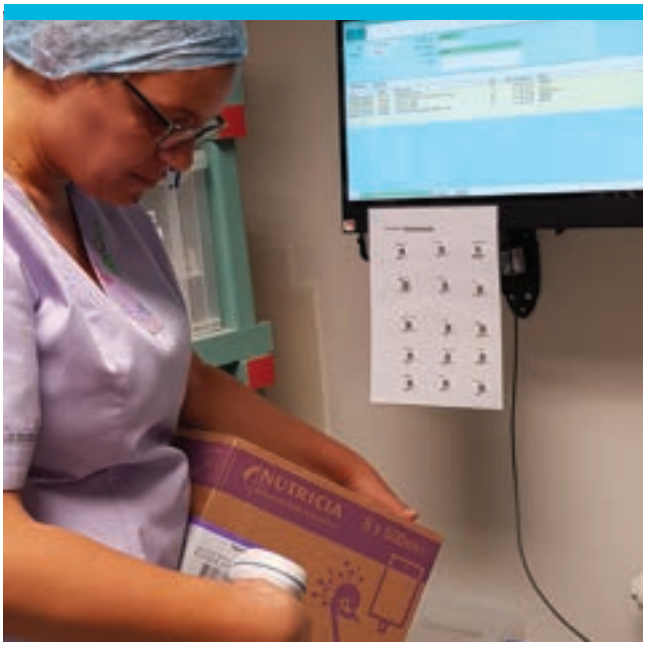


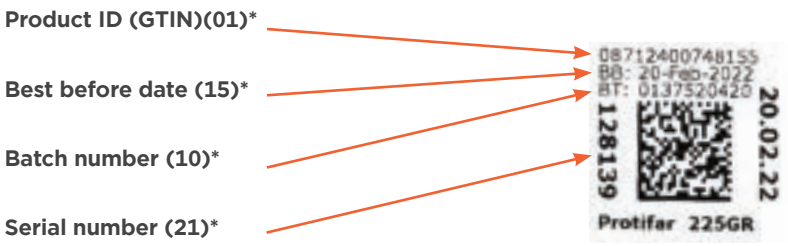
Fig. 2 The hospital staff scan the cases (GS1-128 barcode) of product at Goods In in the store room

The system then generates individual GS1 2D DataMatrix labels with a unique traceability serial number. These are added to each unit (e.g. bottle of liquid feed or tin of powdered formula) so that the traceability data is carried right throughout the hospital. From this point on all product movements are recorded 'as fast as a barcode can be scanned'.

> "The new system provides us with full visibility of all product in stores, on the ward and dispensed to infants. In the event of a recall it is now possible for us, within a matter of minutes, to locate or account for each unit of the affected product."

Bernadette O'Connor
Staff nurse
CHI (Children's Health Ireland) at Temple Street

GS1 2D Datamatrix barcode



(x) = Application Identifier

* Titles are abbreviated or missing due to label size being limited and not to obscure any text on original product label.

Feed preparation

Some of the special feeds are prepared onsite in the feed preparation area (Fig. 1). The SFU staff prepare the feed according to the prescription from the dieticians. As they prepare the feed each item is scanned so that the contents of the prepared feed are recorded. In accordance with HACCP food safety requirements, the temperature of certain feeds at preparation is also recorded.

Additionally, when a container of powder is opened for the first time the expiry date or best before data applied by the supplier becomes invalid, and the new expiry date is a maximum of 30 days from the date of opening (Fig. 3). To facilitate this, the scanning app generates a new GS1 barcode, linked to the serial number applied to the container at the point of Goods In, with a new expiry of 30 days. This ensures the powder isn't used beyond the recommended date and is a fundamental patient safety check.

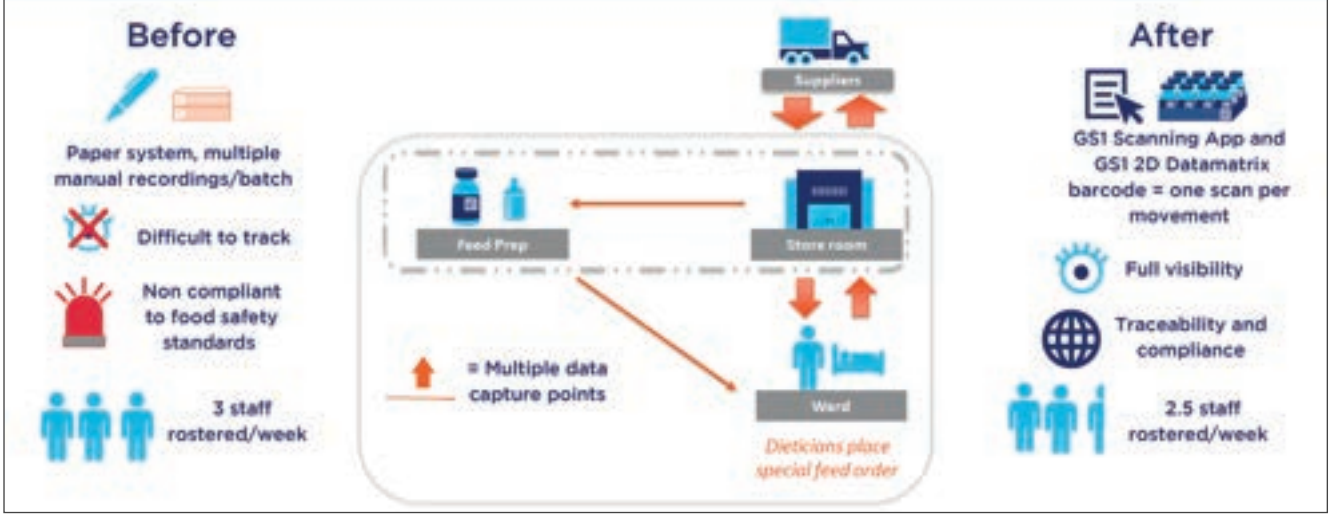
Dispatch to the ward/patient

Special feed orders for patients are requested through the hospital's dietetics system by the dieticians and the SFU staff prepare the products for dispatch. Each product is scanned out of the special feeds unit and linked to the staff, patient and location it is going to e.g. ward. The four-way scanning of product, staff, patient and location, combined with date/time stamping, forms the foundation of the traceability process, recording the who, what, where and when of each dispensed feed.

Returns to stores

Product is regularly returned from the ward when it has not been used by the patient. The return to stock of feeds and products dispensed to a ward but not consumed is also efficiently managed using the GS1 barcodes and has proven to be a great time saver in addition to providing full traceability.

Electronic traceability at Children's Health Ireland at Temple Street



Outcomes and benefits

From the start of the project the team has seen the benefits of having an electronic system to manage a previously labour intensive, paper-based process. The success of the implementation was due in great part to the enthusiasm and commitment of the team (Fig. 4).

Key benefits:

- Patient safety benefits from the additional controls and full traceability of the feeds.
- Electronic batch recall now possible (reduced from hours to seconds).
- The estimated time savings equate to half of a full-time member of staff every week.
- Significant paper savings.
- Staff engagement.
- Reports/audits at the touch of a button.
- Additional unanticipated benefits (e.g. HACCP forms and process improvements).
- Widespread interest both internally and from other hospitals.

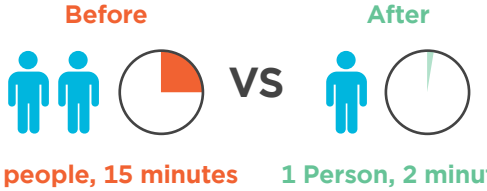
Furthermore, controls within the system based on the serialisation of the products prevent the dispensing or preparation of any expired or recalled product. The intelligence built into the system prompts staff to select short-dated products should they be available, helping to promote better stock rotation, reducing waste and saving the hospital money. The movement of all product is recorded against a ward or patient, ensuring that wasteful, buffer stocks are not built up in several areas around the hospital.

Beyond the initial project objectives, the introduction of the traceability system highlighted where better practices could be implemented for stock rotation and management, reducing and often eliminating waste where previously product had been disposed of.

Frozen and heat-treated feeds

The success of this first phase of implementation has prompted steps towards two further enhancements. Firstly, the labelling of prepared emergency freezer feeds with a GS1 barcode to facilitate the daily stock counts. This process previously took two people 15 minutes every day and can now be done by one person in less than two minutes per day. Secondly, the barcode of heat-treated feeds is used as the identifier against which a full audit trail of the temperature of the product at various stages of the process is recorded.

Operational efficiencies: daily freezer stock count



> Our staff take great pride in delivering the best care for patients. We know where each feed is and a product recall can be done in seconds. This is an excellent example of innovation at CHI at Temple Street to improve patient safety.

Mona Baker
Chief Executive Officer
CHI (Children's Health Ireland) at Temple Street

Operational efficiencies: feed preparation



Next steps

The hospital sees this implementation as the first step in a broader traceability programme. Phase two for the SFU is to scan the feed at the patient bedside. In addition, the hospital is interested in electronic traceability for catering (patient meals), breast milk, hospital assets and the procurement of products.

CHI at Temple Street will be moving to the new children's hospital on the St James's Hospital campus in 2022, so the success of the traceability project in the SFU will be an important component for the move to the new location.

About the author

Sinead Moran
Special Feeds Unit Manager
CHI (Children's Health Ireland) at Temple Street

Sinead Moran is Special Feeds Unit Manager in CHI at Temple Street.

Sinead has worked in CHI at Temple Street for three years. Prior to that Sinead worked in a number of hospitals in the area of CSSD (Central Sterile Services Department) including the Bon Secours Hospital group and the National Maternity Hospital. Sinead has a strong background in traceability having implemented electronic traceability of instrument sets in some of these hospitals and has 21 years' experience in total in the healthcare industry.

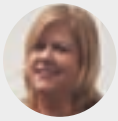




Fig. 3 Each item is scanned in the feed preparation area so the contents of the prepared feed are recorded



Fig. 4 L to R: Sinead Moran, Bernadette O'Connor, Timea Varga, Deirdre Kane, Vilma Slavinskiene, Cherrylyn Panganiban, Marian Draper, Ruth Ennis

About the organisation

CHI at Temple Street, founded in 1872, is an acute paediatric hospital serving some of Ireland's sickest children and providing a referral and care service on a national basis. Seven major specialities at Temple Street today include neonatal and paediatric surgery, neurology, neurosurgery, nephrology, orthopaedics, ENT and plastic surgery. Temple Street cares for 145,000 children per year. Over 45,000 of these children attend the Emergency Department every year making it one of the busiest in Europe. A staff of 85 consultants and over 950 other full time and part time nursing, paramedical and other staff deliver care.
www.cuh.ie

Japan

Medical device management using GS1 barcodes at Tokyo Yamate Medical Center

Challenge
Medical device management was a manual process, medical staff checked the labels and made an entry every time the devices were sent out or returned. This manual process made it difficult to monitor the usage histories of all devices.

Approach
A medical device management system was developed using barcode scanning. All medical devices were scanned every time they were taken out or returned to the store room, as well as when they were used at an operation venue. By linking all the scanned data, the use and maintenance histories of over 1,000 devices in the hospital are captured and verified in real time.

Almost every medical device sold in Japan today now has a GS1 barcode

The GTIN is the indispensable key for linking patient information with medical device information

15”
Reduction in registration time from 50 sec with internal barcodes to 15 sec with GS1 barcodes

Combining monitoring data with GTIN and serial number a new system is expected to facilitate early detection of arrhythmia and malfunction of devices

Tokyo Yamate Medical Center began their GS1 journey by scanning barcodes on medical devices, such as infusion and syringe pumps. This scanning simplified the management of device use histories and reduced the workload of medical staff. It also meant that the use status of devices could be captured easily and accurately. Tokyo Yamate Medical Center is planning to expand GS1 barcode scanning to device monitoring during surgical operations and to the remote (home) monitoring of patients with implantable devices.

Kento Watanabe

Management of medical devices for patient safety

To ensure patient safety, it is crucial to manage and maintain medical devices properly. In many hospitals, medical devices, such as infusion pumps and syringe pumps, are managed by a centralised unit and are used, when necessary, at multiple places, such as theatres, wards, ICUs etc. To facilitate the smooth management of a medical device, a management label with in-hospital product name and/or number is attached to it. The medical staff checked the labels and made an entry every time the devices were sent out of the control room or returned; however, this manual process made it difficult to monitor the usage histories of all devices.

Aware of the inaccuracy of usage records and the growing workload, Kento Watanabe, a clinical engineer at Tokyo Yamate Medical Center, developed a medical device management system in 2013 using in-hospital barcode scanning. All medical devices managed by the unit carried a barcode label containing the in-hospital code; they were scanned every time they were taken out or returned to the store room, as well as when they were used at an operation venue. By linking all the scanned data, the use and maintenance histories of over 1,000 devices in the hospital are captured and verified in real time (Fig. 1).

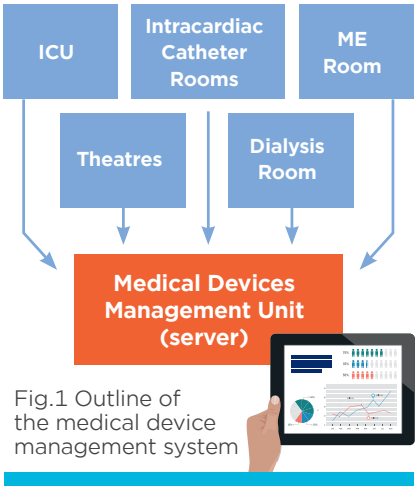


Fig.1 Outline of the medical device management system



Thanks to the internal system, hours spent on record keeping reduced drastically. Compared to manual recording, the processing time per device was reduced from 23s to 11s for lending procedure; from 31s to 5s for the returning procedure; and from 26s to 12s for periodic checks. (Fig. 2).

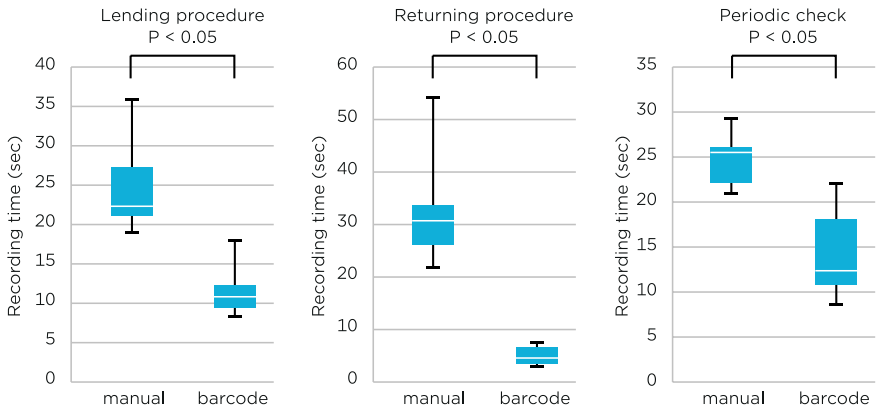


Fig.2 The effect of barcode scanning for device management

GS1 barcodes lead to more accurate and efficient procedures

In 2017, Kento noticed that most of their recently purchased devices had a source-marked barcode, GS1-128, on their body. He also saw that the barcode label contained the GTIN and serial number of the product. “If the code, GTIN, and serial number are unique, we can use GS1-128 instead of in-hospital barcode. Using the source-labeled barcode, device management would become much easier and more accurate. By switching from the use of in-hospital barcodes to GS1-128, we would avoid the task of sticking barcodes on devices and the problem of mislabeling.”

In Japan, the medical device industry started using GS1-128 labeling voluntarily in 1999. After the Ministry of Health, Welfare and Labour announced barcode labeling with GS1-128 in 2008, the rate of GS1-128 marking increased rapidly. For the last several years, the Japan Federation of Medical Devices has been recommending the marking of GS1 barcodes on the body of devices, especially on those that are portable. Based on these circumstances and the progress in Unique Device Identification (UDI) regulations in the US and EU, almost every medical device sold in Japanese market today now has a GS1 barcode.

> “A GTIN is very convenient for getting information about medical devices. Product information can easily be taken from medical device databases supplied by MEDIS-DC (Medical Information System Development Centre), an organisation for standards, and/or other commercial databases. All we need to do is scan the GS1 barcodes on the devices.”

Kento Watanabe
Clinical engineer
Tokyo Yamate Medical Center

Workload reduction by using GS1 barcodes

There are many old devices in the hospital that do not have a GS1 barcode. As per 2018 data, the centralised management unit had 211 types of medical devices and 1,150 in total; only 20% of the devices had source-marked GS1 barcodes. Despite this, Tokyo Yamate Medical Center decided to start using the source-marked GS1-128; this is because most medical devices purchased in the future are expected to have GS1 barcodes on their bodies. Their current system can scan GS1 barcodes, as well as the in-hospital barcodes.

By scanning GS1 barcodes on the devices, the hospital is now able to smoothly transfer device information to their management system.

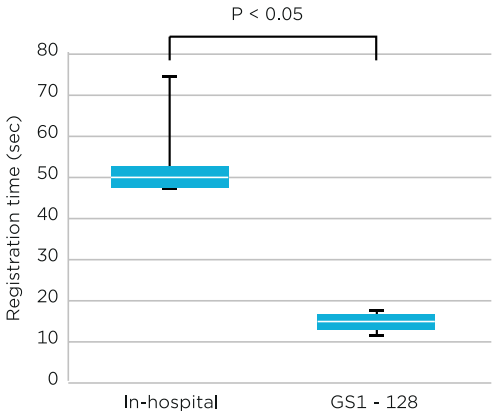


Fig.3 The effect of GS1-128 scanning for registration

Even though they need to arrange and adjust the data to make it compatible with their system, the registration time for devices was still drastically shortened by using GS1 barcodes (Fig. 3). And now, there is no need to apply in-hospital barcodes.

Problem of source-marked GS1 barcodes

Fig. 4 shows some examples of problems encountered in the hospital. Because of these problems, they sometimes have to print a new barcode, stick a printed barcode at a suitable place to read, or check the barcode that should be scanned. Proper source-marking of GS1 barcodes at a user-friendly location is essential for the efficient use in healthcare institutes.

