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Global identifiers for enhancing efficiency and patient safety

A collaborative work between the International Hospital
Federation and GS1

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Global identifiers for enhancing efficiency and patient safety

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This volume of the World Hospitals and Health Services (WHHS) Journal focuses on how global identifiers (barcoding) can support the monitoring of safe healthcare and improve efficiency while reducing waste.

Healthcare automation and digitization offers the opportunity of improving patient safety and efficiency, even if at the same time there are still some challenges that need to be solved. Making sure patients are diagnosed correctly and that they will receive the right treatment at the right time is always an essential concern for healthcare workers. Care is intended to do good to the patients and not to bring them harm. However, there are countless examples of identification errors that have caused harmful effects in patients. A recent, dramatic example involves a doctor that performed brain surgery on the wrong patient.

The use of the automatic identification and data carriers (AIDC) technology, like barcode scanning, proves to be a great enabler of patient safety. Although many countries and hospitals now use barcodes, there is a need for a global system that goes beyond the borders of a department, hospital or country. This technology also offers the opportunity for improvements in efficiency and combating fraud, such as in the stocking of drugs in pharmacies and identification of drugs or devices that are not counterfeit.

Automation and the implementation of barcoding standards in a healthcare environment requires vision and training. This issue of the Journal highlights diverse examples from several countries in which barcode scanning using a global AIDC-system is implemented for patient safety purposes as well as for efficiency and a better healthcare supply chain.

IHF has developed a survey to better understand the use of global identifiers in healthcare organizations around the world; the results reported in this issue underscore that there is a lot of room for further use of global identifiers to enhance the safety and efficiency of health services to patients.

GS1 is a non-profit organization that develops and maintains global standards for business communication. Several of the articles in this issue highlight how GS1 standards and identifiers have capabilities for full interoperability across hospitals, healthcare supply chains and even country borders.

In several countries, AIDC use regulations act as drivers to combat falsified medicines, improve recalls and reduce reimbursement fraud. Manufacturers and suppliers comply with these regulations. Products that are identified by the manufacturer and can be monitored along the supply chain improve patient safety and increase health system efficiency.

As explained by several authors, one of the most critical steps toward patient safety is correct patient identification. Apollo Hospitals Group, from India, describes the results of a long-term implementation, including barcode-scanning and an appropriate mix of culture change in the form of 'Our Patient, Our Responsibility.' New IT developments in Canberra Hospital, Australia, support safer processes to ensure positive patient identification by using identifiers as building blocks. This has led to more than 40 percent reduction in wrong-blood-in-tube incidents based on clinicians scanning barcodes when collecting pathology samples. In Danish hospitals, the focus has been on full traceability of staff and assets, also using global location identifiers. In Brazilian, Colombian and Dutch hospitals, the primary focus has been on closed loop medication administration safety with barcode assisted bedside scanning. In Japan, the Fukui Hospital Surgical Center created an integrated sterilization management system for traceability and patient safety using the global AIDC system, also leading to efficiency gains in the deployment of nurses. The case study from the US describes how collaboration and the introduction of global identification standards brought increased patient safety in operating rooms. In the UK, the National Health Service (NHS) applying standards to people, products and places, helped quantifying the costs and benefits across the organizations. Learnings from each trust have provided a wealth of knowledge to help future NHS implementations.

All these cases show that staff hours can be gained, errors reduced, and the work environment made more sustainable.

The International Hospital Federation is committed to helping its members improve patient safety and efficiency in health care delivery. AIDC global standards make a significant contribution to this effort.

Results from the survey conducted among IHF members

The survey on the use of identifiers received 28 responses, providing information on the awareness of hospital workers and professionals from healthcare organizations with regard to the benefits of identifier technology and also an idea of its implementation level by hospitals.

The distribution of responses according to hospital categories is as follow: 44% are general hospitals, 36% are specialized healthcare providers and 20% are university hospitals, given that one response could combine several hospital types. 58% of the respondents work in the private sector, 21% in the public sector and the rest are from a combination of public and private sector.

70% of the respondents indicated having implemented identifiers in their facilities. Medical devices is the type of item for which proprietary identifiers are used the most; 29% of the respondents use them for this purpose. Compared to the other items, the highest score for international identifiers belongs to pharmaceuticals with 15%.

Pharmaceuticals, patients and staff are the three items for which identifiers are used the most (respectively, 58%, 56% and 53% of respondents indicated full coverage), while linen and physical location come first when considering items for which there is no plan to use identifiers, with respectively 39% and 29% of responses.

A question listed the factors preventing the adoption of identifiers. 74% of the respondents said that cost was a major factor, while the absence of interoperability of information systems hinders half of the respondents.

As for guiding the adoption of identifiers, 63% of the respondents consider costs and 55% the dissemination level to be major factors. Regulatory requirements come third with 37% of responses.

Looking at the benefits deriving from using identifiers, the most important are overall patient safety (for 90% of respondents), physical tracking (80%) and the optimization of the supply chain, tied at third place with the provision of an integrated information system (75%). Increasing staff responsibility is not considered as much of a benefit as the other factors ("major factor" represents 55% of responses), nor is reducing their costs (60%).

To complete the survey, Dr. Oscar A. Miguel, Dr. Enrique Tonelli, CA Enrique Cimino and Dr. Juan Carlos Linares wrote an article on the use of identifiers in Argentina. They reported that this country is in the process of implementing identifier technology for pharmaceuticals, healthcare workforce, patients and medical supplies at the primary level. The adoption of identifiers for pharmaceuticals is supported by the current legislation and also by the benefits brought across the supply chain in terms of traceability and communication with other stakeholders. They also noticed, in accordance with the IHF survey, that this technology is better implemented in university hospitals and specialized healthcare facilities.

The survey was a preliminary work with the purpose to form an idea about the level of adoption of identifiers in healthcare facilities around the world. This work was developed further by looking for cases that would show the benefits of using identifiers. The above led to the preparation of this journal issue, whose topic is traceability and barcoding.