> "GS1 barcodes are wonderful, but we sometimes face problems when we cannot read them; for example, bad printing quality, labeling at inaccessible location such as base or rear of devices, multiple barcodes, and so on."
>
> **Kento Watanabe**
> Clinical engineer
> Tokyo Yamate Medical Center



Defective printing



In-accessible location



Multiple barcodes

Fig.4 Unreadable GS1 barcodes

Toward further improvement in medical device management

Although many medical devices are used in surgical operations and information about their usage gets accumulated, most of it is currently erased after the operation is completed. Very little information is stored as records of operations. The hospital is now planning to establish a database system to store various types of information connected with patient number and GTIN. The goal is that medical staff can access information derived from life support machines such as anesthesia apparatus and artificial heart lung apparatus, and also monitoring equipment to get patients' biometric information. In addition to using the accumulated information for increased patient safety in theatres, they expect the continuously generated biometric data to provide new information for making improvements in medical care. In the proposed database, the GTIN is the indispensable key for linking patient information with medical device information.

Going beyond management within the hospital

Recently, the hospital developed another new system for remote (home) monitoring of patients. The system can automatically collect the monitoring data from implantable devices, such as pacemakers, from patients in remote locations.





To effectively collect and manage the data, the system links monitoring data with the GTIN and serial number obtained from a GS1 barcode. The hospital expects the new system to facilitate early detection of arrhythmia and the malfunction of devices. By enabling early intervention to cure patients, it will greatly contribute to the improvement in life prognosis and their quality of life. By shortening the duration of medical care and the frequency of consultation, remote monitoring will also reduce the burden imposed on outpatients.

Kento pointed out the importance of understanding GS1 standards by not only manufacturers, but also healthcare providers. “Currently our hospitals use GS1 barcodes for the management and traceability of devices, however, if we were able to capture safety-related information, such as recall information from government databases automatically, patient safety would improve significantly. GTIN and GS1 barcodes should play a more important rule in the identifying of medical devices. Proper understanding of GS1 standards by healthcare providers will expand the use of GS1 barcodes. This, in turn, will contribute to the improvement of patient safety and provide economic benefits.”

About the author



Kento Watanabe
Clinical engineer
Tokyo Yamate Medical Center

In addition to possessing the latest knowledge as a clinical engineer, his wide-ranging IT skills play a key role in the management of medical devices at the hospital. He established the medical device management system of the hospital by himself and shares his experience with other hospitals.

About the organisation

Tokyo Yamate Medical Center was established in 1947 and shifted to its current location—Shinjuku, Tokyo—in 1987. The hospital provides advanced medical care with a capacity of 418 beds. In 2017, the total number of inpatients was 107,231 and 4,646 surgical operations were performed. The hospital is working on a project to establish a regional comprehensive medical care system that provides healthcare services, ranging from emergency care to regional and home healthcare.
https://yamate.jcho.go.jp

Poland

Improving efficiency and safety through the automatic identification of medical devices at the University Clinical Centre, Gdańsk

Challenge

Medications and medical devices are the second highest cost in the day to day running of the hospital. Taking into account the requirement to ensure the appropriate level of patient care, and most importantly their safety, the management of the flow of healthcare products is a very important aspect of the functioning of the University Clinical Centre (UCC).

Approach

There were attempts to reduce costs across many areas and one of these was to improve the flow of medical devices. For this, a concept of deposit warehouses enabled by barcode scanning was created, with 24/7 access to medical devices and the hospital only paying for what they actually use.

In the Cardiosurgery Clinic, as soon as the barcode is scanned this information is added to the patient's Electronic Health Record

In the case of a recall finding the affected patients proved to be no problem at all since the medical devices data were scanned into the IT system including their individual serial numbers

Stock taking of the deposit warehouses showed that automatic identification is completely error-free

Once scanned the product cost is assigned to a specific patient giving information about the cost of treatment

The University Clinical Centre (UCC) was founded by the Medical University of Gdańsk and is one of the largest hospitals in Poland. Its connection with the university gives the hospital access to the latest technologies, global-tier medical knowledge and clinical research. UCC covers a full range of medical services, advanced diagnostics, various surgical procedures, transplantation procedures, rehabilitation and palliative care. The hospital has most specialties available within the area of medical service, meaning that it can offer comprehensive treatment to patients, including those suffering from numerous concurrent diseases.

Joanna Nowak

Around 120,000 patients are treated in the hospital annually. The hospital has 33 highly specialised clinics and over 60 outpatient clinics. The constantly growing facility has a state-of-the-art infrastructure and is considered to be one of the most modern hospitals in Poland and Europe. UCC has undergone major extension and modernisation works in the last few years. A modern complex spanning 32,000 m^2 was commissioned in 2012 and another complex of buildings, this time covering 72,000 m^2, will be commissioned by 2020. Apart from its usual medical activity, the hospital also runs educational programmes with a focus on disease prevention.

To keep functioning, a unit that large requires a steady stream of medications, medical devices and other equipment needed to treat patients. Right after salaries, medications and medical devices are the second highest cost in the day to day running of the hospital. Taking into account the requirement to ensure the appropriate level of patient care, and most importantly their safety, the management of the flow of healthcare products is a very important aspect of the functioning of the UCC.

Reducing costs, improving efficiencies

To improve the hospital's efficiency, there were attempts to reduce costs across many areas. One of these was to improve the flow of medical devices while at the same time ensuring uninterrupted access to relevant products in a wide range of types and sizes. From this, a concept for creating deposit warehouses was created. The idea behind a deposit warehouse is that the hospital's staff has prompt,

24/7 access to medical devices and the hospital only pays for what they actually use. This way, costs are reduced while product availability is increased.

The Cardiosurgery Clinic, with the highest value of stock in the entire hospital, was one of the first places to receive this solution. Their warehouse contained heart valves and specialised, expensive medical devices used in cardiosurgery procedures. A tender was announced, agreements were concluded and deliveries began. It turned out that this solution requires very quick and effective acceptance of products into the central warehouse, moving them to the warehouse in the operating block, allocating them to specific patients, informing the supplier about the use and receiving the invoice and then processing it. At that time, the data was introduced to the hospital's IT system manually, which proved inefficient, mainly due to the time needed to do this and the high risk of making mistakes.

When looking into solutions to improve this process, barcodes were seen to have great potential. The changes were introduced as a result of observing other business sectors, receiving education from GS1 Poland via their publications and webinars, and using the team's passion and support of the management. Ultimately, the hospital began the process of handling deposits using the automated identification of products through GS1 standards. Each medical device accepted into the deposit was scanned when being directly introduced to the computerised warehouse and accounting system (provided the device had this kind of marking) and then transferred for deposit in the operating block. After some time, certain improvements were introduced to the IT system for handling the medical part, where patients' data was stored. Both IT systems were joined in a way to allow for the transfer of data between them and with the use of barcodes scanned from these devices. Barcode readers were purchased for the Cardiosurgery Clinic warehouse and a new era of facilitated data flow started in the hospital.

Thanks to this solution the data related to the product's name, GTIN number, expiry date, serial, lot and batch numbers are automatically assigned by medical personnel to the patient's record, right after the surgery. As soon as the barcode is scanned, this information is added to the patient's Electronic Health Record.

The implementation proved to be of great use to the hospital's finances and gave a good return on investment.

The stock, and with that costs, were greatly reduced. Currently, the stock in the deposit warehouses is twice the value of the non-deposited stock of products purchased daily by the hospital. Stock taking of the deposit warehouses showed that automatic identification is completely error-free and there have been no data entry errors whatsoever. Additionally, once scanned, the product cost is assigned to a specific patient, giving information about the cost of treatment.

Most importantly, however, a new value was obtained - in the form of identification of the products.

The hospital's staff know where specific products, identified by their serial numbers and expiry dates, are - but most importantly they know exactly who received them. This information is vital if defects in implanted devices occur.

The hospital can identify the patients who received these products, promptly and accurately. Recently, around 250 patients had to be identified, who were implanted with products with hidden defects identified by the producer several years after the application. Finding these patients proved to be no problem at all, since the medical devices data were scanned into the IT system, including their individual serial numbers. Consequently, the patients were informed about the situation and corrective activities were taken up as per the producer's recommendations.

The implemented solution turned out to be a great tool and other clinics expressed their interest in applying it. By March 2019, there were 17 deposit warehouses in the hospital and their total value is rising year by year.



Next steps

The next step the hospital is considering is to cover all medical devices purchased for patient-related needs with this solution. To this end, the hospital is planning to buy a modern warehouse management system (WMS) so that the data can be introduced to the IT system, using GTINs to identify the product, when the goods are placed in the warehouse and then, when they are delivered directly to patients, they can be scanned directly into the IT system. This will also save the medical personnel time, since scanning is quick, simple and almost completely error-free.

Several years have passed since the implementation of the first warehouse deposit. In the meantime, when preparing new tenders, the hospital encouraged other suppliers to provide medical devices marked according to GS1 standards. This is worth additional points in favour of the supplier when evaluating the bids. Initially, many suppliers reacted with curiosity to the hospital's requirements, with no understanding of the underlying purpose. As time passed, more and more suppliers began implementing GS1 standards to devices which previously didn't have them.

Building awareness and co-responsibility for the process of marking medical devices, as per GS1 standards, by their manufacturers has been of key importance. It allows both the supplier and the hospital to easily monitor the process of identifying the products and to co-create traceability. It is important that the hospital concentrates on treating patients and the supplier delivers products that can be identified with a GTIN, expiry date or lot number, and read with a barcode scanner.

Additionally, by using relevant stipulations and entries in tenders, UCC encourages suppliers to use GTINs assigned to the products. Some suppliers have already started creating lists of products in data sheets including their GTIN. This is of major importance because the hospital can assign the GTIN to the database for specific products already at the stage of uploading the tender agreement into the IT system. When picking the product up from the warehouse or when issuing them from the central warehouse the staff can refer to the data to identify the product. This gives them assurance that the product submitted in the bid is the same product that is delivered to and used in the hospital. Additionally, when sending purchase orders to the supplier, the number is specified in the hospital's order, which may facilitate logistics processes.

Working to eliminate the challenges

It must be noted, however, that product identification should not end with the collective packaging (e.g. a box including a number of individual units). Only a single or several products are administered to the patient at the hospital, not the entire package. It is this single item that should be specifically marked using the GS1 standard. Just like when you are buying a 12-pack of mineral water, you only present a single bottle to the shop assistant operating the cash register. Similarly, the hospital's personnel want to be able to scan the data from a single item, e.g. a bag of sutures, a stapler charge, an electrode, etc. Which is why there should be focus on automatic identification of individual product items. The hospital should not be marking the purchased products by applying stickers or coming up with their own line for marking products.



It is the supplier and the producer who should be supplying every single item in a way that it can be individually identified and read with a barcode scanner.

Today, hospitals wish to know exactly what the cost of treatment is and this system of marking individual products may be of help to them. By scanning the patient's data from their wristband and then scanning individual products, they are allocated to that patient in the IT system, generating a price automatically.

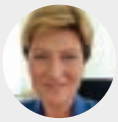
Unfortunately, there are still many groups of products used in hospitals for which GS1 standard marking only extends to the packaging. A good example is surgical gloves, with marking placed on a container with several dozen pairs, whereas only up to a dozen pairs of various types and sizes are used during a single procedure. That is why the hospital is promoting and encouraging suppliers to apply marking on every pair of this particular product.

Yet another problem is a large group of products that are difficult to access since their collective packaging is secured against opening and the relevant documents carry no information about the GTIN number for the unit product. Surgical suture is a great example for this. The analysis carried out in the hospital shows that manufacturers have started implementing GTIN and, optionally, the expiry date and serial number for e.g. 10, 12, 24 and 36 bags on the collective packaging secured against opening with special plastic film. During a surgery, several bags, rather than pieces of packaging, of various types of sutures are used. Once applied, data cannot be scanned from the collective packaging, but should be rather scanned from a specific bag. GS1 standard marking should be assigned to the bag at the stage of uploading data when accepting the delivery, with price included on the IT system so that can also be assigned. So, either the hospital staff have to commit to do the intensive work of unpacking the secured packaging in the warehouse, or the hospital receives the data in a different way, e.g. via an electronic file.

Yet another challenge is posed by the number of barcode types on a medical device's unit packaging and the various types of data carried by the barcodes. It happens that some products carry a GS1 DataMatrix and another linear barcodes on their unit packaging. As it turns out, these barcodes carry slightly different data, e.g. an extra application identifier assigned to one of them. The hospital staff now faces a problem of determining which barcode should be introduced into the IT system so that the same barcode is scanned and assigned to the proper patient by the medical personnel. The scanning of barcodes by the medical personnel needs to be as easy as possible, because their main job is to treat the patient, so all other actions should be simplified to the highest extent. Therefore one single barcode is the desired end goal.

In conclusion, it should be noted that the hospital's management has learned about the extensive possibilities and benefits resulting from the marking of medical devices with GS1 standard barcodes and are looking to develop this topic and introduce solutions stemming from automation in this field. A dream emerged at a certain stage of development of this hospital, for the staff to be able to scan medical devices and the hospital's management believe that soon, thanks to mobile scanners, nurses will not only be able to scan codes of all products or patients' data, but also the codes of medical procedures and staff. The possibilities are limitless...

About the author



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Joanna Nowak, head of medical device supplies in University Clinical Centre in Gdańsk, responsible for procurement, supplies and distribution of medical devices necessary in the diagnostic and treatment proces of patients.

About the organisation

The University Clinical Centre is one of the largest hospitals in Poland, founded by the Medical University of Gdansk. The hospital provides medical, diagnostic and treatment services. Cooperation with the university gives the possibility of access to the modern technologies, world medical knowledge and clinical research. In addition to medical activities, the hospital has educational programs that put pressure on prevention of illness. The mission of the hospital is the slogan "Effectively healing, teaching well and serving science". The University Clinical Centre employs 3,500 staff, serving 120,000 patients per year.
https://mug.edu.pl

Poland

The unique and automated identification of pharmaceutical products to improve patient safety and treatment costing at the Regional Hospital, Poznań

Challenge

Year on year, the hospital has been generating a negative financial result, so one of the initiatives aiming to improve its financial standing was the analysis of the cost of use of medications per ward and per patient – its second largest cost.

Approach

One of the first decisions was to begin implementing barcodes in the issuing of medication. The application of automatic data collection methods in the hospital's logistics plays a crucial role in the process of streamlining the selected intra-hospital logistics processes, which also contributes to improving the hospital's economic efficiency.

15''

The time needed to process a single patient daily was reduced by 15 minutes

Doctors can also use the analysis of the administered medications quantities doses and costs as the basis for effective pharmacotherapy

Scanning of GS1 barcodes eliminates the need to search the IT system's database manually for medications

staff can quickly access the cost of medications administered to a patient



The Regional Hospital in Poznań, Poland has been active since 1973 and is a multi-discipline hospital providing comprehensive care and complete diagnostics. 27 wards and 16 outpatient clinics operate across all locations of the hospital, with 1500 staff employed. The mission of the Regional Hospital in Poznań is to become the leader of the healthcare market in the Wielkopolska region.

Anna Anders

As part of a plan to reduce costs, the hospital analysed the breakdown of operating costs, along with percentage share:

Cost structure	Percentage share
Staff	62%
Medications and medical materials	19%
Non-medical materials	2%
Outside medical services	1%
Outside non-medical services	6%
Depreciation	5%
Miscellaneous	4%
TOTAL	**100%**

Year on year, the hospital has been generating a negative financial result, so one of the initiatives aiming to improve its financial standing was the analysis of the cost of use of medications per ward and per patient – its second largest cost. One of the first decisions was to begin implementing barcodes in the issuing of medication in their transplantology ward. Previously the hospital's logistics were supported with a specific, dedicated IT-solution. The application of automatic data collection methods in the hospital's logistics plays a crucial role in the process of streamlining the selected intra-hospital logistics processes, which also contributes to improving the hospital's economic efficiency.

A standard way of working

In the face of various healthcare-related technical and technological solutions, a need had been identified for standardised communication methods for collecting, aggregating and sharing information in the most effective and efficient manner. Internal solutions that have been popular for many years, are now being replaced by standardised solutions that have been tried and tested in other industries, and that are proven to work across the healthcare supply chain. Both healthcare facilities and patients are no longer viewing the application of these solutions just as the source of competitive edge, but also as a way to reduce operational costs, as well as reduce the costs of patient services. Since automatic data collection technologies and GS1 standards greatly reduce the errors from the use of the wrong medication, hospitals also avoid additional costs related to the prolonged treatment of patients.

Additionally, there are a number of legal regulations that encourage the implementation of barcode scanning, such as:

- The requirement to follow the flow medications, including the production batch.
- The readiness to efficiently withhold or withdraw a medication from the market.
- The requirement to collect pharmacotherapy data in electronic form.
- The verification of authenticity of medications.

Scanning barcodes in hospitals helps satisfy these legal requirements and reduces the number of activities the staff must do manually, such as the recording of data related to medical devices. With that in mind, the hospital's board decided to extend the scope of the pilot project to also include legal requirements. This approach means that the project is not treated as an isolated idea, but as a way to improve the whole hospital's way of working.



Streamlining the process

The project's fundamental aims were:

- Quick access to information on the cost of medications administered to a patient.
- Streamlining the process of administering medications.
- Accurate and automatic identification of medications and patients.
- The elimination of manual data entry that may lead to errors.
- Easier record keeping of the administered medications.
- Improved performance and patient safety.
- Releasing nurse time back to care.

The use of barcodes in the automated record keeping of medications distributed to patients is important on many levels. It gives hospitals quick access to an accurate cost of treatment for a patient and to the batch number of the medication administered. Barcode scanning allows hospital staff to automatically follow the flow of medications, so that medications withdrawn at the Chief Pharmaceutical Inspectorate's request can be quickly located and withheld or withdrawn from the hospital's stock. Also, it allows the hospital to prepare, more efficiently and effectively, for the requirements of Electronic Health Record technology and to confirm the authenticity of medical products in line with the Falsified Medicines Directive.

Barcode scanning can be implemented at many points in the medication journey, starting from the generation of an order at the supplier by the hospital's pharmacy, through recording the acceptance of medications to the hospital's pharmacy, picking the ward's requested medications, recording the acceptance of medications to the ward, picking the medications for the patient and ultimately the automatic recording of the administration of the medications to the patient. It can be difficult to know where to start so the hospital decided to begin with one of its wards, namely the transplant, general surgery and urology ward. The first step of the project was to join forces with the Institute of Logistics and Warehousing and GS1 Poland. Due to the numerous technical and staffing problems, and given the benefits of the application of GS1 standards, we opted not to follow in the footsteps of other hospitals who apply internal code stickers onto packaging, but rather to use GS1 manufacturer codes for the purpose of recording the administration of medications. Since the age of the hospital's ICT infrastructure affects the ability to scan barcodes to the highest degree, it also needed

to be checked from the perspective of its ability to read GS1 barcodes. To ensure the implementation would be efficient, effective and useful from the point of view of the hospital's staff, the IT system needed to work with GS1 standards in order to take the burden of administrative work away from staff. Personnel also needed to be equipped with barcode scanners and wireless internet access, so that scanning can take place wherever needed, at the patient's bedside for example.