Decreasing medication errors through bedside barcode scanning (BCMA): our patients deserve the additional safety barrier

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ABSTRACT: Administration is one the most error prone steps of inpatient medication use. Barcoded medication administration is used at most US hospitals, but limited in European hospitals. This is unfortunate, as this technology can decrease medication administration errors by 50%. To achieve the full benefit of this technology, BCMA requires the continuous monitoring of appropriate use and analysis of alert data.
Our approach is based on two pillars: making sure end users can seamlessly use the technology and that they will use it appropriately.

Introduction

St Jansdal Hospital, Harderwijk, is a 340-bed community hospital in the centre of The Netherlands with 17,350 clinical admissions, 85,000 first outpatient visits and 300,000 subsequent outpatient visits annually. The hospital's vision is to provide safe, effective and efficient care by fully harnessing the power of information technology. In November 2017, St Jansdal Hospital, Harderwijk was only the 4th hospital in Europe to be granted the HIMSS Electronic Medical Record Adoption Model (EMRAM) Stage 7 award. Stage 7 is the highest level of the EMRAM model and is a certificate of excellence for the effective adoption and widespread use of the Electronic Medical Record (EMR).[1]

A closed loop medication system is an essential part of the EMR. **Figure 1** illustrates the typical inpatient use of medication and summarizes how we optimize this cycle by applying the EMR. In this article, we focus on barcoded medication administration (BCMA).

The challenge

Administration is one the most error prone steps of inpatient medication use. In 8 out of every 100 cases, medication is not administered to the right patient in the right form, dose or route.[2] Barcoded medication administration (BCMA) is a mature technology and standard of care in hospitals in the United States. Already by 2013, almost 75% of all US hospitals had adopted this technology and an additional 17% were planning to implement it within the next 3 years.[3] Multiple studies have shown that, when implemented correctly, medication administration errors decrease by 50%.[4] A recent study by the Dutch Ministry of Health concluded that 47 deaths could be prevented annually in the Netherlands

alone if this technology was universally adopted.[5] However, another recent study showed that the full effect of BCMA on medication error reduction is often not achieved due to the emergence of many workarounds.[6] The authors conclude that BCMA needs more post-implementation evaluation.

We describe pre- and post-implementation strategies resulting in high barcode scanning compliance rates. In addition, we implemented a continuous quality improvement cycle to detect and fix workarounds so we can fully harness the medication error reduction potential of this technology (Fig. 2).

Our approach

We focused on two key aspects:

1. *Making it easy to do it right*. Keep the objective in mind, only implement the technology when it is relevant and feasible:

   a. Don't scan everything! We created an institution-wide BCMA policy describing where and what to scan. We only scan those administrations that present relevant patient safety risks due to the systemic effects of the medication. Therefore, we do not require barcode scanning of topical, ear, eye, nose and local administrations.

   b. Make full use of the electronic Medication Administration Record (eMAR). Highlight medication orders that do not require scanning on the eMAR, so nurses know which orders require scanning and which orders may be scanned.

   c. If barcode scanning is required, make sure the items in question are barcoded from the start of the project.
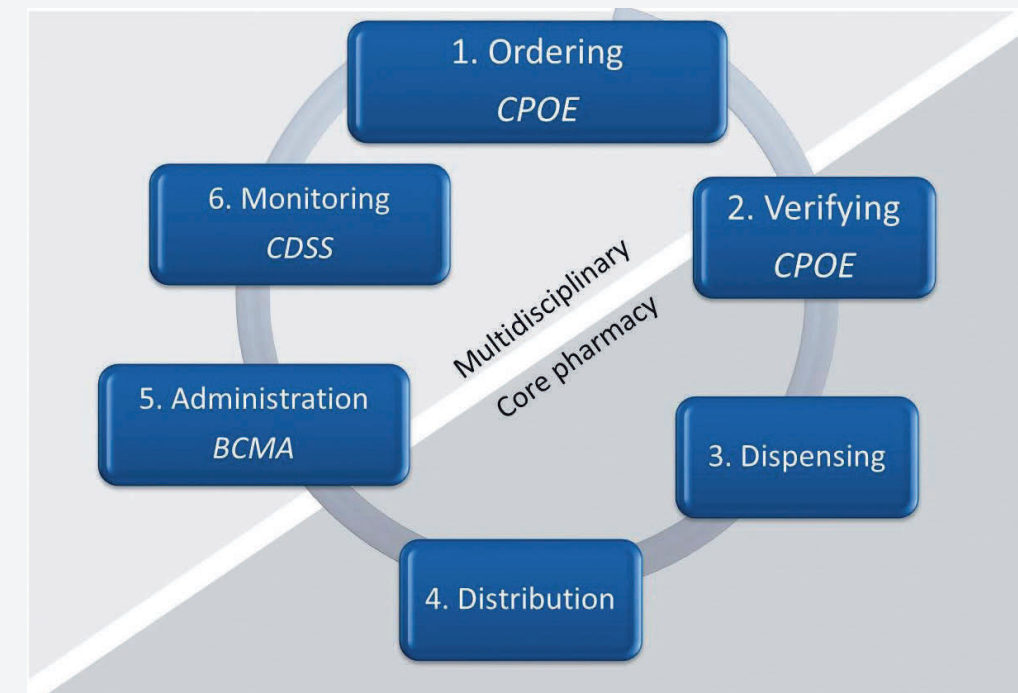
Source: HIMSS Guidance document: "Costs, Benefits and Potential Unintended Consequences of Automating the Pharmacy Medication Cycle in Acute-Care Settings" 2010.