Once this was established, the implementation began with the creation of maps to show the sequence of processes related to the flow of medications in the hospital's pharmacy and wards. The pilot process was preceded by general analysis of the process of providing services to the patients and the identification of any bottlenecks related to the distribution of the medicines. This top-down approach gave an overview of the whole process, making it easier to identify potential efficiencies across all the different organisational units in the examined hospital. We also used these maps when we engaged with the IT provider handling our hospital management system.

The new process was designed with the help of the staff who would actually be using it. A weakness of many hospital implementations is when IT companies fail to take into account the specific needs of the hospital they are working with, missing out on key efficiency gains that a hospital may be able to make. The IT system itself should be configured to assist staff in their ultimate goal - treating the patient as best they can. As much as possible, the aim of the new process was to eliminate the manual input of data or the duplication of work.

The project's subsequent stages covered:

- The evaluation of basic data about the medications and its accuracy.
- Arranging, with the hospital's pharmacy, the schedule of distributing the medicines to the ward.
- Inventory taking of the medicines in the ward and the evaluation of the level of availability of standard barcodes on their outer packaging.
- Training for nurses.
- Beginning the implementation in the ward.

Significant support from our IT department was required for the first few days but it has enabled nurses in the transplantology ward to record the distribution of medications among patients using barcode scanners, our IT system and GS1 standards. This process is planned to be implemented in more wards in our primary location in 2019.





Using data to reduce costs and return time to care

Most importantly, the implementation made it possible to quickly access the cost of medications administered to a patient, which will provide measurable benefits when analysing the ward's results, the patient outcomes, and when working with the Agency for Health Technology Assessment and Tariff System. Doctors can also use the analysis of the administered medications, quantities, doses and costs as the basis for effective pharmacotherapy. Nurses' jobs are made easier as the scanning of GS1 barcodes eliminates the need to search the IT system's database manually for medications. GS1 standards also made it possible to eliminate barriers stemming from the use of foreign languages, name conventions and indexes, which usually need to be adjusted and translated. The use of international GS1 data structures, where the meaning and structure of the data for trade and administrative processes is clearly defined, is beneficial from the point of view of the hospital's economic efficiency.

The application of barcodes in the Regional Hospital in Poznań served to streamline the process of administering medications.

It has improved cost effectiveness, increased patient safety and made the job of staff, especially nurses, easier by eliminating the need to input data manually, which can cause errors and prolong the activity.

It has been proven that the time needed to process a single patient, daily, was reduced by **15 minutes**, meaning that medical personnel can focus more on other tasks, which are further streamlined thanks to the introduction of the standards.

About the author

Anna Anders
Deputy financial director
Regional Hospital, Poznań

Anna Anders was the deputy financial director in the Regional Hospital in Poznań. She was responsible for financial reporting and the development of controlling processes, along with the introduction of operating reporting dedicated to specific areas of the hospital's activity.



About the organisation

The Regional Hospital in Poznań is a multi-discipline hospital providing comprehensive care and complete diagnostics. The hospital currently has 1,500 employees, 27 wards and 16 outpatient clinics. The mission of the hospital is to obtain a leading position on the healthcare market in the Wielkopolska region. The Regional Hospital in Poznań accomplishes this target by focusing on the high quality of services provided, meeting expectations and satisfying the individual needs of each patient, including compliance with his rights.
http://www.lutycka.pl/page.php/1/0/show/1182

Spain

Towards a new management model: surgical prosthesis traceability

Challenge

The Hospital Universitari Vall d'Hebrón did not meet current regulations on traceability records for prostheses. Prosthesis storage and replacement orders were also resulting in logistics costs for the hospital.

Approach

With the goal of improving patient traceability, reducing errors and cutting the administrative workload for medical and nursing staff, Hospital Universitari Vall d'Hebrón decided to implement GS1 standards in surgical prosthesis management.

- **Nursing staff are provided with an easy tool for registering prostheses**
- **Purchasing departments can order replacements from suppliers more quickly**
- **More efficient management of invoicing for implanted prostheses**
- **Implantation card can be printed with the necessary information for compliance with legislation**

Vall d'Hebron Hospital

In a hospital, the most critical part of surgical prosthesis management is connecting it to the patient's history. With the goal of improving patient traceability, reducing errors and cutting the administrative workload for medical and nursing staff, Hospital Universitari Vall d'Hebrón decided to implement GS1 standards in this area, specifically through GS1 barcode scanning.

As well as making it possible to establish traceability records for prostheses, in line with current regulations, this achieved other important goals such as:

- Providing nursing staff with an easy to use tool for registering patient-implantable materials in surgeries and clinics.
- Optimising the control and monitoring of prosthesis costs.
- Improving efficiency in the invoicing process.

Montserrat Gualdo

Introduction

Hospital Universitari Vall d'Hebrón is the largest hospital complex in Catalonia and is part of the state-owned company, the Catalan Institute of Health, under the Catalan Ministry of Health. It's divided into three large medical areas: general care; maternity and childcare. They also cover traumatology and rehabilitation in a specialist hospital. In addition, surgical outpatient procedures are carried out in the Parc Sanitari Pere Virgili, which is located close to the hospital.

Hospital Universitari Vall d'Hebrón therefore covers practically all medical and surgical specialities and boasts clinical support services, university teaching and research centres etc., to round off its medical and nursing activities. It has around 7,000 professionals working across 22 buildings, including 1,146 hospital beds, 182 of which are in intensive care, 45 surgeons, 381 consultation rooms and three emergency areas. Its budget for 2018 was 637 million euros.

The care provided is used as a benchmark in tertiary care and for highly complex procedures such as stroke, adult and child oncology, severe burns, multiple traumas, multiple sclerosis, and foetal surgery.

The hospital carries out a yearly average of over 57,000 admittances, over 30,000 operations, over 870,000 outpatient-consultation visits, more than 200,000 emergencies, and over 10 million laboratory tests.

Its total prosthesis costs at the close of the 2017 and 2016 financial years came to 23.7 million euros and 20.3 million euros respectively, with 2017 seeing a 16.6% increase compared to the previous year.

Chart one shows that the specialist surgical area with the highest total prosthesis costs in 2017 was traumatology and orthopaedics, representing over 35%, followed by haemodynamics at 16.5%, arrhythmias at 12.9%, and heart surgery at 9.8%.

This was because the hospital has an area specialising in orthopaedic surgery and trauma and rehabilitation, although it was also influenced by the Catalan Ministry of Health's policy to reduce waiting list times for certain pathologies such as those requiring knee and hip implants.

SERVICE DESCRIPTION	2016 (€)	2017 (€)	% variation
TRAUMATOLOGY	7,144,856	7,505,768	5.1%
HAEMODYNAMICS	3,348,900	4,242,490	26.7%
ARRHYTHMIAS	2,631,764	2,740,848	4.1%
HEART SURGERY	1,987,966	2,222,958	11.8%
VASCULAR SURGERY	1,236,799	1,428,917	15.5%
ANGIOGRAPHY	745,041	1,506,181	102.2%
OPHTHALMOLOGY	406,838	536,435	31.9%
MAXILLO-FACIAL SURGERY	325,996	392,286	20.3%
BREAST PATHOLOGY UNIT	206,279	149,787	-27.4%
GENERAL SURGERY	201,570	235,680	16.9%
OBSTETRICS AND GYNAECOLOGY	160,717	115,860	-27.9%
PAEDIATRIC HEART SURGERY	144,756	256,576	77.2%
ENDOSCOPY	134,027	117,596	-12.3%
RECONSTRUCTIVE SURGERY/ BURNS	304,136	385,282	26.7%
UROLOGY	105,577	139,970	32.6%
PAEDIATRIC SURGERY	43,003	151,722	252.8%
THORACIC SURGERY	10,801	27,215	152.0%
OTHER SERVICES	1,199,314	1,552,650	29.5%
TOTAL	**20,338,338**	**23,708,222**	**16.6%**

The challenge

The Catalan Institute of Health (ICS) launched a medium-term modernisation programme involving process re-engineering and standardisation of its information systems by introducing the SAP platform, first in the financial area and later in healthcare, for all its component entities.

A financial SAP was implemented in the Hospital Universitari Vall d'Hebrón in 2007 followed by a healthcare SAP there in 2010. From then on, and through the process re-engineering carried out in the various financial areas, every type of fungible material such as medical equipment, reagents and prostheses were basically purchased collectively for all the ICS hospitals, to exploit economies of scale, from the preparation of the corresponding public invitations to tender to their subsequent awarding and logistical distribution.

The logistics operator Logaritme, an entity partly owned by the ICS, provides logistical services for the storage and distribution of all types of supplies for the ICS's various hospitals and primary healthcare centres.

The reality of this model was analysed on the organisational and financial level, and its main conclusions were as follows:



1. The Hospital Universitari Vall d'Hebrón did not meet current regulations on traceability records for prostheses.
2. Prosthesis storage and replacement orders for suppliers were managed by the external logistics operator with the resulting logistics costs for the hospital.
3. It re-labelled the packaging of prostheses, making it difficult to return them to the supplier for any reason, such as expiry and loans.

Solution

The hospital sought to achieve three goals:

1. Tracing the prostheses by registering the serial number of each type of prosthesis used for each patient. In other words, "who has what".
2. Implementing a prosthesis-storage registration and control system.
3. Reducing the logistics costs for the hospital.

The analysis conducted presented the opportunity to carry out a strategic change in prosthesis management, in all aspects, moving on from a centralised management model to a local management one.

To implement it, we redefined our purchase and logistics distribution processes. We integrated the information systems, the healthcare SAP and the financial SAP with external storage management systems. The hospital has a computerised management system for prosthesis composites used in traumatology surgery, and logistics cabinets for the other surgical specialities, located in traumatology and rehabilitation hospitals and in general, maternity and childcare hospitals respectively, for inpatient and outpatient surgery.

The change in model was reported internally and externally, with a timetable for implementation in the different surgical areas. The model was changed slowly and steadily, beginning with the services that were leaders not only in their healthcare work but also in opinion and management, with less resistance to change.

Externally, we gradually met with each of the prosthesis suppliers who won the tenders for the various surgical specialities to explain the change in the purchase and logistics model, and the replacement and delivery circuits.

They were asked to label all prostheses from then on with GS1 standards, specifically with the GS1 barcode. We also took the opportunity in those meetings to ask the various suppliers to work alongside the hospital to compile an inventory of all the prostheses in storage and to identify references without GS1 barcodes so that they could be relabelled or moved.

The day-to-day management of the healthcare storage systems, the use of the items in the surgery storage facilities to cover planned and emergency surgery, and the replacement of those items create uncertainties for the suppliers and the healthcare centres' supply departments as well, which is why establishing channels that regulate relations between suppliers and the hospital is not only advisable but necessary.

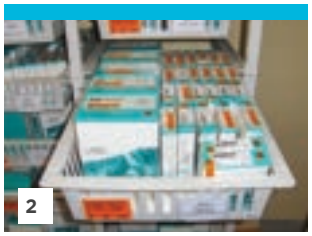
The tenders and awards of aggregate purchases by the Catalan Institute of Health and local purchases by the Hospital Universitari Vall d'Hebrón established which prostheses would be regularly used by all the surgical specialities.

Based on this process, and to computerise the management of items in storage, as mentioned above, the Hospital Universitari Vall d'Hebrón has two systems: an external computerised system for the comprehensive management of surgical prosthesis composites for traumatology and orthopaedic surgery, and an automated dispensing logistics cabinets for the other surgical prostheses. These external registration and storage control systems provide information on replacements, withdrawals and returns, quantity, lot/series, location and retrieval.

In 2017, the hospital managed an average of over 7,600 different items in storage. Our automated dispensing cabinets hold over 1,200 items; the largest category is vascular, cardiac and thoracic surgery prostheses with 326 different items, followed by prostheses for haemodynamics and ophthalmology, with 271 and 268 different items, respectively.

For knee and hip prostheses, we have external computerised systems for composites, with a total of 1,250 different items. It is crucial in both cases for the industry to label their products with GS1 barcodes.





Examples of the use of composites for the external computerised storage-management systems





Examples of the use of automated dispensing cabinets for the external computerised storage-management systems

However, the Hospital Universitari Vall d'Hebrón has over twice as many different items in storage that are managed without any external system, stored in boxes together with the instruments required for implanting them. These include spinal implants, whose traceability we do not follow, and synthetic bone implants for use in traumatology and maxillo-facial surgery.

The pictures on the previous page show examples of the use of the external computerised storage-management systems, which may use composites (pictures 1 and 2) or automated dispensing cabinets (pictures 3 and 4).

The hospital now follows a system for registering prostheses in the healthcare SAP. During an operation for a specific patient, all prostheses that are implanted in that patient must be registered so that the material implanted, the supplier, reference, lot/series and expiry date are all known.

This solution does not depend on the route taken by the prosthesis, depending on whether it is in storage or in transit.

Registrations can be made through one of the three available options:

1. By accepting the proposal sent by the external computer systems' interface to the healthcare SAP. Prostheses are replaced in these systems through GS1 barcode readings.
2. If there is no proposal, for example, where the prosthesis in question is in transit, it will have to be registered in the healthcare SAP by reading the label with the GS1 barcode that appears on the box.
3. Finally, if neither of the above options is possible, the registration can be done manually, given that there are search functions which help in manual registrations by reference, supplier etc.



Conclusion

By using this model, Hospital Universitari Vall d'Hebrón have seen the following improvements:

1. Nursing staff are provided with an easy to use tool for registering prostheses for patients in surgery.
2. The information registered in the healthcare SAP lets us see the prosthesis' traceability.
3. The interconnection with the financial SAP allows purchasing departments to order replacements from suppliers more quickly.
4. The hospital's invoicing department can manage the invoicing for the implanted prostheses more efficiently according to the principles of the Department of Health, as well as the invoicing of third parties.
5. Thanks to prostheses being registered by patient in the healthcare SAP, the implantation card can be printed with the necessary information for compliance with current legislation.
6. As a consequence of the change in the prosthesis management model, increased spending on prostheses has not led to a proportional increase in the costs of the logistics operator.
7. Investing in models that combine technological solutions, space design and improvements in information systems promotes resource optimisation and efficiency.

The processes are currently being analysed to ensure that spinal prostheses can be traced, by using the healthcare SAP with reference and serial numbers. They're also looking at reducing the number of incidents relating to non-registration in the healthcare SAP, something that leads to increased workloads in all the areas involved.



About the author



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Montserrat Gualdo is deputy director of economic management at the Hospital Universitari de la Vall d'Hebron. She was previously financial economic director of the Hospital of Traumatology and Rehabilitation of the Vall d'Hebron Health City. She's written articles for the Journal of Care Quality and Entire Hospital Magazine, and she is also a resident tutor on economic management.

About the organisation

Hospital Universitari Vall d'Hebrón is the largest hospital complex in Catalonia and is part of the state-owned company, the Catalan Institute of Health, under the Catalan Ministry of Health. It's divided into three large medical areas: general care; maternity and childcare. They also cover traumatology and rehabilitation in a specialist hospital. In addition, surgical outpatient procedures are carried out in the Parc Sanitari Pere Virgili, which is located close to the hospital.
www.vallhebron.com

UAE

Dubai Health Authority implements GS1 standards to empower automated pharmacies

Challenge
Before the adoption of GS1 standards, DHA did not have a barcoding system in place and was therefore quite prone to medication errors.

Approach
All pharmaceutical companies, agents, and suppliers now supply pharmaceuticals to DHA with a Global Trade Item Number (GTIN) and the 2D DataMatrix. By leveraging GS1 standards and adopting a fully integrated system for its pharmaceutical transactions, DHA has made crucial advancements in providing quality services in the provision of medicine.

96%
decrease in the risk rate of medication errors for inpatient services

95%
of the nurses no longer experience missing dose medication

Patients' level of trust in outpatient services grew to
92%

$480,000
cost reduction in two years

The aim of Dubai Health Authority (DHA) is to transform Dubai into a leading healthcare destination by fostering innovative and integrated care models. In 2017, DHA adopted the use of GS1 standards for all pharmaceutical products being supplied and used within DHA hospitals and health centres. All pharmaceutical companies, agents, and suppliers now supply pharmaceuticals to DHA with a Global Trade Item Number (GTIN) and the 2D DataMatrix based on GS1 standards. Some of the benefits seen include improved traceability, reducing medication errors, productivity gains, and saving time and costs. By leveraging GS1 standards and adopting a fully integrated system for its pharmaceutical transactions, DHA has made crucial advancements in providing quality services in the provision of medicine.

Dr. Ali Al Sayed

Unified and efficient healthcare for all

Dubai Health Authority (DHA) is the largest healthcare provider in the emirate of Dubai and provides a unified and efficient healthcare system, one that is effective and accessible for all. DHA's values embrace consumer centricity, efficiency, an engaged and motivated workforce, accountability and transparency, and innovation and excellence.

Dubai Health Authority channels their services through the DHA healthcare facilities throughout Dubai, which includes a total of four hospitals, 13 primary health centers, and seven specialty centres. In total, these DHA healthcare facilities accommodate almost 2,000 beds, with almost a million patients each year.

DHA's healthcare facilities include dozens of specialised centres, such as cardiology, oncology, obstetrics, gynecology, neonatology, paediatrics, as well as surgical and medical departments, intensive care units, operating theatres, and clinical support throughout the facilities.

Adopting GS1 standards

In 2017, DHA implemented a new management system by leveraging GS1 standards in all pharmaceutical transactions taking place in its hospitals and health centres. DHA is the first healthcare provider and government authority in the region to implement GS1 standards. GS1's system of standards allows for smart and comprehensive solutions in pharmaceutical and medication dispensation management.

It guarantees the safety of patients by assigning a unique identifier (GTIN) in a GS1 DataMatrix to each medicine, thus reducing the chances of any errors when dispensing medication and ensuring pharmaceutical safety and medicine consumption with complete end-to-end traceability. This allows manufacturers and distributors to work together to comply with DHA's regulations. DHA mandated all pharmaceutical companies, agents, and suppliers to supply pharmaceuticals with a GTIN in the 2D Data Matrix. The GS1 barcode system is compatible with Epic (the electronic patient record system) and smart pharmacy systems.

Starting from scratch: the initial process

Before the adoption of GS1 standards, DHA did not have a barcoding system in place and was therefore quite prone to medication errors. "We started with GS1 from scratch, as we realised we needed to have a barcoding system as a prerequisite of the implementation of an automation system in DHA," says Dr. Ali Al Sayed, the director of the pharmacy department. DHA initially considered creating their own in-house barcoding system, but with sustainability being one of their goals, they concluded that an in-house system would not be very sustainable and would prove to be a huge effort for DHA, as well as for the suppliers.

> We were very lucky to have partnered with GS1 UAE - adopting GS1 standards means implementing a sustainable solution, one that is applicable anytime, anywhere."
>
> **Dr. Ali Al Sayed** Director of pharmacy department Dubai Health Authority

DHA immediately began communication with all its pharmaceutical companies and suppliers, informing them of the adoption and implementation of the GS1 system of standards.

These companies and suppliers would need to label each medicine pack with a GS1 DataMatrix as part of the purchasing data requirement to comply with the new DHA regulations and ensure that it becomes a smoother and more efficient process for all.

> A major advantage of adopting GS1 standards is that these are international standards. Because of this, most of the suppliers' inbuilt barcode from the manufacturers themselves were based on GS1 standards, which made the integration process even smoother. Since GS1 is so well established and well known worldwide, it was very easy to adopt the GS1 standards and to map the GTIN information with our own in-house coding."
>
> **Dr. Ali Al Sayed** Director of pharmacy department Dubai Health Authority

Before adopting GS1 standards, there was an immensely probable chance of wrong medication preparation and dispensing. With GS1 standards and the integration of barcoding within DHA's HIS (Hospital Information System) SALAMA, scanning the barcodes on each item upon preparation and dispensing now leaves almost zero chance of any medication errors. Additionally, without any barcoding system in place, DHA's new HIS, SALAMA would not have been used to its full potential, and the execution of smart pharmacies would have been inconceivable altogether. The GS1 system of standards needed to be used if their project for smart pharmacy was going to be put into motion.



Challenges before and during implementation

Dr. Ali Al Sayed recalls several challenges before and during the implementation of the GS1 system of standards, "First, we had a huge stock so to manually barcode the entire stock proved impossible. With the implementation of GS1 standards, we would have full control of the stock and accuracy with handling it. Secondly, we had to opt for a smart solution so as to utilise as little resources as possible in a sustainable way. We also had to have a smart solution for medicine suppliers so that it would be easier for them as well. We thought about implementing our inhouse system, but it would have been very difficult to maintain it. We were the first governmental entity to implement GS1 standards and to barcode the primary packs of the medicine. It was a new concept in the market, so it was a challenge to adapt to it, there was no comprehensive understanding of what barcoding really is. But with time and with support from GS1 who were with us through the entire process of implementing barcoding, and with the integration of barcoding with SALAMA and with smart pharmacy solutions, it was ultimately a very successful operation."

Three of the most critical challenges in hospital pharmacy that DHA cites are patient safety, providing the best patient experience, and efficiently tackling the increasing demand for DHA services. DHA conducted several surveys at their healthcare facilities before and after implementation to gain insight into how GS1 standards have made a difference. Before the implementation of GS1 standards, several problems that persisted primarily for DHA were patient waiting time, returned medications, maintaining the expiry date of medication, risk of medication error, missing doses, and constant phone calls.

Nurses and pharmacists relayed their previous pharmaceutical experiences. Based on a survey conducted on inpatient services before the implementation of GS1 standards, the nurses observed that the waiting time to receive the first dose was 30 minutes, the waiting time until the missed dose medication was received was also 30 minutes, and that there were daily phone calls to the pharmacy during preparation of the single unit dose medication. Pharmacists observed that the medication preparation for the first dose took 30 minutes, the average time spent checking the patient profile was five minutes, the time spent on checking expired medication per ward took between 30 to 60 minutes, and that they were constantly sending medications to the nursing unit.

A similar survey conducted prior to implementation on the previous pharmaceutical outpatient services in DHA showed that the service waiting time was 15 to 20 minutes, and the service delivery time was two minutes. The occupancy rate was between 130 to 240, and there was the possibility of medication error. The overall customer satisfaction level was 69%, with the satisfaction of the speed of delivery service at 50%, the ease of use at 83%, the quality of service at 68%, accessibility at 78%, and the level of trust at 85%.

When DHA introduced the DHA outpatient smart pharmacy first in 2017, there were similar challenges before adopting GS1 standards. The waiting time was 20 minutes, and there was a high risk of medication error. Moreover, the medication review for appropriateness was only at 77%.



Waiting time



Returned medications



Maintain the expiry date of medication



Risk of medication error



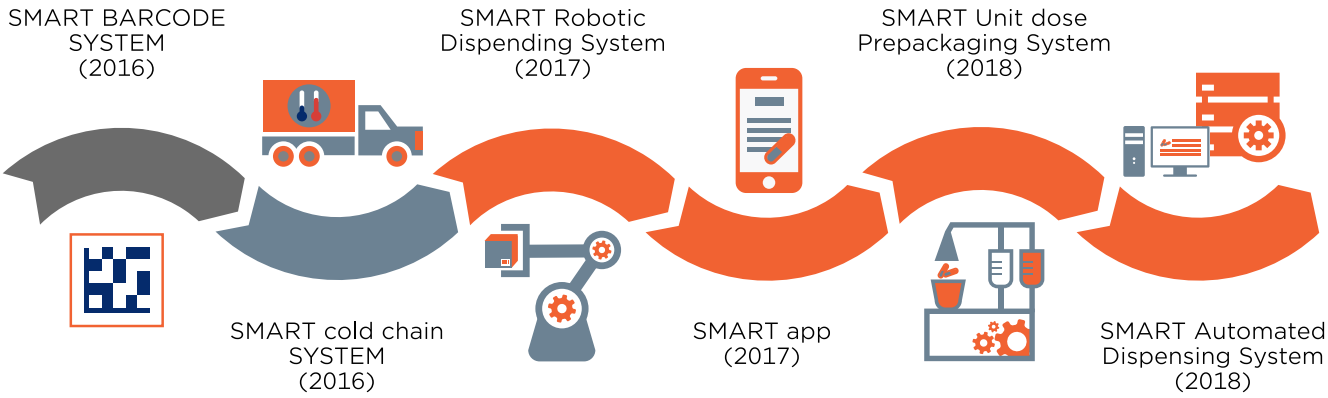
Missing doses



Constant daily phone calls

There was also a massive increase in demand for DHA services; there was a significant increase in Dubai's population in 2016, and more people began to turn to DHA for their services. While there were only 2,019,148 outpatients in 2016, by 2018 there were 2,257,393 outpatients with a 28% increase. The number of prescriptions also increased; with a 25 increase over two years, the total number of prescriptions rose from 1,770,380 to 1,894,307. There was also a 30% increase in the number of transactions taking place within the DHA smart pharmacies; in 2016 there were 4,524,957 transactions, and in 2018 there were 4,977,453 transactions in total.

DHA's solution



DHA initiated their solution to the challenges they were facing by first putting the GS1 system of standards into practice, which then led to the next steps in their solution. The smart barcode system was implemented, and 35,911,492 items were barcoded. DHA made it obligatory for all pharmaceutical companies, agents, and suppliers to supply pharmaceutical products with a GS1 GTIN in a 2D DataMatrix. It was the first step in a larger project that aims to ensure the safety of the supply chain and the drugs supplied to the authority, and to avoid any counterfeiting of drugs.

The next step was the Smart Cold Chain System. This system entails computer tablets becoming integrated with the medical refrigerators that register and document the temperature automatically, as well as smart devices showing the temperature graph range to which drugs were exposed during transportation. The Smart Cold Chain System also includes voice alerts and text messages to be sent out in case the temperature was to exceed standard limits.

The Smart Robotic Dispensing System for outpatient pharmacy was the third step of DHA's solution. This is a complete dispensing solution for fast, medium, and slow items, and dispenses 8,000 medicines in one hour. It decreased the waiting time down to two minutes, which also allowed more time to be spent on clinical care.

The Smart Robotic Dispensing System also manages inventory and optimises space.

DHA launched a Smart App next. This provided all the required information for all healthcare providers in DHA and helped them in making their clinical decisions.

The fifth step of the solution was the Smart Single Unit Dose Prepackaging System. This comprises of an oral solid and liquid system as well as a packaging system, and complete automated printing labels. Moreover, the system greatly reduces the risk of administration medication errors and reduces medicine utilisation costs.

The sixth and final stage of DHA's solution was the Smart Automated Dispensing System for inpatient pharmacy. It encompasses a smart automated dispensing cabinet, a smart single unit dose cart, and a smart anesthesia cart. It assures that the medication is taken on time, thereby enhancing patient safety. The Smart Automated Dispensing System also includes a complete medication profile for each patient, inventory control, and an automatic reporting system. The workload on the pharmacy and nursing staff was also reduced with the implementation of this step.











DHA also implemented an Automated Inpatient Closed Loop Medication Management System at their hospitals. This system automates the entire process from the point of medication ordering by physicians, review and supply of medication orders by pharmacists, to the point of administration by nurses. The system aims to improve patient safety and work efficiency.

The changes and benefits seen as a result of leveraging GS1 standards

By 2018, after the implementation of GS1 standards, significant improvements were recorded in inpatient and outpatient services. Some of the most notable benefits seen are improved traceability, reducing medication errors, major productivity gains, greatly saving time and costs, improved interoperability and reliability, and effective inventory management from the reduction of stock kept in storage.

As described earlier, surveys conducted prior to implementation meant DHA were able to monitor all the improvements made.

% The follow up survey conducted on inpatient services in 2018 demonstrates that the waiting time to receive the first dose and until the missed dose medication was received, both of which were previously **30 minutes**, was reduced to **3 to 5** minutes only, and over **80%** of pharmacists did not experience returned medication.

The management of the expiry dates were sped up considerably, and automatic report tracking was implemented, allowing the maintenance of the expiry date of medication to become easier and more efficient. In addition to this, there was a 96% decrease in the risk rate of medication errors. Over 95% of the nurses no longer experienced missing dose medication, and there was a 95% reduction in phone calls by the nursing unit during the preparation of single unit dose medication, which were previously taking place daily.

Customer satisfaction also shot up substantially, as illustrated by the follow-up outpatient services survey in 2018. The overall satisfaction went up to 94%, with the satisfaction with delivery service at 95 %, and the satisfaction with ease of use at 96%. Satisfaction with the quality of service increased to 96%, and accessibility increased to 93%. The patients' level of trust also grew to 92%.

Since implementation in 2017, drastic improvements have been seen. The waiting time was cut down to only two minutes, and the risk of medication error went down to almost zero %, and the medication review for appropriateness shot up to a 100%. In addition to this, DHA was also able to reduce costs by AED 1,744,344 (approximately $480,000) in the two years.

> With the guidance of GS1, we started the right way, and the entire course was very successful. The entire integration process, reading the barcodes with our own HIS, Salama, and reading the barcodes with our automation solution, is all going very smoothly."

Dr. Ali Al Sayed
Director of pharmacy department
Dubai Health Authority

DHA's next steps

DHA has around 1,400 active pharmaceutical products in its portfolio. In two years, 36 million packs have been dispensed for both out-patients and in-patients and labelled with GS1 barcodes by manufacturers and distributors.

Moving forward, DHA's next steps include tighter control of cost and inventory management, optimising use of space, assisting the inpatient condition, and maintaining a successful track and trace implementation. The next phase will also include working with GS1 UAE to ensure the safety of medicine.

> Adopting barcodes can either be very successful or very risky. If you don't adopt an international and intact system, there can be serious consequences. Any mistake in barcoding or in the integration of barcoding has fatal consequences on patient safety. Because of that, we were very keen to opt for international standards and a controllable environment. We are still working with GS1 UAE to reach this ideal implementation and to properly utilise the GS1 UAE's BrandSync portal, and to integrate the portal with our system. The GS1 system of standards was the main pillar on which we built our smart pharmacy solutions and for utilising our HIS, SALAMA to the full extent."

Dr. Ali Al Sayed
Director of pharmacy department
Dubai Health Authority

About the author



Dr. Ali Al Sayed
Director of pharmacy department
Dubai Health Authority

Dr. Ali Al Sayed is currently the director of the pharmacy department in Dubai Health Authority, where he has been working for over 30 years. He has a Ph.D. in Health Services Administration, an M.S. in Pharmacy Administration, and a B.Sc. in Pharmaceutical Sciences. He has formulated and implemented several policies and programs for DHA's pharmacy department. Dr. Ali Al Sayed has also executed numerous DHA pharmacy services such as the Dubai Drug Coding System, the implementation of Patient Care Services and Medication Errors Reporting System. Dr. Ali Al Sayed has also established and implemented SMART application and automation of DHA's pharmaceutical services.



About the organisation

The Dubai Health Authority (DHA) was established in 2007, and its aim is to provide an accessible, effective and integrated healthcare system, protect public health and improve the quality of life within the Emirate. The DHA's mission is to transform Dubai into a leading healthcare destination by fostering innovative and integrated care models and by enhancing community engagement. In addition to overseeing the health sector for the Emirate of Dubai, the DHA also focuses on providing services through DHA healthcare facilities including hospitals, specialty centres and DHA primary health centres throughout Dubai. www.dha.gov.ae

UK

Realising more than £1m of savings through an effective inventory management improvement programme

Challenge
Following a trust-wide review of supply chain processes, practices and systems, Taunton and Somerset NHS Foundation Trust realised that there were areas where they could be operating with greater efficiency.

Approach
The success of the programme was central to the procurement of an effective inventory management system that would enable the automation of inventory management processes. After reviewing their options, they decided to implement Ingenica Solutions' 360 – the first GS1-certified inventory management solution in the NHS.

More than 30 hours per week of time saved from manual stock control, realising a saving of £36,000

More than £426,000 one-off cost savings

Product recalls took on average 48 hrs Now staff are able to locate the product within two minutes

A total saving of £1m, by reducing stock by 34%

Taunton and Somerset NHS Foundation Trust

National Health Service (NHS) trusts in England are being driven to improve operational efficiencies in order to achieve greater cost savings amidst the growing financial pressures on the sector.

The procurement team at Taunton and Somerset NHS Foundation Trust, realised that they were experiencing unwarranted levels of wastage, stemming from the lack of a robust inventory management system. By automating their inventory management processes, the trust has been able to realise more than £1m of cost savings to date, as well as saving more than 30 hours a week of clinical staff time.

Monika Nott

Introduction

In 2015, the then secretary of state for health and social care, the Rt Hon Jeremy Hunt, commissioned a report conducted by Lord Carter of Coles into the operational productivity of acute trusts in England's NHS.

Lord Carter estimated that the acute trusts could save £5bn by 2020 by reducing unwarranted clinical variation. He estimated that £1bn of this could be achieved by non-clinical teams, with a portion of these savings attributed to procurement[1].

Challenge

One of Taunton and Somerset NHS Foundation Trust's key principles is to run as efficiently as possible, at a cost of 10% less than the average hospital in England. However, following a trust-wide review of supply chain processes, practices and systems, they realised that there were areas where they could be operating with greater efficiency.

The trust's inventory management system was largely reliant on clinical staff spending considerable amounts of time ordering and managing products manually on a daily basis.

There was no reliable electronic stock or inventory management system in place, and inaccurate data collection caused much of the problem.

Inventory was often duplicated across multiple storage locations causing unnecessary product wastage due to overstocking, and without any effective track and trace processes in place, product recalls often took 48 hours to complete when required.

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf

It was at this point in 2014, that the trust procurement team began work on an inventory management improvement programme (IMIP). The aim of the programme was to improve clinical consumable availability, reduce costs and enable traceability for product recalls, as well as to allow products consumed to be tracked to patients and to support improved financial reporting at service-line and patient level.

Solution

The success of the programme was central to the procurement of an effective inventory management system that would enable the automation of inventory management processes. After reviewing their options, they decided to implement Ingenica Solutions' 360 – the first GS1-certified inventory management solution in the NHS, and an enabler for GS1 standards[2] and Scan4Safety[3].

A three-phase implementation plan was developed to begin trialling the programme. Phase one started in 2016, centring on high-value departments – head and neck theatres, general theatres, central stores, orthopaedic theatres and day surgery.

Ingenica's 360 solution was fully integrated into existing systems within each of these departments, linking into the trust-wide product catalogue, Oracle. Clinical teams were also provided with portable hand-held scanners capable of scanning multiple product Global Trade Item Number (GTIN) barcodes or data matrices at any given time.

This integration meant that inventory consumption could be monitored in real time, from the shelf to the patient, improving end-to-end traceability throughout the supply chain.



Products could also be tracked and traced easily, improving visibility for both clinical and procurement teams. Product GTINs, and trust locations mapped to Global Location Numbers (GLNs), enabled merchandise to be tracked to shelf level, so staff could have sight of what stock they had, how much was in stock and exactly where it was.

Benefits

From the first phase alone, Taunton and Somerset NHS Foundation Trust achieved more than £426,000 of one-off cost savings.

The number of procurement transactions were reduced as they had access to accurate inventory data, providing details of actual stock requirements. This saved a valuable 10.3 hours of time per week – an annual productivity saving of £5,200.

Approximately 7,000 lines consumed could instead be automatically ordered via Oracle to pre-approved levels based on actual consumption. In turn, this meant that 99.6% of required product was in stock and available to clinicians as and when needed.

Aside from the compelling financial savings, the new system released valuable clinical staff time.

% Time traditionally spent on manual stock control could instead be spent directly on patient care. In head and neck, this equated to a **90%** reduction, **81%** in orthopaedic theatres, **86%** in general theatres and **98%** in day surgery.

In real terms, this amounted to a total of more than 30 hours per week of time saved, realising a saving of £36,000.

These time savings were also translated to time saved executing product recalls. With the previous process, product recalls took an average of 48 hours on each separate occasion. With effective track and trace measures in place, staff were able to locate the product within two minutes, with a further 30 minutes to quarantine the item.