Available from: https://www.himss.org/system/files/Downloads/PharmacyGuidanceDocumentAcuteCareSetting.pdf

CPOE: Computerized Provider Order Entry
BCMA: Barcoded Medication Administration
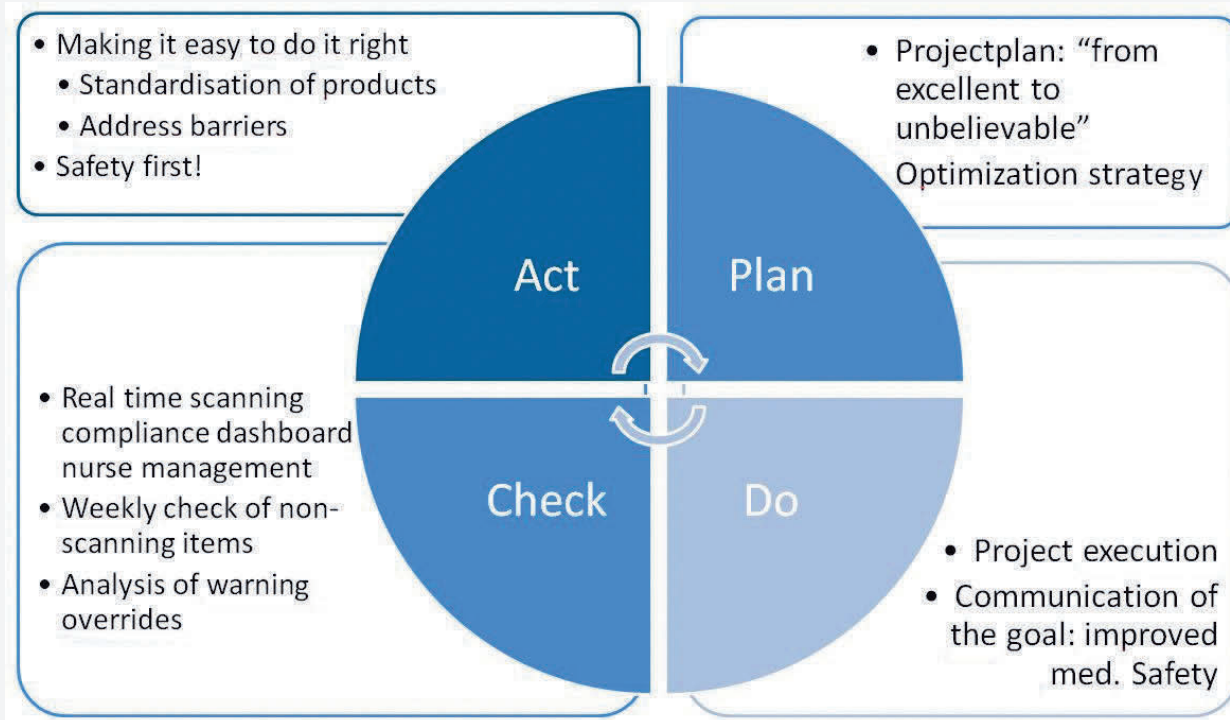CDSS: Clinical Decision Support System

We used a mobile printer/scanner combination which allowed us to barcode medication stock on the floors and in our Automated Dispensing Cabinets prior to go-live.

4. Create custom barcodes for the primary package (individual tablet/capsule) based on the secondary package. These barcodes are already loaded onto our EMR through our national G-Standard medication loading system, which eliminates the need for the custom "mapping" of barcodes.

2. *Safety first, so adhere to our policies and procedures!* Our institutional BCMA policy is the basis of our BCMA implementation. We created a nurse manager BCMA compliance dashboard which shows daily BCMA compliance for each ward. The dashboard also has a preformatted pivot table which ranks nurses by lowest to highest BCMA compliance and is used by managers to provide direct feedback to their nurses. Last, we use the dashboard to provide feedback to the user when relevant alerts have been ignored.

Our results

1. We achieved 95% patient identification and 90% scanning compliance at go-live (12% higher than other BCMA adopters using the same EMR in the Netherlands).

2. Continuous post-implementation feedback increased medication scanning compliance by an additional 6% to 96%.

3. BCMA prevented 654 medication administration errors in 50,254 administrations during the first month after going live.

4. Continuous focus on nursing workflow resulted in a reduction of the number of alerts/10.000 administrations by 16%, from 403/10.000 administrations at go-live to 340/10.000 administrations in September 2017.

5. Continuous data monitoring showed 42 overrides of relevant alerts in one month and highlighted several workarounds and system errors (Tab. 1).

6. Nursing staff appreciate the continuous feedback and the focus on the goal of BCMA (e.g. zero BCMA preventable medication errors).

FIGURE 2: BCMA SCANNING COMPLIANCE OPTIMIZATION

- Making it easy to do it right
- Standardisation of products
- Address barriers
- Safety first!

- Projectplan: "from excellent to unbelievable" Optimization strategy

Act

Plan

Check

Do

- Real time scanning compliance dashboard nurse management
- Weekly check of non-scanning items
- Analysis of warning overrides

- Project execution
- Communication of the goal: improved med. Safety

Source: St Jansdal Hospital. Scanning Optimization Quality Improvement Process

TABLE 1. MOST FREQUENTLY OCCURRING SCANNING ISSUES AND WORKAROUNDS

Type	Issue	Cause	Fix
Workaround	A duplicate print of patient wristband is scanned instead of the actual band worn by the patient.	Easier Didn't want to wake the patient	Periodic audits and direct feedback to nurse and nurse manager: a patient sleeping is not a valid reason for deviating from a safety measure
System issue	Medication scanning compliance is low at night and high during daylight	Scanner laser light is bright and always on	Setting on scanner: fixed.
System issue	Multiple "barcode does not scan" alerts for products that normally scan perfectly	Caps Lock key on keyboard is on: barcode is case sensitive	Setting on scanner to ignore Caps Lock on keyboard: fixed.
System issue	Patient has order for combination product, ingredients are given separately	Formulary constraints	Addition of most frequently occurring items to the formulary and EMR pop-up to change order to individual ingredients at admission

Source: St Jansdal Hospital Electronic Medical Record Source Data.