The consistent real-time data capture enabled the trust to forecast stock levels based on product usage information that supports patient-level costing. This has had a dramatic effect on consignment stock management and space utilisation, preventing clinicians and procurement professionals from over-ordering.

[2] https://www.ingenicasolutions.co.uk/why-ingenica/gs1-standards

[3] Scan4Safety is the initiative led by the Department of Health and Social Care in the UK that is enabling the delivery of better patient care, improved clinical productivity and supply chain efficiency in the NHS by using GS1 standards. More information is available here: https://www.scan4safety.nhs.uk

> We now know what we need, not what the supplier thinks we need. The results we have achieved so far have made a huge difference to clinical staff as well as wider trust teams, and we look forward to sharing our learnings with other trusts in the same position."

Monika Nott
IMIP project lead
Taunton and Somerset NHS Foundation Trust

Next steps

Phase two of the programme is currently being rolled out to a further seven departments – intensive care unit, high-dependency unit, surgical assessment unit, maternity theatre, audiology and ED, sterile services department and endoscopy. Upon completion of phase two, the trust plans to start phase three, centring on the wards.

Following completion of all the phases in 2020, the trust intends to implement additional functionality using RFID to manage assets and also plans to interface it with the joint registry for reporting.

The team at Taunton and Somerset NHS Foundation Trust are working closely with the Southern Adoption Group for Scan4Safety, sharing their learnings to translate these invaluable benefits to neighbouring trusts, improving operational efficiency and patient care and safety for the wider population.

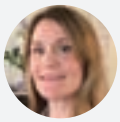
Conclusion

> % Since starting the project in 2014, the trust has proudly achieved a dramatic total project saving of **£1m**, by reducing stock in live sites by **34%**.

The trust has increased operational productivity and more clinical time is now spent treating patients instead of managing inventory.

The benefits achieved have provided great value to the teams involved, the wider trust and, most importantly, the population of 340,000 patients they serve.

About the author



Monika Nott has been a senior manager in both private and public sector, with 12 years of experience in the private sector before moving to the public sector.

She has held various supply chain and digital project and implementation roles during this time. From 2016, Monika has been leading the implementation of the inventory management improvement programme (IMIP) across the trust.

Monika has taken private sector experience and best practice into the public sector, and helped to add value and improve efficiencies through IMIP, with patients at the centre of all that Monika and the project team do.

Having the right product at the right time and in the right place for the right patient is paramount.

Monika Nott
IMIP project lead
Taunton and Somerset NHS Foundation Trust

About the organisation

Taunton and Somerset NHS Foundation Trust is an acute trust in a rural part of the UK, with an annual spend of £65m.

Musgrove Park Hospital Taunton is the largest hospital in the trust and is also the largest in Somerset, serving a population of 340,000 people.

Musgrove Park has 630 beds across 34 wards and 15 operating theatres, employing 4,000 staff to enable them to deliver care to the population it serves. www.tsft.nhs.uk



UK

Using barcode scanning technology to reduce medication errors in dispensing

Challenge
The Royal Cornwall Hospitals NHS Trust supply process was not routinely closed loop, and required the re-keying of important information from one system to another. This open-loop system increased the likelihood of human error.

Approach
In an effort to reduce the number of medication dispensing errors, the trust introduced barcoding into their dispensing process. They then assessed the prevented error rates, the speed of dispensing and staff perception, to review efficacy.

97%
of users agreed that scanning reduced the likelihood of medication errors

Overall prevented dispensing error rate was reduced by
76%

Faster dispensing and reduction in re-work correcting errors equated to 0.2 whole time equivalents or £4,400 per annum

42%
agreed that scanning improved their dispensing speed

Royal Cornwall Hospitals NHS Trust

There are an estimated 37.8 million dispensing errors made in England each year, representing 15.9% of all medication errors[1]. Small differences in drug name, strength and form, make dispensing more susceptible to human error. By introducing GS1 standards and universal unique identifiers, along with the use of barcode scanning technologies into the dispensing process, the Royal Cornwall Hospitals NHS Trust was able to reduce the overall prevented dispensing error rate by 76%.

Iain Davidson

The role of technology in healthcare

Driving digital maturity within healthcare has become a key objective for the UK's National Health Service (NHS), and implementation of a comprehensive digital electronic health record is a large part of this.

By automating processes and maximising the use of digital technologies, healthcare providers have the capability to improve patient safety and clinical efficiency, releasing clinicians' time to care. Within the medicines domain, two key aims are closed-loop medicines administration and closed-loop medicines supply.

The utilisation of barcode scanning has revolutionised industries like retail and has the potential to deliver broader benefits within the healthcare environment.

The Department of Health and Social Care's Scan4Safety programme – based on a bedrock of GS1 standards – aims to embed the use of barcode technology, and the use of standards within the NHS.



[1] http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf



Human error and the patient safety risk

Implementing automation within acute hospital pharmacy settings is already having a profound impact. For example, robotics is currently being used to improve accuracy and efficiency in picking and labelling medicines in bulk. However, this supply process is not routinely closed loop, and requires the re-keying of important information from one system to another. This open-loop system increases the likelihood of human error.

Tackling the challenge

In an effort to reduce the number of medication-dispensing errors within their trust, Royal Cornwall Hospitals NHS Trust introduced barcoding into their dispensing process. They then assessed the prevented error rates, the speed of dispensing and staff perception, to review efficacy.

The prevented dispensing error rates were monitored over two independent 12-day periods – the first period where barcode scanning was not mandatory, the second where it was. Any errors were recorded on an error-monitoring form.

To ascertain the effects on speed of dispensing, they timed a group of 26 participants using a test script. Each participant was asked to dispense items for the same named inpatient, both with and without the use of barcode scanning technology.

Staff perception was then assessed using a questionnaire. Further insights were gained in two focus groups with the 32 staff members that completed the survey.

Achieved outcomes

% Where barcode scanning had been implemented, results demonstrated a significant reduction in overall prevented error rates in dispensing. Rates fell from **0.78%** to **0.19%**, a statistically significant reduction of **76%** (P<0.001).

The barcode-assisted dispensing process was also statistically significantly faster than the manual process with the median time to label eight test prescription items falling from 177 seconds to 165 seconds – a rate 6.7% faster than the original manual process (P=0.015).

When surveyed, 97% of users agreed that scanning reduced the likelihood of medication errors, with 42% agreeing that scanning improved their dispensing speed.

> “The combined time savings as a result of a faster dispensing process and a reduction in re-work correcting errors, was equivalent to 0.2 whole time equivalent (WTE). That is a significant amount of time given back to the department so we can focus on other patient facing tasks.”
>
> **Iain Davidson**
> Chief pharmacist
> Royal Cornwall Hospitals NHS Trust

Assuming an average staff banding of band 3 (£22K per annum based on NHS Terms & Conditions), this equates to a saving of around £4,400 per annum.

“Barcode scanning has shown a clear improvement to patient safety and it should be routine practice across all dispensaries.”

Staff perception scores on ease of use of the technology and the impact on patient safety were high. However, only 67% of staff expressed that they would want to use barcode enabled scanning as an integral part of routine pharmacy operations. In focus groups, staff fed back that this lower than expected figure related to the need to better design both the software and the workstations to fit barcode scanning workflows and also in part due to the fear of becoming de-skilled.

Delivering future patient safety improvements

Building on these results, the trust now has plans to integrate GS1 standards into other steps within the dispensing process and barcode medicines administration.

Their ultimate aim is to achieve a complete closed-loop medicines administration and supply system, with data recorded end to end at every touchpoint throughout the process.

Soon, they aim to use barcode scanning on wards to improve patient safety when nurses are administering medicines directly to the patient, at the point of care.

Beyond the walls of the acute care setting, Royal Cornwall Hospitals NHS Trust have identified the potential to further extend these benefits out into the community. Implementing GS1 standards and barcode scanning into community pharmacy, the care home setting, or directly in a patient's home, can provide additional levels of safety by instantly warning the caregiver or patient to any medication alerts.

Conclusion

The outcomes achieved by Royal Cornwall Hospitals NHS Trust, clearly demonstrated that the adoption of GS1 standards and barcode scanning technologies could not only improve patient safety, but also release much needed staff capacity.

However, organisations and IT companies need to consider how barcode scanning changes the workflow, and design their systems accordingly, to facilitate the change management process that is required with staff.



About the author



Iain Davidson
Chief pharmacist
Royal Cornwall Hospitals NHS Trust

Iain joined the Royal Cornwall Hospitals Trust as chief pharmacist in April 2010. Prior to this he was chief pharmacist at Newham University Hospital and worked as a clinical pharmacist at the Chelsea and Westminster Hospital NHS Foundation Trust and Guy's and St Thomas' NHS Foundation Trust.

As chief pharmacist, Iain has overall responsibility for the management and optimisation of medicines within the trust and has taken a lead on the digitalisation of this area, with the automation of dispensing, digitalisation of ordering, and the implementation of electronic prescribing and medicines administration.

He is a keen advocate of the electronic patient health record, having completed a Masters qualification in Health Informatics at the University of Sheffield, and was also in the role of chief clinical information officer at the Royal Cornwall for two years. He is also a founding Fellow of the Faculty of Clinical Informatics.

About the organisation

The Royal Cornwall Hospitals NHS Trust is the main provider of acute and specialist care services in Cornwall and the Isles of Scilly.

It serves a population of around 430,000 people, employs approximately 5,000 staff, and has a budget of approximately £380m. The trust is responsible for the provision of services at three main sites – Royal Cornwall Hospital, West Cornwall Hospital and St Michael's Hospital – with a total of approximately 750 inpatient beds.
www.royalcornwall.nhs.uk

UK

Interoperability and GS1 standards – a roadmap to success in pathology and medicines administration

Challenge

Their pathology system was extremely labour intensive, and relied heavily on manual data entry. Royal Papworth Hospital NHS Foundation Trust's pathology system increasing numbers of patients needing treatment, this process became progressively harder to manage, creating as much as 24-hour delays within the pathology department.

Approach

They began work on a larger-scale, complex project to integrate five separate systems, including one for electronic prescribing and medicines administration (EPMA), with their existing electronic patient record (EPR), leveraging GS1 standards. The results enabled them to share vital patient information, improve patient safety and increase traceability across two trusts.

24 hrs
reduction in real-time pathology information being available to clinicians

All medicines administration information was linked into the patient record, providing clinical decision support to the trust's clinical teams

Increased traceability and patient safety benefits saved over £50k in the first year

£42,000
saved by automation of medicines administration

Prior to 2017, pathology at Royal Papworth Hospital NHS Foundation Trust was a systematic but manual process. However, when the time came to integrate their pathology services with a neighbouring trust, they found the need to introduce an interoperable solution that could interact with both trust systems using GS1 standardised information.

During this time, Royal Papworth began work on a larger-scale, complex project to integrate five separate systems, including one for electronic prescribing and medicines administration (EPMA), with their existing electronic patient record (EPR). The results enabled them to share vital patient information, improve patient safety and increase traceability across both trusts.

Andrew Raynes

Integration and interoperability for healthcare in England

Integration has become a top priority for healthcare organisations in the UK. This first came with the introduction of 44 Sustainability and Transformation Partnership (STP) regions across England in 2015.

Now these regions are evolving into integrated care systems (ICSs) to create a foundation for integrated health and social care where providers work together, sharing patient records, operational information and systems to improve patient care.

Hospitals, GP practices, and local authorities are now collaborating to bridge the operational siloes across the health and care landscape. However, enabling different systems to seamlessly interact and share information is a challenge many providers face.

Tackling the challenge

For Royal Papworth Hospital NHS Foundation Trust, this became a key priority as part of their integration plans with neighbouring trust, Cambridge University Hospitals NHS Foundation Trust (CUH), to share a pathology service.

To make this happen successfully, they needed to have a process in place where they were able to link the systems at each trust, enabling clinicians to order tests and share patient information and pathology results in a timely manner.

However, the system in place was extremely labour intensive, and relied heavily on manual data entry. Any order placed at Royal Papworth had to be transcribed into the EPR system, Epic, at CUH. Results would then be returned into Royal Papworth's document management system in PDF format and manually entered into their own EPR system, Lorenzo.

With increasing numbers of patients needing treatment at both hospitals, this process became progressively harder to manage, creating as much as 24-hour delays within the pathology department. Not all errors were logged, often due to the sheer volume of them from the clinical end when manual request forms were filled in incorrectly by clinicians. It would have been a full-time job tracking and tracing them. The Patient Administration Systems (PAS) database was notoriously inaccurate as well, with patient identifiers often entered in wrongly or not at all (e.g. NHS numbers) which lead to errors and/or delays in the lab.

At this point, the decision was made to undertake a complex integration project, to make sure their clinicians could order tests and receive results electronically.

Achieving interoperability

The information technology team at Royal Papworth had to integrate a total of five individual systems as part of the interoperability project. However, the major challenge they faced was to create an interface between Epic and Lorenzo.

Integration at such a level had never been referenced by other trusts in England, so the task was the first of its type for the National Health Service, and they were able to achieve a bi-directional interface in just seven months.

Andrew Raynes, chief information officer and director of digital at Royal Papworth Hospital NHS Foundation Trust, said: "Our move to the new hospital on the Cambridge Biomedical Campus meant that the requests and results project to enable ordering and acknowledging lab results, required interoperability as a key component across five systems. This was highly complex and, because the project was the first of its type in the UK, it meant we didn't have any real reference points from which to learn.

"We had a highly effective project team, and through the leadership of our chief medical information officer, (CMIO) Dr Chris Johnson, chief operating officer, (COO) Eilish Midlane, the pathology team and our key stakeholders – including our partners at CUH, Clinisys and DXC Technology – we ensured regular touch points to monitor progress.



"Open standards such as Health Level Seven International (HL7) and Fast Healthcare Interoperability Resources (FHIR), meant interoperability was achievable. In this particular instance, the system was designed to recognise which laboratory the test was done in – Royal Papworth or CUH's laboratories – and to send information for the specific tests to the correct system where the analysis would take place.

Linking the two systems enabled blood test orders and results to be shared between DXC Technology's Lorenzo, and Epic directly, which enabled them to fully automate the pathology service and remove the manual burden.

> "Barcode standards such as GS1's demonstrate just how vital interoperability is to scanning lab samples, ensuring a reduction of 24 hours to real-time information being available to our clinicians, which supports patient safety and efficient processes."
>
> **Andrew Raynes**
> Director of digital and chief information officer
> Royal Papworth Hospital NHS Foundation Trust

EPMA was also implemented as a component of the Lorenzo EPR programme. Royal Papworth Hospital became the first organisation to use the Lorenzo infusions prescribing module, and digitised more than one million clinical documents in the process.

Both inpatient and outpatient areas of the trust were switched over to electronic prescriptions. In doing so, any prescribing and administration information could then be automatically fed back into the patient record.

Outcomes in pathology

Using GS1 standards, staff were able to accurately identify the patient ahead of testing (using a GS1 barcoded patient wristband) and before samples were taken.

Barcodes were also applied to samples, enabling them to be tracked and traced within the pathology service and across the two trusts (image 1). This allowed them to generate a Positive Patient ID (PPID) pathway, resulting in the right tests being requested on the right patient using the right sample types, increasing patient safety and improving operational efficiency and traceability of specimens in the pathology department.

By introducing a system centred around GS1 standards, pathology staff were able to acknowledge laboratory results through scanning, saving valuable time.

Lab-based staff at CUH were no longer required to type details into the system. Instead details could be entered directly onto Epic, saving an average of between three and five minutes per specimen.

With the additional benefit of the bi-directional interface from Epic to Lorenzo, results could be accessed instantaneously, providing timely access for clinical teams, saving an average of 24 hours each time and reducing the risk of transcription errors from the printed results.

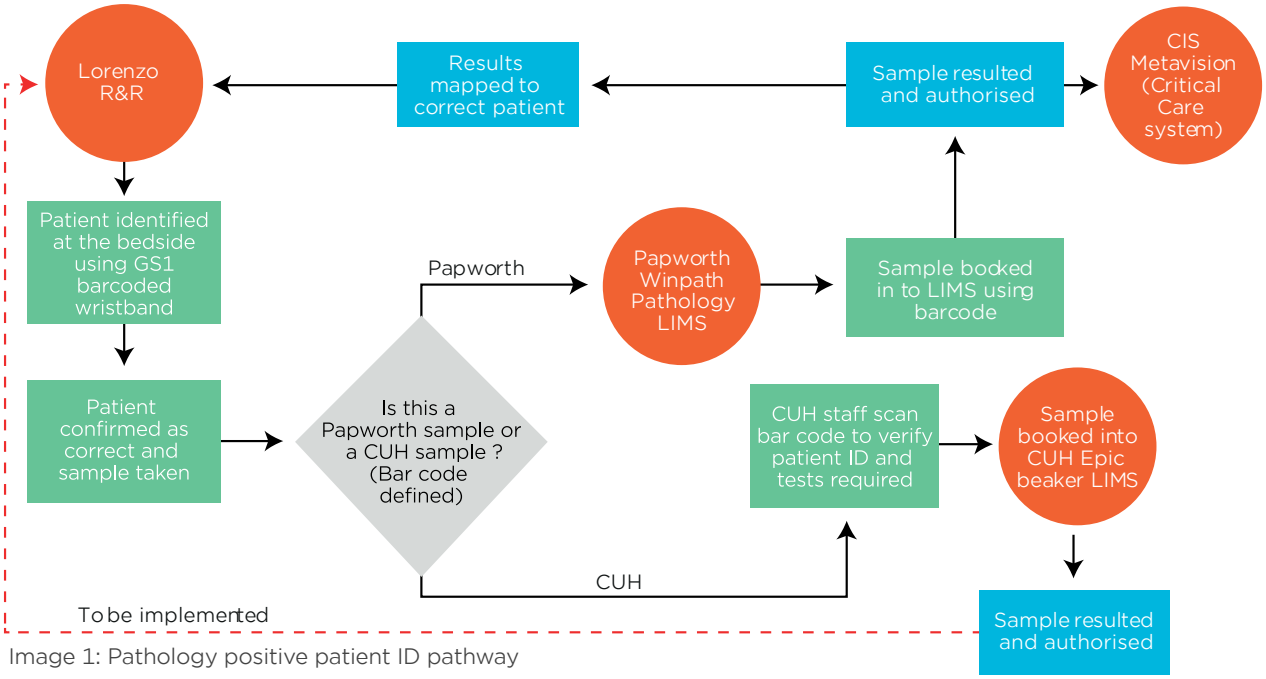


Image 1: Pathology positive patient ID pathway

The impact on medicines administration

The adoption of GS1 standards at this stage enabled the Global Trade Item Number (GTIN) on each medication to be scanned and the details logged onto the EPMA system. Then, by integrating EPMA into the Lorenzo system, all medicines administration information was then linked into the patient record, providing clinical decision support to the trust's clinical teams.