Lessons learnt

1. You have only one chance to make a first impression: use a mobile scanner-printer solution to quickly barcode ALL your floor stock so almost everything scans upon go-live.
2. BCMA implementation does not stop at go-live, it requires continuous focus on medication administration safety.
3. Create a preformatted dashboard which can be easily accessed by nurse managers and team leaders.
4. Use the dashboard to make it even easier to do it right: the EMR is a great source for finding and addressing workarounds and non-adherence cases.
5. Praise your nurses, they deserve it! The do the hard work, so keep focusing on supporting nursing workflow.
6. Scan relevant medications ONLY!

Conclusions

Barcode scanning at the bedside is a mature technology and has the potential of decreasing the number of medication administration errors by 50%. This article outlines our efforts to correctly implement this technology and continuously monitor its use.

However, the biggest drawback for institutions against adopting this technology is the lack of a barcode on the primary unit of dispense (e.g. the individually packaged tablet) in about 20% of the products found in the hospital pharmacy. Based on the secondary barcode (the one on the outer box), our hospital pharmacy manually affixes barcode labels to each individual tablet, ampoule etc. that does not contain a barcode, which is labour intensive. In addition, the barcodes of 80% of barcoded medications are not standardized, they are sometimes poorly readable and need to be manually linked to the right product in the EMR ("mapping"). Indeed, barcode scanning technology can be implemented more rapidly and effectively if two conditions are met:

1. A standardized barcode is part of the labelling of every primary package; the GS1 standard is a great example of how standardization leads to further efficiency gains. This barcode standard also includes a lot number and expiration date, making inventory control and expiration date checking possible with a single scan.
2. The barcode data of the primary package is part of the EMR's drug information database update that is already performed monthly.

Even with the aforementioned drawback, we have demonstrated that barcode scanning can already be implemented effectively and efficiently. Let's not wait any longer and prevent patient harm by introducing an additional electronic barrier between medication errors and our patients. They deserve it!

Biography

Pieter Helmons, Ph.D, MAS

From 2007-2011 Pieter Helmons was the Pharmacoeconomics Specialist at UCSD Medical Center in San Diego, California. Since 2011, Pieter Helmons works as a hospital pharmacist at St Jansdal Hospital Harderwijk, The Netherlands. He obtained his PhD in Pharmacy Informatics in 2014 and is recently appointed as the Chief Pharmacy Informatics Officer (CPIO).

References

1. EMRAM: A strategic roadmap for effective EMR adoption and usage. https://www.himss.eu/healthcare-providers/emram. Date accessed: June 18th, 2018

2. Hassink J, Jansen M and Helmons, P. 2012. Effects of bar-code assisted medication administration (BCMA) on frequency, type and severity of medication administration errors: a review of the literature. *European Journal of Hospital Pharmacy. Science amd Practice* 19:489-494

3. Fox B, Pedersen C, and Gumpper K. 2015. Am J Health-Syst Pharm. ASHP national survey on informatics: Assessment of the adoption and use of pharmacy informatics in U.S. hospitals—2013. *American Journal of Health System Pharmacy*; 72:636-55

4. Helmons P, Wargel L, Daniels C. 2009. Impact of bar-coded medication administration (BCMA) on medication administration errors and accuracy in multiple patient care areas: a before-and-after study. *American Journal of Health System Pharmacy* 66(13): 1202-1210

5. Barcodes on the primary package of medication in the hospital: a return-on-investment analysis (2016, Dutch). Dutch Ministry of Health. Available from: https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/rapporten/2016/11/07/barcodering-op-de-primaire-verpakking-van-geneesmiddelen-in-ziekenhuizen/barcodering-op-de-primaire-verpakking-van-geneesmiddelen-in-ziekenhuizen.pdf

6. Van der Veen W, Van den Bemt P, Wouters H, Bates D, Twisk J, De Gier J, Taxis K for the BCMA Study Group 2018. Association between workarounds and medication administration errors in bar-code-assisted medication administration in hospitals, *Journal of the American Medical Informatics Association* 25 (4):385-392

From the simple scan of a barcode to a complete patient safety strategy

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ABSTRACT: Centro Médico Imbanaco de Cali (Imbanaco) uses GS1 standards to simplify and automate its clinical processes for increased efficiencies and enhanced patient safety. The hospital has launched several initiatives focused on ensuring the traceability of medicines, medical devices and other supplies to enhance patient safety and reduce errors. Based on automated ordering processes, Imbanaco has experienced a 98 percent improvement in inventory shrinkage and waste, in addition to a 25 percent reduction in inventory levels at its satellite pharmacies. Furthermore, the time needed to create a patient invoice has been reduced from nearly an hour to only 18 minutes.

About Colombia's leading hospital

Imbanaco is a private hospital located in Cali, Colombia. Its more than 2,500 physicians, nurses and other administrative and healthcare staff service approximately 1.5 million patients each year. In July 2017, Imbanaco received the Gold Seal of Approval® accreditation from the Joint Commission International as the fifth Colombian hospital to achieve all the quality standards required by the JCI committee.

One of Imbanaco's primary goals is to continuously evaluate and adopt innovative technologies and practices so as to ensure a high level of care and safety for its patients.

For more than a decade

As early as 2007, Imbanaco started implementing GS1 standards to efficiently identify and capture information about all products, such as pharmaceuticals and medical supplies. The same standards were also used as part of invoicing and inventory control activities in the main distribution center and pharmacies. Prior to this, the hospital used paper-based activities and information was processed manually.

In that same year, Imbanaco led the way to the adoption of the GS1 DataMatrix barcode—a two-dimensional (2D) barcode capable of holding large amounts of data in a very small footprint. This new barcode enabled Imbanaco to automate

the identification of the medical devices, pharmaceuticals and medical supplies used in patient care. The size of the GS1 DataMatrix has enabled the hospital to include the management and control of drug blisters, bottles, vials and syringes, as well as other small devices.

In 2010, Imbanaco's Board of Directors recognized the clear benefits of using GS1 standards, resulting in granting their financial support to extend the use of standards to internal processes like medication administration, pharmacovigilance and inventory management for patient safety and improved efficiencies.

In 2010, Imbanaco started the construction of a new, much larger facility. Its challenge was to expand the care and treatment areas by 300 percent with only a 15 percent increase in operational costs for nurses and staff and other administrative costs. As part of the expansion, there were new technologies like automated dispensing cabinets (ADCs), supply carrousels, traceability solutions for surgical instruments (tray and surgical devices), RFID proximity access control systems and connectivity solutions for medical device data integration—all of them designed to help the hospital gain efficiencies.

Migration to traceability

In 2014, Imbanaco commenced its multi-phase project to migrate its processes, products, systems and people to a

FIGURE 1: 10-YEAR TREND OF PRODUCT CONSUMPTION AND SCANNING
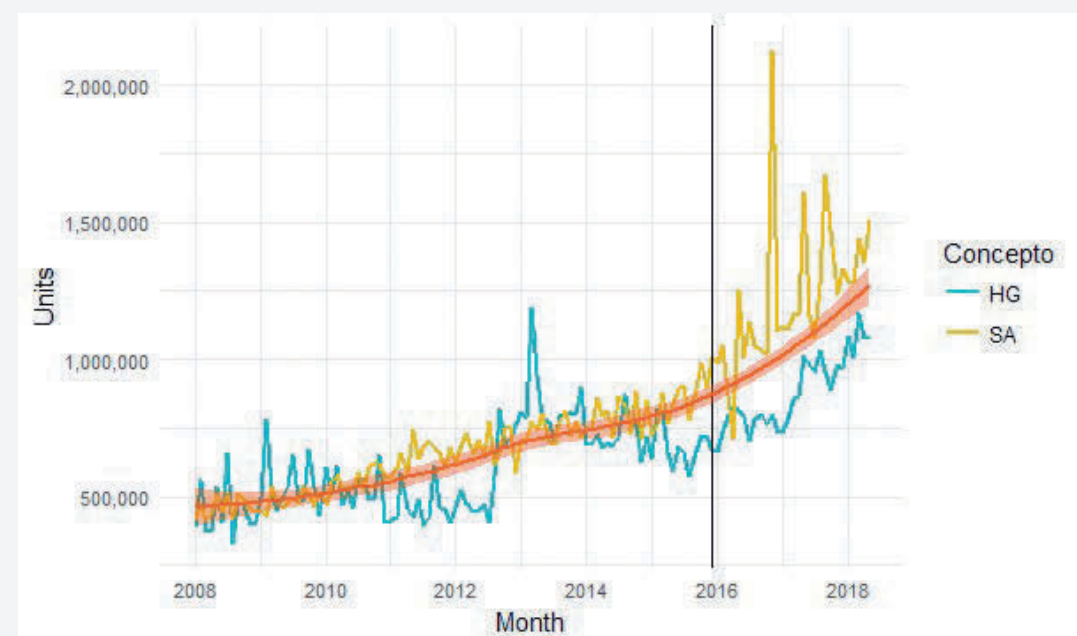
Source: Centro Médico Imbanaco
HG: Charged to patient; SA: Charged to the floor; Black vertical line: Milestone date of new facility opening (Dec. 2015)

traceability system using GS1 standards. To do this, the project required the following actions:

- Generating GS1 identifiers to update the master data catalogue
- Using GS1 standards to uniquely identify single-dose medicines, medical devices, trays, surgical instruments and supplies, including ADCs
- Training more than 350 nurses and physicians on the new GS1 barcodes
- Preparing all IT systems to handle the new GS1 standards-based system

Laying the GS1 identification foundation

Only about 4 percent of medicines and medical supplies received into Imbanaco's central warehouse are uniquely identified with a GS1 Global Trade Item Number® (GTIN®[1]), along with a serial number, batch/lot number and expiration date. This data is encoded in a GS1 DataMatrix barcode that is then applied to a single dose of medicine, medical device or medical supply.

As for products without a GS1 identification, Imbanaco re-labels each of them with the same data provided by the suppliers (GTIN, serial number, batch/lot number and expiration date) encoded in GS1 DataMatrix barcodes to fulfil its commitment to patient safety.

Today, more than 7,500 barcode labels are printed and applied daily to medicines and medical supplies in Imbanaco's warehouse before being delivered to each department. This represents more than 96 percent of the products used by the

1 The GTIN ® is a trademark registered of GS1 AISBL

hospital. At the same time, all trays and surgical instruments without unique identifiers are marked by Imbanaco's provider using direct marking technology, which assigns an internal device identification number in a 0.25 mm DataMatrix barcode.

For Imbanaco to achieve full traceability, this level of identification (and investment) is critical. Only with this identification system in place can Imbanaco track products as they are used throughout the hospital and with patients, as well as trace their origins back to each supplier.

Automated inventory management

Once pharmaceuticals, medical devices and supplies have been individually identified with DataMatrix barcodes, they are stored in one of two automated carousels or a fixed storage

BOX 1: UPDATING THE MASTER DATA CATALOGUE WITH GTINS

Prior to the traceability project, the vast majority—about 96 percent of nearly 22,000 products—did not have unique identifiers (GTINs) assigned to them and were not part of the hospital's master data catalog.

While Imbanaco could have requested that its suppliers provide and update this information, it decided instead to move forward, generating the GTINs internally so that GS1 barcodes could be created and applied to all single-dose medicines, medical devices, supplies and other items.