This integration with the patient record allowed for conflict-based warnings to be generated instantly, alerting the clinician to any potential duplication, drug interactions, and contraindications.

Fewer missed doses were also reported on the trust incident reporting system. Staff were able to use the system to help standardise and trace prescribing and administration activities, attributing them back to the user and creating an audit trail that allowed for increased traceability and patient safety benefits, with savings of more than £50k in the first year.

Automation of medicines administration meant that administrative and pharmacy staff could spend less time completing forms and other admin tasks, saving **£42,000** for the trust each year. In doing so, the trust was also able to limit their carbon footprint by **£1,594**.

Additional benefits were seen for patients, for example, better bed management information has enabled clinical decision making, resulting in fewer days in hospital, reducing the length of stay and freeing up as many as 130 "bed days". The discharge prescribing process was also streamlined, and clinicians no longer had to spend vital time rewriting routine charts.

Royal Papworth achieved considerable benefits from integrating their systems and achieving interoperability across both sites through the standardisation of data.

"The UK's secretary of state for health and social care, and the Wachter Review's tech vision, both say that interoperability is the way forward, and we have shown that to be correct," added Andrew Raynes.

"Standards and open systems are what really matter, and Royal Papworth is ahead of the curve. We have put policy about interoperability into practice – it is achievable."

Next steps towards becoming a GS1 exemplar site

Royal Papworth Hospital have now opened a new site which includes five operating theatres and two hybrid theatres, five heart catheterisation laboratories (for non-surgical procedure), and six inpatient wards with around 300 beds, including a 46-bed critical care unit and more than 20 day beds.

The trust is embarking on a journey to become a GS1 exemplar site – becoming fully GS1 compliant across all key areas. In order to achieve this, a nurse-led steering group has been set up and a roadmap for core enablers has been developed.

As a priority, they will be focusing on implementing Global Location Numbers (GLNs), RFID tagging for the asset management of medical equipment, and Global Service Relation Numbers (GSRNs) for patient and staff identification.

They also intend to extend GS1 barcodes to their smart fridges and for use during blood tracking as the development evolves, in order to establish a fully compliant and interoperable trust with end-to-end traceability.

About the author



Andrew Raynes
Director of digital and chief information officer
Royal Papworth Hospital NHS Foundation Trust

Andrew Raynes is currently director of digital and CIO at Royal Papworth Hospital NHS Foundation Trust.

He joined Royal Papworth from his former role as information management and technology programme director at Barking, Havering and Redbridge University Hospitals NHS Trust in East London.

Andrew Raynes has more than 20 years of experience working in the NHS and overseas within health, care and the private sector. Andrew has an MSc in Healthcare Informatics and is a Fellow of the British Computer Society (BCS). He is also a non-voting member of the trust's board of directors.

About the organisation

Royal Papworth Hospital is the UK's leading heart and lung hospital, treating more than 100,000 patients each year from across the UK. Since carrying out the UK's first successful heart transplant in 1979, Royal Papworth now performs more heart and lung transplants than any other UK centre.

98% of patients say they would recommend Royal Papworth Hospital to their friends and family.

Royal Papworth Hospital is a member of Cambridge University Health Partners (CUHP), a partnership between one of the world's leading universities and three NHS Foundation Trusts.

CUHP delivers world-class excellence in healthcare, research and clinical education, improving the health of people across Cambridgeshire and the wider regions.
https://royalpapworth.nhs.uk

US

Demonstrating the benefits of scanning UDI barcodes on the front lines

Challenge

The Veterans Affairs (VA) Medical Center in Miami, Florida, spent countless hours each week manually entering product codes into systems for hundreds of medical implants and other products that were received, placed into inventory, and ultimately used in patient procedures and care.

Approach

To address these challenges, the hospital introduced barcode scanning to its inventory management processes. As medical device manufacturers mark their products with unique device identifiers, per the U.S. Food and Drug Administration's (FDA) Unique Device Identification (UDI) Rule, these unique device identifiers are available for point-of-care scanning.

$ 5-10,000
estimated savings each month

Scanning eliminates human error from manual data entry

70 seconds
Manual entry

20 seconds
Scan entry

Saving 50 seconds per entry saves the hospital more than 1 hour per week

The Veterans Affairs (VA) Medical Center in Miami, Florida, once spent countless hours each week manually entering product codes into systems for hundreds of medical implants and other products that were received, placed into inventory, and ultimately used in patient procedures and care. To stay on top of correct product names and expiration dates, to prevent inadvertent human error, and to positively impact patient safety—a better system was needed.

Although implementation of the U.S. FDA UDI Rule is ongoing, according to the VA hospital, nearly 90% of products used by their operating rooms have such barcodes today. As medical devices and implants are received, the Miami VA hospital scans the barcodes, capturing this valuable product information automatically. The information is then stored in the hospital's Medical Device Management System (MDMS) called UDITracker®, provided by Champion Healthcare Technologies, a GS1 US Solution Partner.

Margreth Spruill

Solution

To address these challenges, the hospital introduced GS1 barcode scanning to its inventory management processes. As medical device manufacturers mark their products with unique device identifiers, per the U.S. Food and Drug Administration's (FDA) Unique Device Identification (UDI) Rule[1], these unique device identifiers are available for point-of-care scanning.

For manufacturers that have chosen to use the GS1 System of Standards to implement the rule, the GS1 Global Trade Item Number (GTIN) is used as the UDI device identifier (DI) and GS1 Application Identifiers (AIs) are used to represent UDI production identifiers (i.e., batch/lot, serial number, expiration date, and/or production date). This information is encoded in a GS1 barcode, such as a linear GS1-128 barcode or a two-dimensional (2D) GS1 DataMatrix barcode and, as such, is available for scanning.



[1] For information about the rule, see the U.S. FDA Unique Device Identification System.

Benefits

By using barcode scanning and the UDITracker® system, the Miami VA hospital has improved the efficiency of its operations since it can now easily and accurately keep track of implants and other medical devices. Improvements in productivity and inventory management have also been realised.

The hospital realised a $5,000 to $10,000 savings each month by using inventory that might otherwise have expired.

Most important, patient safety has improved since scanning barcodes helps to eliminate human error from manual data entry. Also, capturing uniform device identification information saves tracking time, and could conceivably save lives in the event of a recall.

Making processes easier

The VA Medical Center in Miami is one of 170 VA hospitals in the United States and is a primary care center for nearly 150,000 veterans in South Florida, offering them 24/7 comprehensive services. Located amid several major healthcare providers in the heart of the city, Miami's VA Medical Center is a mini-trauma centre for vets.

"Not all hospitals can do all the cases that we do. If you're a vet and you're injured, most vets will come to us," says Margreth Spruill, a surgical technician with the Miami VA hospital.

Miami VA's Spruill, a veteran herself with notable computer skills, noticed that implants and other medical devices being delivered to the operating room displayed linear barcodes, leading her to convince the hospital UDI administrator to supply her with scanners.

Spruill reports, "I knew that scanning would make life easier in managing all of the inventory we had to check-in and check-out every day."

In a hospital that does as many as six cataract surgeries and at least three implant surgeries per day, a fair amount of serial numbers need to be recorded in patient records every day. Using manual data entry left substantial room for error in a busy hospital environment.

The hospital works with Champion Healthcare Technologies, a technology company that optimises tissue and implant management workflows. Champion provides the hospital with UDITracker®, an inventory management and tracking platform specially designed for UDI tracking.

Champion is currently working with the VA hospital to integrate implant usage information into the hospital's proprietary electronic health record (EHR) system. Implants and other devices are scanned on the front-end upon receipt of the products and again when products are checked out of inventory for procedures. The data captured for implants is also added to the patient EHR, adding full traceability to the patient.

Champion's system helps the hospital scan and store implant UDIs (including GTIN and any production identifiers, or PIs) in its systems. This process helps the hospital overcome challenges related to non-availability of dedicated fields to store GTINs in its Enterprise Resource Planning (ERP) system.



"I knew that scanning would make life easier in managing all of the inventory we had to check-in and check-out every day."

Margreth Spruill
Surgical technician
Miami Veterans Affairs Medical Center

An implant by any other name

Using a manual data entry approach, technicians would type in certain pieces of product information obtained from the label, including product name. This was causing issues because team members varied in how they recorded the product name: one team member might enter a product name one way, while another technician might enter it as something else.

Sheer volume also posed a challenge. The hospital performs eye surgeries each day, for instance. Consider that a single manual entry of a device code takes 70 seconds. A scan of the same device takes just 20 seconds. Multiplying the 50-second time savings by approximately 100 procedures in a given week, equates to the hospital saving more than one hour in that week.

Spruill relates a case in point: "The other day I had a case involving 10 dental implants. Because they were not barcoded, I had to type every one of those in by hand, plus transfer them from the dental service into the OR service to keep inventory straight. It took me almost an hour to type all of that into our system, do the transfers, and get the information into the patient record. The very next case was a knee implant, where we had just as many implants and related accessories – but they were barcoded and in UDITracker® so I could just scan them in. Scanning took me less than five minutes. That perfectly illustrates the time difference."

Scanning as seen through an implant lens

As shipments of implants and other medical devices are received in the hospital's warehouse, information such as the transaction number, purchase order (PO) number, and date of receipt is recorded in the UDITracker® system. The products are then handed off to the appropriate clerk.

The clerk scans each product's barcode to capture the product's GTIN and any other encoded information (like the batch/lot number and expiration date) and enters it into the inventory system. The product is then physically placed on the shelf of the operating room's (OR's) inventory.

When a surgeon orders a lens for implantation, the clerk removes it from the shelf and scans its barcode once more in a pre-op setting.

With that, the UDITracker® system is updated to show that the implant was used, and forever links it to the patient receiving the implant—making it possible to track the implantable device from point-of-receipt to point-of-care, and for the patient's lifetime if there is ever a recall. This improves efficiency, safety, and patient care.



Accuracy is also greatly enhanced. When someone manually inputs a product, they might leave off a number, or they'll think the number "8" is the letter "B" or they'll misread it. When someone gets it later on in the process, it is compared with what's in the EHR, the implant sheet and the actual implant sticker. The barcode can actually help catch errors.

Had a barcode been available for scanning at the outset, however, the need for this corrective procedure would be eliminated.

Miami's Spruill gives Champion high marks for its assistance and expertise in the healthcare arena. "We do training maybe once every six months or as needed as we get new users. It's very informative and helps us keep our operations efficiently moving. Champion plays a major role for us," Spruill says.

Champion helped the hospital "cleanse" its database of imprecise product names and non-unique manufacturer catalog numbers, and move to standardised, unique device identifiers (GTINs) instead so all product information is aligned and can be readily found.

> We can locate and use items that are due to expire first. To check expirations manually on packages, lens by lens, is extremely time consuming – especially when you have hundreds of lenses. The expiration date information [contained in the barcode and captured by UDITracker® when scanned] saves us money as well as time."

Margreth Spruill
Surgical technician
Miami Veterans Affairs Medical Center

Time is of the essence

With inventory tightly and accurately controlled, product expirations can be reduced, saving waste and money. The programme enables a search by expiration date, quickly displaying the products with the closest expiration.

"We can locate and use items that are due to expire first. To check expirations manually on packages, lens by lens, is extremely time consuming—especially when you have hundreds of lenses," Spruill says. "The expiration date information [contained in the barcode and captured by UDITracker® when scanned] saves us money as well as time."



In the event of a recall, scanned product data residing in UDITracker® can prove to be invaluable for speed and accuracy. UDITracker® includes a recall feature that enables users to click on the item being recalled, and the technology shows every patient in which the device was used and where the remaining devices are stored. Aside from the time savings this represents, the patient safety aspects are profound.

"When we had a tissue implant that was recalled, I went into the system, typed in the product code number and the system pulled it right up, supplying every name within a matter of minutes—everybody that used it and in what department," Spruill says.

> Managing inventory to ensure implants are there when our veterans need them is what we always aim to do."

Margreth Spruill
Surgical technician
Miami Veterans Affairs Medical Center

* Source: Miami VA Hospital

The voice of experience

Spruill admits that busy people resist change, but that implementing barcode scanning quickly proves its worth— ease-of-use, time savings and accuracy—to even the most doubtful professionals.

Spruill recommends that those considering the changeover to scanning barcodes arrange for a demonstration at facilities already using it. And when it comes time to introduce scanning into a facility, proper training should be coupled with the appropriate scanning equipment. For example, some products are marked with linear barcodes and some products are marked with 2D barcodes, so hospitals should invest in image-based scanners which are capable of reading both.

The hospital is also poised to expand the use of scanning as it updates its proprietary Computerised Patient Record System (CPRS) with a commercial EHR system.

Spruill advises that in the end, it's all about taking care of those who have taken care of us—our veterans. "Managing inventory to ensure implants are there when our veterans need them is what we always aim to do," says Spruill.

The value of barcode scanning

- **Increased efficiency:**
  The Miami VA hospital can now easily and accurately keep track of implants and other medical devices in a highly efficient and precise way.
- **Greater productivity:**
  In the hospital, scanning linear barcodes (e.g. GS1-128 barcodes), instead of using manual data entry, results in a time savings across surgeries can add up to at least one day per month.
- **Better inventory management:**
  The ability to readily identify and then use products nearing their expiration dates eliminates waste and saves money. The hospital estimates a $5,000 to $10,000 monthly savings when using inventory that might otherwise have expired.
- **Improved patient safety:**
  Scanning eliminates human error from manual data entry, and capturing uniform product identification information throughout distribution and use saves tracking time and conceivably could save lives in the event of a recall.

About the author



Margreth Spruill
Surgical technician
Miami Veterans Affairs Medical Center

Margreth Spruill has worked for the VA Medical Center in Miami since 2010. Margreth is a veteran herself, she was previously a First Sergeant and an Operating Room Platoon Sergeant in the US Army. She has a keen interest in computers and assisted in implementing scanning to manage inventory at the VA hospital.

About the organisation

Miami Veterans Affairs Medical Center

The Miami VA Healthcare System serves veterans in three South Florida counties: Miami-Dade, Broward and Monroe. The Miami VA Healthcare System is an accredited comprehensive medical provider, providing general medical, surgical, inpatient and outpatient mental health services. The Miami VA Healthcare System operates 372 hospital beds, including a four-story community living center attached to the main facility. www.miami.va.gov

Champion Healthcare Technologies

CHAMPION HEALTHCARE TECHNOLOGIES

Champion Healthcare Technologies is a technology company that is dedicated to preserving the integrity of healthcare. Champion solutions, like UDITracker®, are specifically designed to provide oversight and insight into workflows and systems utilised by hospitals. www.championht.com





Suppliers

Responsible for creating and delivering the products and devices needed at all levels of patient care, suppliers 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're safe for use. Take a look at the following case studies to see how they're doing this.

Czech Republic

A medical device manufacturer's experience of UDI and its implementation

Challenge

Although it may seem that Unique Device Identification (UDI) only means the addition of a barcode on a label and the entry of certain information into the UDI local database, LINET found the implementation of UDI to be a very complex task requiring money, equipment, people and time.

Approach

The main objective of UDI implementation must be a process that is sufficiently robust and ensures that each medical device is clearly identified, and that correct information will be entered at the correct time into a relevant UDI database. This process must be integrated into the manufacturer's quality management system.

Creating a UDI process should involve almost all departments

To have a UDI system in place is a proactive advantage for manufacturers

UDI helps with traceability throughout the supply chain

UDI is used globally in communication with national authorities

LINET spol. s r.o. is a major European manufacturer of hospital and nursing beds. The company's portfolio includes solutions designed for intensive care, products for regular in-bed treatment and also specialised beds for old people's homes and long-term care facilities. The LINET range also includes a wide range of accessories such as anti-pressure ulcer mattresses, mobile equipment, and healthcare furniture.

LINET headquarters, as well as its production plant, continue to be based in Želevčice u Slaného in the Czech Republic, where it has been located since its establishment in 1990. The plant manufactures around 60,000 hospital beds per year, the vast majority of which are exported to more than one hundred countries worldwide. LINET employs around 1,000 staff. Since 2011, LINET spol. s r.o. has been a division of the multinational holding organisation LINET Group SE, with registered offices in the Netherlands.

Jan Štěrba

Unique Device Identification of medical devices

UDI (Unique Device Identification) is a unique, globally-used standard for identifying medical devices along a healthcare provider's entire supply chain and for the lifetime of a product. The aim is to increase patient safety and optimise healthcare by facilitating the traceability of medical devices, such as in the case of withdrawal of products from circulation.

The first non-binding document setting out the framework and rules of the system was published in 2011 by a voluntary international group, Global Harmonisation Task Force (GHTF) within the IMDRF (International Medical Device Regulators Forum), comprising representatives of national authorities and trade associations in Europe, USA, Canada, Japan and Australia.

Broadly, the UDI system consists of:

- Creating UDI using a globally accepted standard.
- Labelling product(s) and/or product(s) packaging using UDI.
- Entering information into UDI public databases (UDID).



The UDI designation must be placed on a product in a format legible to humans, with information that can be decoded by a machine, using barcodes, for example, UDI consists of two parts: a device identifier (DI) and a production identifier (PI), which make up unique device identification (UDI). A DI is a unique numeric or alphanumeric code identifying a medical device model and it is also used as an access key to information stored in a UDI database. It is a static code, generated only once for a specific device model. The PI is a numeric or alphanumeric code identifying a device unit in production. The PI may have different types depending on the type of equipment produced (e.g. a serial number, date of manufacture, expiry date, production batch number, software version, etc.). This is known as the 'dynamic' part of UDI.

Expansion of UDI to new markets

Currently, the UDI system has only been implemented in the USA. Since 2013, the FDA (Food and Drug Administration) government agency has required UDI to be assigned to certain medical devices by entering its information into the GUDID database (Global UDID). Other jurisdictions expecting to initiate the use of the UDI system in the coming years are the European Union, Russia, China, Japan, Australia, Brazil, South Korea and Argentina.

What is expected from a medical device manufacturer?