Source: Centro Médico Imbanaco

FIGURE 2: QUANTITY OF DATAMATRIX BARCODES APPLIED BY IMBANACO ON SINGLE MEDICINE DOSES
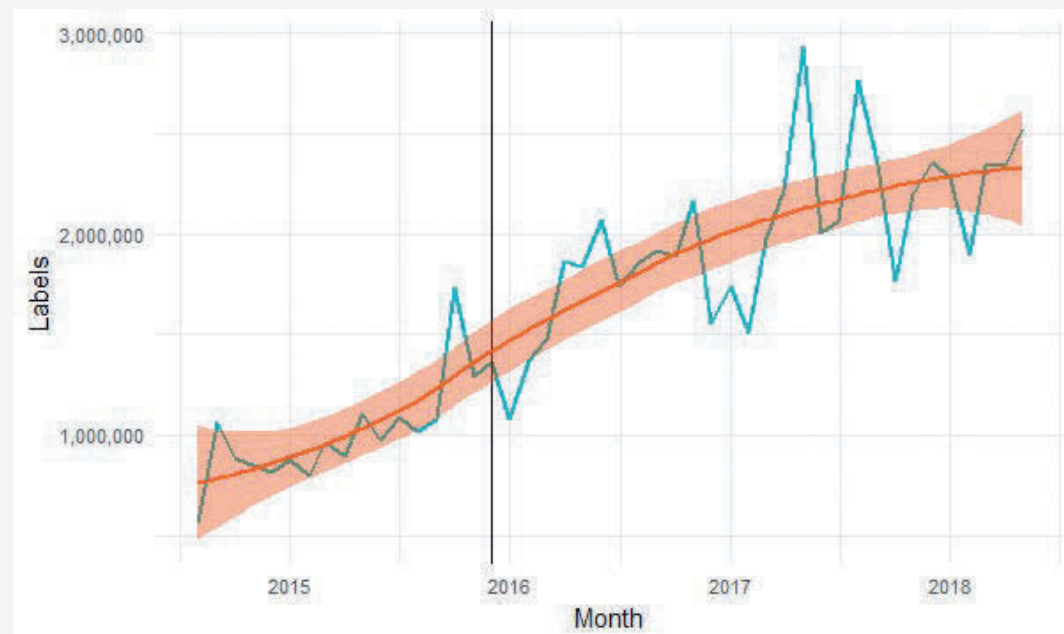
Source: Centro Médico Imbanaco.
HG: Charged to patient; SA: Charged to the floor.
The vertical black line represents the milestone of the new facility's opening date (Dec. 2015).

FIGURE 3: SUMMARY OF DISPOSED EXPIRED MEDICINES

Source: Centro Médico Imbanaco

structure, each of them also individually identified with GS1 standards and barcodes.

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

As medicines and medical devices are distributed and administered to or used by patients, their barcodes are scanned at each point of service to track their location and progress throughout the care process. This information is automatically integrated into the hospital's information system so that Imbanaco always has near real-time information and visibility into inventory levels and can charge the appropriate costs to patients' accounts.

The inventories are automatically replenished when they reach pre-determined levels. Imbanaco has automated the monitoring and management of its inventory so that patient care is not compromised. The hospital's goal is to make inventory always available to minimize patient care delays or even eliminate them. Requests for additional products are generated automatically and, if necessary, purchase orders for suppliers are generated as well.

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

Elimination of expired medicines and their disposal

In 2009, Imbanaco started checking the medication expiration date during the bedside scanning of the product's barcode. During 2009 and 2010, a new feature was implemented to closely monitor the expiration of pharmaceuticals and their disposal.

During 2010 and 2011, an inspection process was performed using barcode scanning to remove all expired medicines from all available stock (e.g., crash cars, bags, emergency boxes and shelters). In 2015, the warehouse management system was implemented; no medicines expired during that year nor in 2017, therefore, no disposals were recorded.

Reducing medication errors

At the same time that product information is recorded in the inventory system, it is also recorded in patients' electronic health records and in Imbanaco's billing system for invoicing.

When admitted to Imbanaco, each patient is presented with an identification wristband that has his or her own unique identification number encoded in a GS1 barcode. As for neonatal patients, a printed stamp with the same information is applied on the back.

As medications are administered to patients, the GS1 barcode on the single dosage is scanned together with the barcodes on the patient's wristband. In the near future, the hospital plans the capability to scan the caregiver's badge that contains his or her identification to complement record-enhancing traceability. As a result of bedside scanning, medication errors have been reduced significantly.
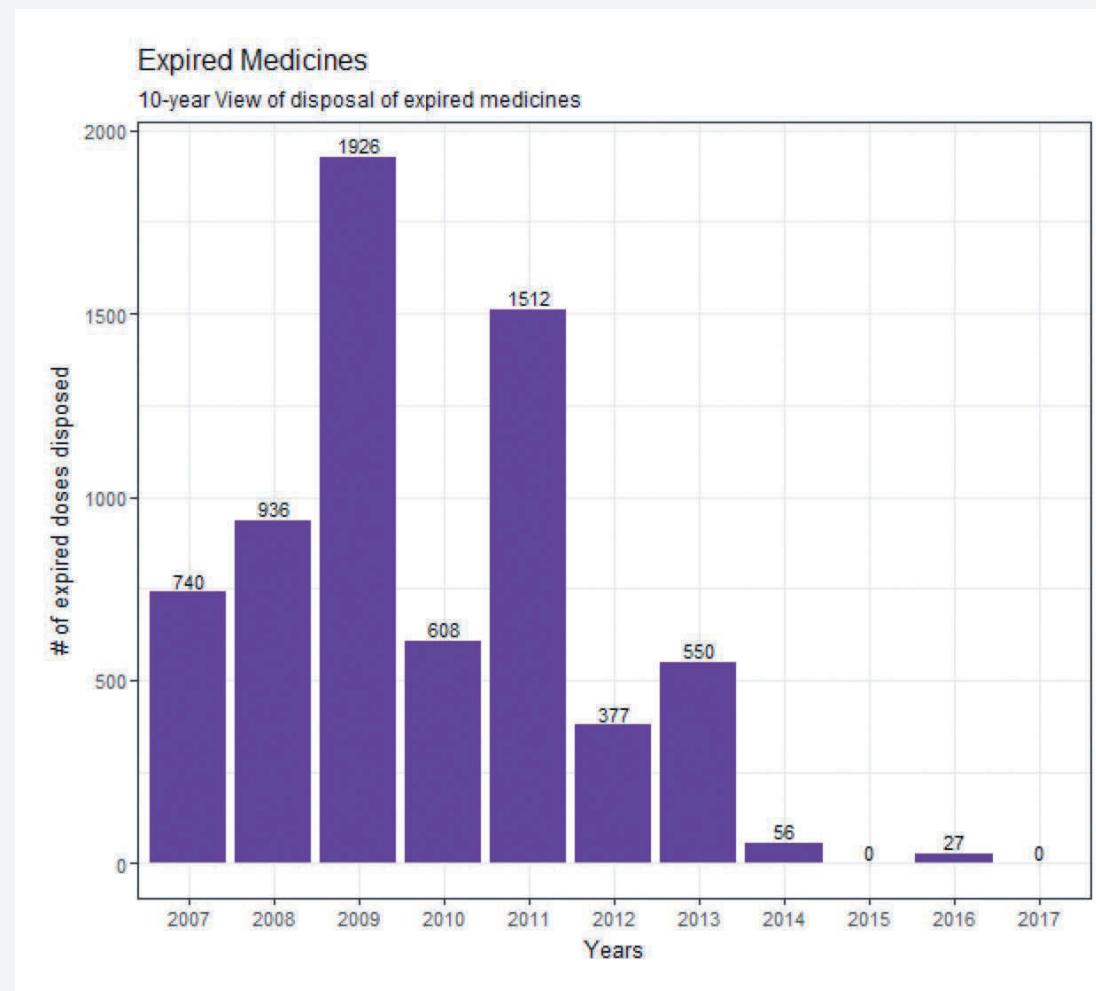
In preparation for the next step in safe medication administration, all prescriptions will include a GS1 barcode integrated with ADCs to control dispensing quantities at administration time.

Automating the issuance of invoices

As a healthcare provider in Colombia, Imbanaco is required to issue an invoice to each patient *before* leaving the hospital. Therefore, when it comes to patient discharge, speed, accuracy and consistency of billing services are all necessities.

To do this, the hospital efficiently captures all relevant care costs for improved billing and accounts receivable. During hospitalization, the patient's GS1 barcode identification allows Imbanaco to instantly access the record of the prescription drugs administered to the patient and the procedures performed and then compile all charges for billing purposes upon discharge.

The accuracy of charges to a patient account during their treatment or hospital stay has increased by 90 percent. Data accuracy has also reduced the time needed to create an invoice.

By automating administrative processes like billing, Imbanaco is able to achieve the following:
- Reduce the time needed to calculate stock and replenishment levels
- Reduce documentation time
- Increase data entry accuracy
- Increase the time spent with patients
- Reduce patients' waiting time for procedures, results from procedures and the final invoice when discharged from the hospital

GS1 identification in operating theaters
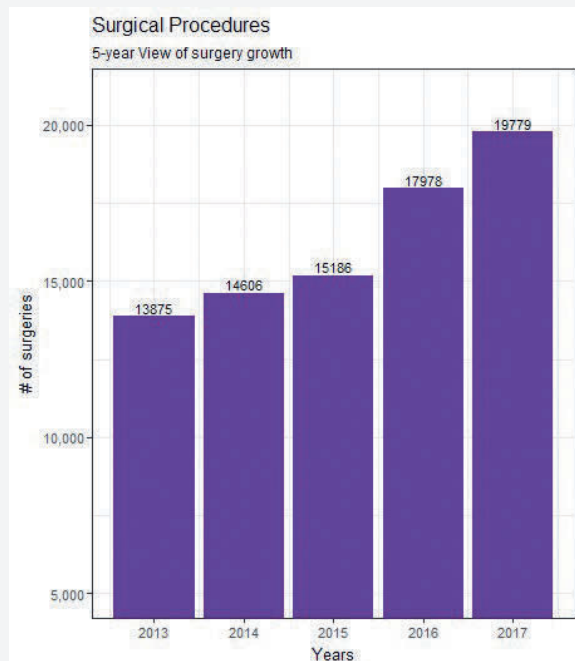
In order to maintain the highest infection control standards, Imbanaco has optimized the flow of sterile processing of surgical instruments and non-implantable materials at its sterilization center.

To achieve this in the complex framework of a sterilization center, traceability is essential. Previously, Imbanaco had tried to track each instrument manually, which was labor intensive

and not very effective. Now, the hospital has announced the implementation of an automated traceability system based on the efficient use of a Unique Device Identifier (UDI) for each instrument by 2H 2018.

This will enable Imbanaco to locate each instrument in its traceability system efficiently and accurately, including on which day and by whom it was used, what class of procedure was performed and on which patient. Since each instrument is uniquely identified, Imbanaco can also trace and evaluate the quality of materials and number of times used compared to the standards set by the manufacturer, as well as use big data to set better controls and enable more effective decisions about its instruments.

FIGURE 5: SUMMARY BREAKDOWN OF TIME SPENT BY NURSES

Activities	2007	2010	2014	2017
Documentation	50%	65%	75%	50%
Clinical	20%	20%	15%	30%
Communication	20%	10%	5%	15%
Other	10%	5%	5%	5%

Source: Centro Médico Imbanaco

Conclusion

Imbanaco is currently collaborating with pharmaceutical and medical device manufacturers and other suppliers to use GS1 standards for the identification of their products *prior* to shipment and arrival at Imbanaco's warehouse. As more and more of its suppliers use GS1 standards, Imbanaco will be able to save on time and costs and gain further efficiencies in its operations.

Another current effort involves entering standardized patient identification in support of patient transfer processes to help with the electronic exchange of clinical history records and the reception of patients outside of Colombia.

Additional initiatives include implementing traceability of sterile implants and using UDI (GS1 standards) in procurement and sourcing processes. Imbanaco is also collaborating with other local hospitals to create a medications data pool for information sharing purposes.