A medical device manufacturer who puts, or plans to put, a medical device onto the market where UDI is required, must create and maintain a globally unique UDI for its medical devices. The manufacturer is responsible for understanding the requirements of national authorities, and other relevant entities, in respect of the correct designation of medical devices using UDI in a machine-readable format that is also legible to humans. The manufacturer will also be responsible for submitting and updating information in the UDID.

A leading global hospital bed manufacturer's experience

Does it sound simple? Unfortunately, it is not. Immediately after initial analysis, staff at LINET realised the extent and consequences of the UDI system. Although it may seem that UDI only means the addition of a barcode on a label and the entry of certain information into the UDI local database, the implementation of UDI is a very complex task requiring money, equipment, people and time. The author therefore recommends that any producer reading this article and planning to introduce the UDI system (e.g. because of preparations for the new EU Regulation 2017/745) start well in advance and not underestimate the preparation needed.

The main objective of UDI implementation must be a process that is sufficiently robust and ensures that each medical device is clearly identified, and that correct information will be entered at the correct time into a relevant UDI database. This process must be integrated into the manufacturer's quality management system.

Selection of a strategic partner

One of the first necessary tasks is also the selection of an issuing agency. This agency is an approved organisation that will operate the system for allocating unique device identification in accordance with the requirements in its area of jurisdiction. At present, the following three entities are globally recognised: GS1, HIBCC and ICCBBA. As the UDI system spreads globally, it is expected that other authorised entities will be established and appointed, for example, only for local markets. Before any selection is made, it must be emphasised that the authority will become a strategic partner and ask key questions. Are you already using any existing identifiers from any of these institutions (e.g., GTIN from GS1)? What standard is recognised by the market where you plan to sell? Do customers expect a specific standard? What services do you expect? LINET selected GS1 Czech Republic as its strategic partner to work on these areas.

Selection of an optimal method

Depending on the availability of resources, the size of the company and the portfolio, the manufacturer must also determine in what manner it wants to implement UDI requirements. This can be by its own means, in cooperation with an expert in the given field, or by fully outsourcing UDI implementation. Each option has its advantages and disadvantages. However, keep in mind that non-transferable responsibility for the UDI system is still associated exclusively with the manufacturer. This also applies to OBL manufacturers (Own Brand Labeller—an entity that introduces another manufacturer's medical devices to the market under its own name).

Another key decision is how the manufacturer will enter data into the UDI database. If it has a small portfolio of products and releases its product, for example, in only one country that has its own UDI database, it may enter the information into the UDI system manually via a web interface[1]. However, for global suppliers of medical devices, this activity should be automated using an appropriate software solution. Although software will reduce the risk of potential errors, its implementation is more expensive and requires thorough verification and validation of the given tool.

It is clear from the above that preparing and creating a UDI process should involve almost all departments governed by the quality management system (again, depending on the size of the company and diversity of the product portfolio). The project should ensure all of the above but must also provide the following at a minimum—integration of UDI into the existing information system, a single source of UDI information, and installation, testing and validation of the software for printing barcodes. Furthermore, staff require training, labels need to be modified and UDI added. Equipment for printing and verifying UDI on the labels must also be purchased and installed, and the requirements in respect of record maintenance and reporting should be put into practice. After the project is complete, it has to provide continuity for any planned work, operations and maintenance associated with the equipment for printing operations, software maintenance and any training necessary for maintaining the information system.

Readiness for implementation of the European legislation

LINET initiated UDI implementation in 2015 in conjunction with the requirements of the US market. In the same year, consultation with GS1 Czech Republic staff took place which provided excellent support in the planned introduction of UDI. Almost a year later, LINET was successfully registered in the American UDI database (GUDID) and launched the first products on the US market with the identification required. Although this requirement was not imposed on any other country at the time, the company decided to apply the new version of its identification label to its entire portfolio, not only to products designated for the US market. LINET therefore has a head start in preparing for compliance with the requirements of the new European regulation for medical devices in 2020.



[1] In the future under MDR (new EU Regulations for medical devices), this will depend on the phase of implementation.

Next steps

LINET uses for submission of relevant information in GUDID web interface only, because its current portfolio for US market is limited and it can be handled manually without additional costs. As a next step to adapt to the new UDI requirements of other jurisdictions (EU, KSA, ...) the company is preparing an automatic solution for the submission of relevant information to one data pool (e.g. Global Data Synchronisation Network (GDSN) certified data pool). This data can then be sent to individual databases or can be available via subscription by customers as well. Despite higher initial costs, this solution will help to improve current process, limit human errors, save time and satisfy national authorities and customers.

To have a UDI system in place is also a proactive advantage for manufacturers during communication with hospitals or other healthcare providers, because although UDI system is not globally required by law (yet), many customers are requiring it as part of tender specifications.

Benefits

UDI helps with traceability throughout the distribution supply chain – from manufacturer to customer. This identification number is used globally in communication with national authorities e.g. in case of adverse event or other undesired incident and helps manufacturers to trace medical devices.

Conclusion

The UDI system is being developed to facilitate adequate device identification through distribution and use on patients. This system is newly forming across various regulatory jurisdictions at varying levels of system maturity. When the UDI system is fully implemented, the labels of most devices will include a UDI in human and machine-readable format. In addition, globally harmonised meta-data about devices will be available in UDIDs as populated by regulated entities.

It's therefore key that if you work in this area, you begin work on compliance as soon as you can, to ensure you're in the best position possible to meet with requirements.



About the author



Jan Štěrba
Head of regulatory affairs & quality assurance
LINET spol. s r.o.

Jan Štěrba works as a Head of regulatory affairs & quality assurance at company Linet spol. s r.o,. global manufacturer and distributor of hospital beds and mattresses.

Jan has got a practical experience with development and conformity assessment of medical devices and implementation and maintaining of Quality Management System mainly in accordance with ISO 13485:2016, ISO 9001:2015, FDA and MDSAP requirements. He was involved in preparation for UDI compliance with U.S. Federal law. Now he manages preparation of company compliance with new European Medical Device Regulation 2017/745.

Jan is an active member of Czech association of suppliers of medical devices (CzechMed), where he cooperates on developing of national medical devices regulation and its harmonization with European legislation.

He holds Masters degree in biomedical engineering.

About the organisation

LINET spol. s r.o. is Europe's largest producer of innovative, high-quality healthcare beds, antidecubitus mattresses, furniture, and comprehensive solutions for hospital, nursing care facilities and gynecological practices. LINET headquarters, as well as its production plant, is based in Želevčice u Slaného in Czech Republic, where it has been located since its establishment in 1990. The plant manufactures around 60,000 hospital beds per year, the vast majority of which are intended for export to more than one hundred countries worldwide. www.linet.com



Germany

PHOENIX group becomes FMD compliant with Movilitas

Challenge
Falsified Medicines Directive (FMD) significantly challenged PHOENIX group as all its business areas were affected by the directive. In particular, the company's FMD requirements for wholesale and 3PL activities were challenging to fulfil. They needed a solution which allowed capture of the current status of those medicines that a wholesaler has to scan according to FMD.

Approach
Movilitas.Cloud proved to be the right solution. It is not only connected to the European Medicines Verification System (EMVS) and to all 32 National Medicine Verification Systems (NMVSs) in Europe, but also acts as a connection between PHOENIX's systems and the systems of partners.

Pack coding is now based on GS1 standards and includes the GTIN, lot expiration date and serial number

Real-time feedback on the status of a pack -allowing immediate triggering of required actions if there are issues

Without GS1 standards FMD would not have been possible

Increased reporting capabilities with details including not only the number of scans but also a quality report

Falsified medicines pose a serious health risk to patients. The European Falsified Medicines Directive (FMD), which had to be implemented by February 2019, aims to eliminate this risk. The directive demands a secured pharmaceutical supply chain through end-to-end verification of prescribed pharmaceutical products, thereby increasing the safety for patients. All supply chain partners have to fulfill specific requirements to reach compliance. PHOENIX group, a leading healthcare provider in Europe, has been FMD-compliant since April 20th, 2018. The company has chosen the Movilitas.Cloud solution to implement the FMD requirements in 17 countries for wholesale and pre-wholesale activities.

Marco Steinkamp
Karin Bischof-Arden

What requirements do stakeholders need to fulfill to comply?

FMD works with basically two verification systems: the central system, which is referred to as the European Medicines Verification System (EMVS), communicates with separate country-based systems for each EU Member State, which are referred to as the National Medicines Verification Systems (NMVSs). FMD mainly involves four different stakeholders: manufacturers, wholesalers, hospital pharmacies, and retail pharmacies.

Manufacturers

Life science manufacturers or Marketing Authorisation Holders (MAH) need to upload the relevant commissioned product data to the EMVS, which will then communicate the data to the National Systems.

Wholesalers

Wholesalers and 3PLs (pre-wholesalers) generally have the same obligations as manufacturers, except that they do not place any products in the market. They have to secure the supply chain and verify any suspicion of falsified medicines. This boils down to authenticating products that are returned through verification in the National System or deactivating/ re-activating the product serial number in the National Systems with a reason code.

Hospital pharmacies

EU FMD is also mandatory for hospital pharmacies, to prevent the distribution of counterfeit medicines to patients. Hospitals therefore also need to authenticate and deactivate medicines before dispensing them to the patients (or re-activate them in certain cases) and use the National Systems for this.



Besides its requirements, FMD also comes with a number of potential opportunities for hospital pharmacies: reduction in wasted medicines, in expired medicines, in local medicines shortages, as well as increased opportunities to engage in patient care, more rapid product recalls, better inventory management, and improvement in the pharmacy workflow.

Retail pharmacies

In the end, the whole purpose of the EU FMD is to protect the patient and improve patient safety by securing the supply chain. Before dispensing a medicine to a patient, it must be authenticated by scanning and verification against the respective National System. Once a pharmaceutical product has been dispensed, it is de-activated in the system.

How PHOENIX group fulfilled its FMD requirements in 17 countries for wholesale and pre-wholesale activities

PHOENIX group wants to offer the best service and care for its customers and ensure the safety of the medicines that reach patients. These core principles shape the entire company. For this reason, PHOENIX group has been working diligently and pro-actively on the implementation of the EU Falsified Medicines Directive across all its business areas, so that they are fully compliant with the legislation in all markets. “Our goal was to reach legal compliance on the reporting date of February 9, 2019”, says Karin Bischof-Arden, who was part of the serialisation project at PHOENIX group.

However, FMD also significantly challenged PHOENIX group as all its business areas were affected by the directive. In particular, the company’s FMD requirements for wholesale and 3PL activities were challenging to fulfill. “As a wholesaler we only have to scan a small portion of the products which we distribute further”, explains Bischof-Arden, “moreover, common solutions for manufacturers aim at tracing the serial numbers’ life cycle. In our case, however, the serial number of a product appears the first time it is scanned, and we only need to know or update its current status.” Thus, a lean and efficient solution had to be found, which allows capture of the current status of those medicines that a wholesaler has to scan according to FMD.



Figure 1: FMD stakeholders

Movilitas.Cloud proved to be the right solution. It is not only connected to the European Medicines Verification System (EMVS) and to all 32 National Medicine Verification Systems (NMVSs) in Europe, but also acts as a connection between PHOENIX's systems and the systems of partners.

Thus, PHOENIX can decide whether the serialised information of a product is routed to the NMVSs or to the repository of its partners after scanning, or to both. In addition, this solution combines features of a stand-alone (Movilitas.Mobile) and an ERP integrated solution (Wholesaler API). The stand-alone solution's features enable the scanning of pack codes with mobile devices. The pack coding is based on GS1 standards and includes the GTIN, lot, expiration date, and serial number. The ERP integration allows PHOENIX group to maintain scanning processes that already existed before FMD. In this case Movilitas.Cloud operates in the background and routes all serialised information to the NMVSs or partner systems.



Figure 2: Movilitas.Cloud ecosystem

Another key benefit is that the solution provides real-time feedback on the status of a pack - which is of particular importance for wholesalers as it allows them to immediately trigger required actions and lets them know which pack caused issues.

With regard to 3PL activities, PHOENIX group needed to know how many scans they perform for a particular MAH. The Movilitas.Cloud solution also entails detailed reporting capabilities, including not only the number of scans but also a quality report.

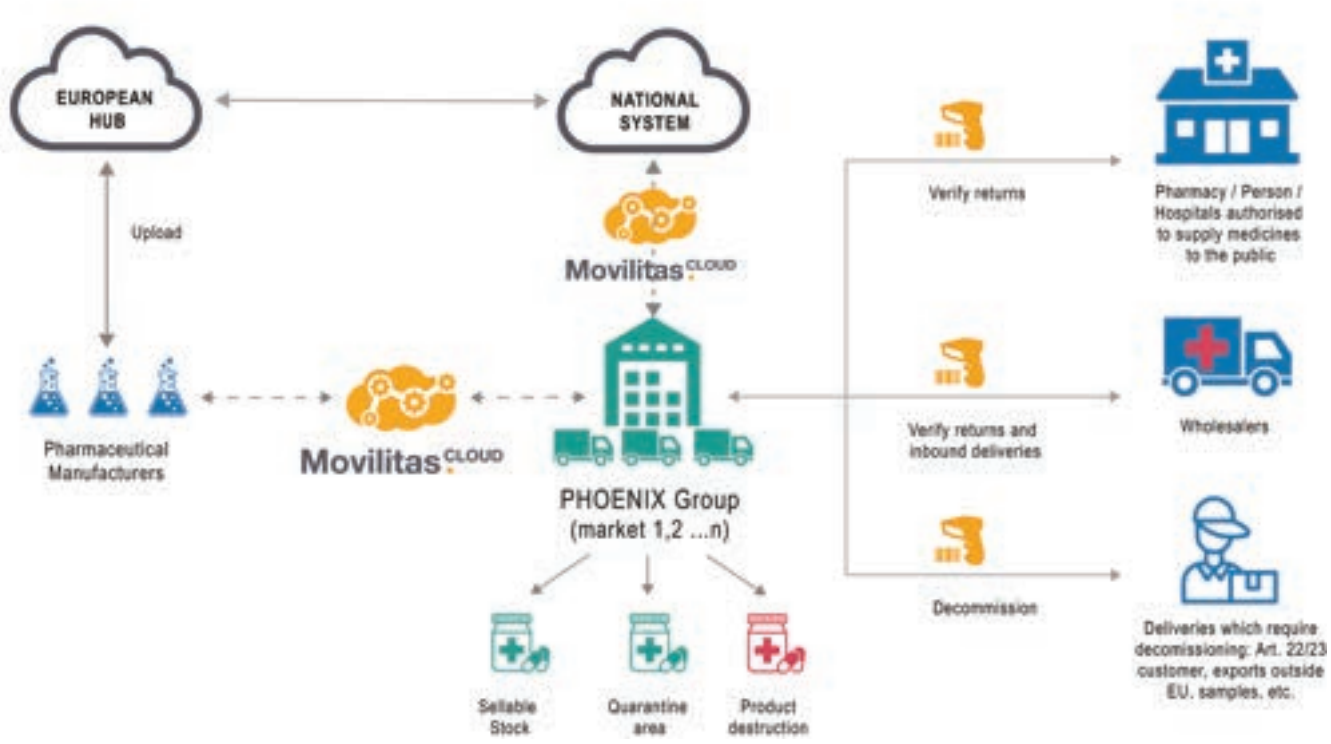


Figure 3: PHOENIX group's FMD solution by Movilitas

The role of GS1 standards for FMD

GS1 standards for product identification and labelling are crucial for the successful implementation of such a project. Varying pack codes would not have been sustainable as it would be impossible to scan all the different coding and receive serialised information in such a manner that the PHOENIX systems can interpret the data correctly and work with it. Thus, PHOENIX group relies on manufacturers' compliance to GS1 standards.

Current situation

FMD is still in its stabilisation period and existing gaps need to be closed to reach a completely secured pharmaceutical supply chain across Europe. Many medicines are not correctly coded yet, a lot of data needs to be uploaded to the EMVS, and process optimisation is required in many areas. However, with the right FMD solution in place, these steps are achievable.

About the author



Karin Bischof-Arden
Head of business consulting
PHOENIX group – Corporate IT

Karin Bischof-Arden is the head of business consulting at PHOENIX group's corporate IT department. This department acts as an interface between central group IT and local business, with its main focus on ERP solutions supporting healthcare distribution. Prior to this, Karin was a project manager, responsible for development of project management methodology, tools and education. She has a BASc in Business Administration - Retail Management from Baden-Wuerttemberg Cooperative State University.

About the author



Marco Steinkamp
Global sales director Track & Trace
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Marco Steinkamp studied Logistics at Fontys University of Applied Science in Venlo (NL). Afterwards he became an employee at British American Tobacco in 2005 and worked here for 10+ years. For six years he was a member of local and later also the global supply chain organisation within BAT. For four years he worked in the Global Track & Trace programme in various roles on local and global level e.g. being the responsible project manager in the Logistics as well as afterwards in the Manufacturing environment. With this End to End Supply Chain Track & Trace experience and expertise he joined Movilitas Consulting as the European Sales Director for Track & Trace in May 2015. And since 2017, he has been the global sales director for Track & Trace.

About the organisation

Delivering transformative solutions and opportunities while guiding clients on their journey to connected insights is the mission for Movilitas, headquartered in North American with offices across Europe, including Mannheim, Germany. Since its foundation, the company has emerged as a trusted SAP solution partner for the value chain with deep expertise in the fields of track and trace, cloud solutions, digital manufacturing, mobile solutions, and warehouse logistics. Focused on helping businesses gain a competitive advantage in today's on-demand economy, Movilitas is delivering a new era of supply chain visibility and connectivity that provides the foundation for the intelligent enterprise.
www.movilitas.com



Japan

Using GS1 standards and RFID technology is a win-win for Johnson & Johnson Supply Chain

Challenge
RFID technology is not new, having been deployed in parts of the retail sector for the past 15 - 20 years. However, its use in healthcare has been sporadic, and implementation of RFID is challenging if global standards aren't used.

Approach
JJSC received a request from a hospital for a customer-specific RFID tag on products. The RFID team quickly launched a rapid test-and-learn cycle to prove technical and business feasibility and explored existing system connections to provide a globally accessible serialised tracking solution. JJSC also took the opportunity to implement standardisation utilising GS1 standards.

99.96%
first pass read accuracy

80%
time reduction compared to manual scanning

70%
faster exception handling

Gaining support from the Japanese medical device industry to adopt solution as industry standard

Radio-frequency identification or "RFID" is emerging as an important technology to make product identification and traceability more efficient. It transmits the identity of an object wirelessly, using radio waves, and it requires little human intervention. RFID has the ability to better connect the end-to-end supply chain. Johnson & Johnson Supply Chain (JJSC) is developing innovative ways to apply RFID technology to meet customer needs and improve processes and product visibility.

Blair Korman

Meeting the needs of customers

RFID technology is not new, having been deployed in parts of the retail sector for the past 15-20 years. However, its use in healthcare has been sporadic, and implementation of RFID is challenging if global standards aren't used. For more than 10 years JJSC has investigated several options, worked to improve technical challenges and has implemented a few localised solutions.

JJSC received a request from a hospital for a customer-specific RFID tag on products. Our RFID team quickly launched a rapid test-and-learn cycle to prove technical and business feasibility and explored existing system connections to provide a globally accessible serialised tracking solution. We also took the opportunity to implement standardisation utilising GS1 standards. While there were challenges, the team ultimately delivered a compliant system that met the customer's need.

While the solution was not scalable, we studied what would be required for a larger-scale implementation and developed a standard to use in all future RFID projects. We learned through this first pilot that GS1's EPC Tag Data Standard (TDS) could be followed, and we created a technology framework to use with the next pilot.

> Implementing RFID using GS1 standards is a win-win. We are able to respond to a customer's request to RFID tag and also improve the supply chain by taking the data that GS1 standards provide and applying it across our operations.

RFID solution developed for Global Orthopaedics in Japan

Establishing a GS1-compatible RFID standard attracted attention from medical device manufacturers, distribution centres and hospitals across Japan. Building on our experiences, JJSC tackled a larger challenge for the orthopaedics business in Japan - to change the way medical devices are labelled and scanned, ultimately providing for a more agile customer experience. It started as a pilot to demonstrate how RFID could improve the loaner kit replenishment process in the Japan Global Orthopaedics distribution centre. Using a GS1-compliant RFID labelling process, RFID tags were placed on each sterile item in the loaner kits at the distribution centre. The tags were read and missing items were automatically identified, eliminating manual scanning and identification. The pilot leveraged the JJSC RFID standard operating procedure, which is based on GS1's "Gen2" UHF RFID standard. Since the Serialised Global Trade Item Number (SGTIN) is a main pillar within GS1's EPC Tag Data Standard (TDS), we also leveraged SAP's Advanced Track & Trace for Pharmaceuticals solution for provisioning serial numbers that had been put in place for JJSC.

Results

We created a highly accurate, cost-effective, scalable, GS1-compliant and user-friendly RFID solution.

% The pilot generated impressive outcomes: **99.96%** first pass read accuracy, **80%** time reduction compared to manual scanning and **70%** faster exception handling.

We are gaining support from the Japanese medical device industry to adopt our solution as the industry standard, as it leverages GS1 standards. GS1 Japan has identified this solution as setting best practice to be followed by other medical device manufacturers in Japan.

Others in the medical device industry are meeting regularly to monitor the Japan pilot, to understand the pilot results and potentially use the GS1 standards in their solutions. This is a big win for our customers who will benefit greatly from a common RFID standard.

About the author



Blair Korman
Senior project manager
Johnson & Johnson
Supply Chain

Blair Korman is a senior project manager for Johnson & Johnson Supply Chain leading UDI compliance efforts and driving the RFID initiative to standardise tagging operations. Blair's experience in logistics, packaging, labelling, and front-line operational supervision support her work with the UDI requirements developing globally and with U.S. Food and Drug Administration compliance. Blair continues to collaborate with RFID industry groups to encourage GS1 RFID standards and the adoption of RFID within the customer supply chain.

About the organisation

Johnson & Johnson Supply Chain includes three business sector supply chains—Consumer, 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. www.jnj.com

US

Introducing serialisation at Johnson & Johnson Supply Chain

Challenge
In the healthcare industry, supply chains have become increasingly complex and vulnerable to falsified medicines. Every step in the supply chain offers an opportunity for counterfeiters, and the impact of product counterfeiting and diversion is global.

Approach
Through work on serialisation and traceability, JJSC is creating identifying information at all levels of production. Every pack level, pallet, case, and sellable unit will have unique identifying information of a product number and a serial number, shared using a GS1 2D DataMatrix.

Instantly confirm the authenticity of products for customers

50% reduction of picking time

100% inventory accuracy

Prescription drugs can be traced back to their original source

Imagine trying to navigate a city with no addresses. The only information you have to go on is what the building looks like, or what landmarks it's near. With identifying information it would be so much easier. Johnson & Johnson Supply Chain (JJSC) is leading the work of mapping the products from the Johnson & Johnson companies. By using a variety of tools and mediums we are working to identify, trace, and make the products that the Johnson & Johnson companies create easily locatable.

Leandro Oliveira

Challenge

Counterfeit drugs and drug adulteration have been worldwide issues for decades. In the healthcare industry, supply chains have become increasingly complex and vulnerable to falsified medicines. Every step in the supply chain offers an opportunity for counterfeiters, and the impact of product counterfeiting and diversion is global.

% Pharmaceuticals are the largest market for counterfeit goods and it's estimated to be worth **$200** billion a year.[1]

Solution

Through our work on serialisation and traceability, JJSC is creating identifying information at all levels of production. Every pack level, pallet, case, and sellable unit will have unique identifying information of a product number and a serial number, shared using a GS1 2D DataMatrix. GS1 standards provide the foundation for this information to be used and enable automated solutions to be built.

By implementing serialisation and traceability, JJSC increases patient safety, maintains customer confidence in Johnson & Johnson company products and retains trust in supply chain processes and systems that deliver product to trade partners, hospitals, retailers and patients.

By bridging the physical with the digital, we increase our ability to communicate transparent, real-time data across the supply chain. With this information in hand, JJSC has a direct line of sight to our customers most pressing needs. Our products are reaching customers in the way that is most efficient and effective for them. As a result, we are creating a better information flow around our supply chain and a deeper understanding for the life cycle of products.

[1] Havocscope Global Black Market Information, 2016

Benefits

This system is in operation around the world for J&J pharmaceutical products and it has brought many measurable short and long-term benefits to our supply chain.

> Immediate advantages include increased efficiencies, reduced errors in receiving, the elimination of manual entry of lot/expiry in inventory management, and the creation of heads up display.

In the future, issues management and claims/credit management will be realised, and accuracy and efficiency of tracking, tracing, and managing product inventory could improve at all points throughout the supply chain.



Interoperability is also important as it provides crucial supply chain visibility for trading partners on both ends of the transaction. It allows real-time sharing of consistent, compatible data detailing product attributes, source, current location, and destination. All of this data means that prescription drugs can be traced back to their original source and every stop along their journey to point of sale. In terms of patient safety, this enables high-assurance validation of the drugs' authenticity and prevents acceptance of counterfeit products at the pharmacy destination. It also means that if a serious problem does occur, a recall can be efficiently executed, and the source of the problem can be quickly identified.

In the US, we're able to instantly confirm the authenticity of products for customers. In the European Economic Area we have successfully deployed all the foundational capabilities for pharmacies and hospitals to scan and verify the authenticity of the product. For a global company, being able to track and trace our products around the world is vital for understanding our reach and is part of our responsibility to keep our products safe.

In Brazil, we've been manufacturing and distributing serialised products since January 2017. Prior to that, the sites received several monthly customer complaints regarding missing products within sealed shipper cases. Since the January 2017 go-live, however, implementation of serialisation and aggregation initiated the automation of the shipper packing process and verification of the shipper prior to shipment closure. Subsequently, we have received zero customer complaints of missing packs within shipper cases.

Also in Brazil, the picking process involved manual sorting to fulfill customer orders. After a more robust packing control with supplementary automation was implemented, picking steps were simplified and processing time decreased by approximately 50%. Goods Receipt process requires accepting, verifying and registering product documentation and loading product pallets into bins. In the post-traceability environment, serialised pallet labels and scanners confirm receipt of product with minimal paper verification and manual effort. Each of the six distribution centers in Brazil enabled with traceability execute this process several times daily delivering a cost savings per year.

Inventory accuracy is beginning to indicate improvement with post-implementation cycle counts for missing products confirming consistent improvement since go-live. Better warehousing control and more automation delivered by the implementation of serialisation has resulted in significant improvement in inventory accuracy, with some warehouses cycles at 100% accuracy.

Packing Manual Checks is a process performed manually and visually by a warehouse operator to verify customer order contents to ensure the accuracy of the order. After serialisation, the business processes would be automated. In some warehouses, automation would come in the form of a packing, or checkout station, using a combination of software and hardware solutions, eliminating the need for the process to be executed manually, producing a yearly cost savings. This is a typical example of a benefit not coming directly from the serialisation, but from automation that is possible using product serialisation as an enabler to it.

Conclusion

As we become increasingly able to build on the automation and intelligence supplied by serialisation, we'll continue to see quality, cost and efficiency benefits. We've already seen cost and efficiency savings, and these are still only in the early stages of the implementation. As the impact of this spreads further and further within our organisation, these benefits will only grow.



About the author



Leandro Oliveira
Senior manager for digital identification & traceability
Johnson & Johnson Supply Chain

Leandro Oliveira is a senior manager for digital identification & traceability managing serialisation and traceability, unique device identification and global data synchronisation for the Asia Pacific region (APAC). For the past four years, Leandro led the serialisation program in Latin America. For Brazil he managed the first serialisation implementation and successfully led enterprise deployment for Russia, pilots in different markets, and the Advanced Track & Trace – Pharmaceutical platform upgrades. Leandro joined Johnson & Johnson Brazil in 2010 and has managed Supply Chain projects in the Make, Quality, Procurement, Planning and Deliver areas. Prior to joining Johnson & Johnson, Leandro worked in the energy, oil and gas industries as a project manager across different markets including Brazil, Europe and the Middle East.

About the organisation

Johnson & Johnson Supply Chain includes three business sector supply chains—Consumer, 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.
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GS1



Government initiatives

Increasingly, GS1 standards implementation is starting with governments, including their use in healthcare policies and recommendations. The next case study illustrates one of the latest initiatives taking place at a national level.

Chile

“Speaking in the same language to save time and increase efficiency and safety” - the standardisation of logistics in Chilean healthcare

Challenge
For a long time, CENABAST had acquired large quantities of products with different identification formats which caused multiple difficulties in their management.

Approach
They collaborated with GS1 Chile to improve the process of product information management in relation to their suppliers. This would improve operational indexes and incorporate best available practices, which would give greater agility to its logistics chain and lower the costs of the intermediation process that they perform in the public health sector.

Within one year all suppliers were aligned with GS1 standards

DataMatrix and/or GS1-128 is able to deliver all the traceability information needed

The positive impact in accuracy of the data now handled the speed of operation and the saving of time and effort

The three largest pharmacy chains in Chile now use GS1

The main objective of Chilean Public Healthcare is to promote equity and quality in access to healthcare. The good level of public health they have achieved (better than other countries with similar socioeconomic development) is reflected in aspects such as the increase in life expectancy at birth, the reduction of highly avoidable health events such as maternal and infant mortality, and treating infectious diseases that can be controlled with vaccines and measures of sanitation and hygiene. The Healthcare System in Chile is made up of a public system (FONASA), a private system (ISAPRES) and other specialised ones (armed forces and foundations).

José Luis San Juan

The Ministry of Health has two main agencies, the Subsecretary of Public Health who governs the Institute of Public Health and the Superintendence of Health, and the Undersecretary of Assistance Networks, which governs the Supply Central of the National System of Health Services (CENABAST) and the National System of Health Services (SNSS) responsible for various types of health services.

CENABAST is a public institution, under the Ministry of Health, whose mission is to manage the purchasing processes defined by the Ministry and other governmental health entities, to provide and ensure the availability of medicines, food, supplies and medical devices to the Network of Health (hospitals, clinics and public health services nationwide) according to what they need.

Supported by GS1 Chile, one of the most important players in the distribution chain, CENABAST, made a strategic decision. For a long time, the institution had acquired large quantities of products with different identification formats and barcodes which caused multiple difficulties in their management. CENABAST, seeing the complexity that this resulted in, institutionally defined the need to standardise the identification of products in a GS1 format to streamline their logistics processes.

Recognising that the use of global standards makes this process more efficient and fluid, CENABAST, together with GS1 Chile, decided to work in collaboration on the objective stated on the next page.

> GS1 Chile and CENABAST will collaborate to improve the process of information management associated with the products that CENABAST manages in relation to its suppliers. This will improve operational indexes and incorporate best available practices, which will give greater agility to its logistics chain and lower the costs of the intermediation process that CENABAST performs in the public health sector."

José Luis San Juan
Head of the Health Area
Global Traceability Trainer GS1

Impact on the supply chain

The interaction of CENABAST with its trading and traceability partners is very varied, given the diversity and quantity of suppliers (pharmaceutical laboratories and others), logistics operators, and health institutions that are its final customers.

As its first activity, for the entire chain of suppliers, CENABAST decided to disseminate an instructional document prepared by GS1 Chile with detailed instructions for identification throughout the product hierarchy. This document became an obligatory part of the public tenders of the Institution.

The incorporation of this requirement in bids had a high impact and was a key part of the implementation of global standards throughout the logistics chain. It meant that all suppliers aligned with GS1 standards, from the large multinationals that simply assimilated in Chile the practices already used internationally, as well as from other suppliers that had some difficulties and needed more support, both from CENABAST and from GS1 Chile. After a period of approximately one year, all suppliers were delivering their products in the manner specified.

How were GS1 standards implemented?

CENABAST has always known that, for Commercial Units, the GS1 DataMatrix is a much more powerful and versatile symbology than the EAN-13 and that it is internationally established as the recommended format for the field of healthcare. As is known, the EAN-13 only delivers the GTIN, while the DataMatrix is able to deliver all the traceability information, which is essential for a safe administration to the patient.

In the commercial units, it was preferable for now to continue with EAN-13 and GTIN-13 since pharmaceutical retail was not yet prepared for reading and processing the DataMatrix.

That remains as phase two, as well as the identification of the unit dose.

In the shipping or packaging units, it was decided to implement labels in GS1 format, with GS1-128 containing all the traceability information such as the GTIN, lot and expiration date. Finally, in logistics units (pallets), both single product and mixed, it was required to place logistics labels with a GS1-128 and SSCC (Serial Shipping Container Code) plus the corresponding application indicators.

Along these lines, all logistic formats, except for the unit dose, were identified with GS1 global standards for the benefit of all stages of the supply chain.

CENABAST together with GS1 Chile, did a great job of implementation both internally and externally with its commercial partners and suppliers. In addition to changing its corporate system to an Enterprise Resource Planning World Class, it acquired and put into operation new data capture equipment with state-of-the-art scanners and industrial wireless networks with a high level of wireless security.

With its traceability partners, they made sure to spread the work of implementation through instructions, prepared by GS1 Chile, given in the tenders. These became mandatory after a trial period. In addition, GS1 Chile, in conjunction with CENABAST, provided training to approximately 300 collaborators of the Institution so that they could fully understand and commit themselves to the project. Training was also given to the technical staff of each of its most important suppliers (another 300 people).



Benefits

There was a period of transition where CENABAST admitted labels with errors and inaccuracies, but after some time, the Institution became stricter, rejecting product orders that did not adapt to the requirements of the bids. This meant that in a relatively short time, all suppliers began using GS1 standards, both to satisfy the requirements, but also to capture their own barcodes automatically. This gave them more accuracy and their own real-time data, saving the manual entry of each process.

Another additional benefit was the incorporation of GS1 standards into pharmacy chains. In Chile, the pharmaceutical market is concentrated in three large chains that supply the whole country at user level. These chains are supplied directly by suppliers and laboratories and although they have used the EAN-13 and its reading of the GTIN-13 at the point of sale, historically the use of logistic labels in boxes and pallets was not standard. They worked with internal codes, both when receiving products from their suppliers and in the transportation and delivery of them from distribution centers into retail pharmacies.



Since CENABAST adopted GS1 standards, the three pharmacy chains progressively, and with support from GS1 Chile, decided to implement and also request that their suppliers (the same ones from CENABAST) use GS1 standards in their product hierarchy.

Today, with the compliance of the three pharmaceutical chains, we can ensure that this supply chain also works in line with GS1 global standards.

The positive impact of CENABAST's GS1 implementation has been observed in the accuracy of the data now handled, the speed of operation and the saving of time and effort. This has also benefitted the operations of suppliers, because they can also take advantage of these benefits in their own internal operations.



Next steps

Despite all that has been achieved, there is still a lot left to do to ensure patient safety and quality of care in Chile, and to make everybody aware that "safer, more efficient care starts with a simple scan."

Conclusion

It is evident that inefficiencies in general logistics have financial consequences: reduction of profit margins, product losses and errors of dispatch, among others. In the health sector this is even more critical. For example, if due dates are not taken into account, large volumes of products expire and must be eliminated, causing significant losses to the national budget. And most importantly, any health error can cause a medical problem or even the death of a patient.

For these reasons, implementing GS1 standards, together with barcode-reading devices and software that are compatible with GS1, is vital for standardising products and processes to ensure the safety and efficiency of Chile's health system.



About the author



José Luis San Juan
Head of the Health Area
Global Traceability Trainer GS1

Of Spanish nationality, with residence in Chile since 1994, with studies at the Complutense University of Madrid. He worked at the School of Mining Engineers of Madrid for 10 years as deputy manager of Technological Development. In Chile he worked at Fundación Chile and later at SONDA S.A. as a senior data capture consultant for 9 years.

At GS1 Chile since 2006, he has been a consultant in international standards and since 2008 he has been a certified traceability auditor and subsequently he was certified in Milan as a global traceability audit trainer. He specialises in the design and implementation of technological solutions in data capture, logistics optimization and traceability based on global standards. He is head of the regional healthcare group for Latin America, Professor in Logistics Diplomas at the University of Santiago de Chile and a national and international speaker on new technologies, data capture and traceability.

About the organisation

The Central Supply of the National System of Health Services (CENABAST), is a public, decentralised institution under the Ministry of Health, whose mission is "to contribute to the welfare of the population, ensuring the availability of medicines, food, supplies and equipment to the Health Network, through the management of a service of excellence, efficient and quality supply, to improve the health of all the people who live in Chile". https://www.cenabast.cl/en/main-page



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 100 leading healthcare organisations worldwide.

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