FIGURE 4: SUMMARY OF SURGERY PROCEDURES

Source: Centro Médico Imbanaco

Imbanaco is implementing two strategies to ensure instrument traceability using standards. For future acquisitions, the hospital has requested that suppliers provide instruments with direct UDI markings. One of the hospital's suppliers already marks its surgical instruments with GS1 unique identifiers. For now, the hospital has decided to move forward, generating an internal identification code to mark trays and surgical instruments. More than 35,000 individual trays and instruments have been marked this way.

Training nurses and physicians

In a busy working environment, mistakes are inevitable. By using GS1 identification and scanning strategies for medications, patients and locations, Imbanaco has achieved the reduction of inevitable errors.

Every three years, Imbanaco measures nurses' activities based on four major categories. Starting in 2017, there has been an increase in the time spent by nurses with patients, reaching 30 percent spent on clinical activities.

Biographies

José Luis Sabogal is the Chief Information Officer at Centro Médico Imbanaco de Cali. He has actively promoted technological innovation that started with the development of the homegrown version of the SIAM ERP, making Centro Médico Imbanaco de Cali a key leader for the implementation of cutting-edge medical technologies in the region. His vision of the future has positioned him as a leader of committees such as the GS1 Advisory Board.

Andrés Rodríguez is the Chief Operations Officer at Centro Médico Imbanaco de Cali. He is a supply chain professional with 24 years of experience leading and managing advanced logistics and operations for several worldwide renowned companies in the Colombian market. Andrés is a business administrator with post-graduate studies in Supply Chain, Integrated Logistics, Marketing and Finance.

Juan Camilo Rincon is a former Project Manager Coordinator for Centro Médico Imbanaco de Cali. He has participated in the implementation of key technological innovations for logistics and patient safety, acting as the link between suppliers and vendors and Imbanaco's IT, Biomedical Engineering, Procurement and Clinical and Medical Coordination Departments.

Brazil's Hospital Israelita Albert Einstein makes significant progress toward the full traceability of pharmaceuticals

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ABSTRACT: Hospital Israelita Albert Einstein (HIAE) is using GS1 standards to enable the traceability of all medicines with the goal of improved patient care and safety. HIAE has partnered with suppliers and worked internally to ensure all single-dosage medicines are assigned a unique identifier in a GS1 barcode including batch/lot number and expiration date. With GS1 standards, the hospital can scan the medicines' barcodes as they travel from receipt to patient bedsides and HIAE's surgical center, completing an end-to-end traceability system. More than 240,000 units are labeled at suppliers' sites each month, saving HIAE over 600 hours and R$13,620 in labor costs monthly.

The need: Improved patient care

The Hospital Israelita Albert Einstein is an integrated healthcare system located in São Paulo, Brazil, with more than 13,000 employees, including over 1,200 physicians. In 1999, HIAE became the world's first hospital to receive Joint Commission International (JCI) accreditation. In 2018, HIAE became the first JCI-accredited hospital to receive the seventh consecutive re-accreditation certificate. The hospital provides healthcare services that span the spectrum: promotion, prevention, diagnosis, treatment and rehabilitation.

With a commitment to patient care, HIAE set out to develop an internal system that would allow the tracking of medicines as they were delivered from suppliers to the hospital and their administration at patient bedsides. The hospital's vision was to create an intra-hospital traceability system that would enable the visibility of individual doses of medicines throughout the hospital's receipt, distribution, dispensation and administration processes.

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

To achieve traceability, it was imperative that the barcode would include complete identification: product type, batch/lot number and expiration date. Furthermore, for administration purposes, each dosage needed to be identified and labeled.

The solution: Re-labeling in the pharmacy

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

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

In 2005, at the beginning of the project, HIAE repackaged approximately 80,000 oral solids and re-labeled about

FIGURE 1: RE-LABELED AMPOULES

Source: Hospital Israelita Albert Einstein

250,000 ampoules or vials *per month*, supporting its 460 beds, emergency care and two outpatient units. Today, in 2018, more than 200,000 oral solids and 200,000 ampoules or vials are still re-labeled *per month*, supporting 630 beds, emergency care and seven outpatient units.

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

FIGURE 2: IDENTIFICATION OF ORAL SOLIDS

Source: Hospital Israelita Albert Einstein

However, since drugs could be incorrectly identified, re-labeling has introduced risk into the process. To prevent errors, a post-labeling quality control step needed to be developed and added. All this added up to high costs, mainly related to labor. Finally, HIAE needed to pay special attention to the quality of barcodes, considering that a faded or "smudged" barcode could not be read when scanned, thus compromising the ability to capture data and ensure traceability.

Phase 2 of the solution: Suppliers join in

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

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

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

Today, HIAE requires that all of its suppliers codify their products at the dosage level with the GS1 DataMatrix barcode. Currently, about 70 products are received from suppliers bearing GS1 DataMatrix barcodes, amounting to about 240,000 single-dosage units each month.

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

With medicines labeled at suppliers' manufacturing sources, HIAE is saving more than 600 hours and R$13,620 in associated labor costs every month, as its pharmacy no longer needs to re-label medicines. Furthermore, this minimizes the risk of inaccuracies in the identification process.

FIGURE 3: AMPOULES LABELED WITH GS1 DATAMATRIX BARCODES

Source: Hospital Israelita Albert Einstein

Challenges along the way

The transition to scanning GS1 DataMatrix barcodes has presented its own set of challenges for the hospital. Some suppliers printed different information in the human readable format while others printed barcodes that scanners could not read, such as on black backgrounds.

The hospital was also faced with the challenge of how to "best engage" with its suppliers, initially encouraging and then eventually requiring the application of barcodes. HIAE also had to upgrade the barcode decoding logic in the hospital ERP system in order to capture the correct information from each identifier's AI (application identifier). Its barcode readers had to be reconfigured because of the AI structure in GS1 barcodes. GS1 Brazil provided very helpful guidance throughout the implementation.

FIGURE 4: MEDICINE INFORMATION ENCODED IN GS1 BARCODES
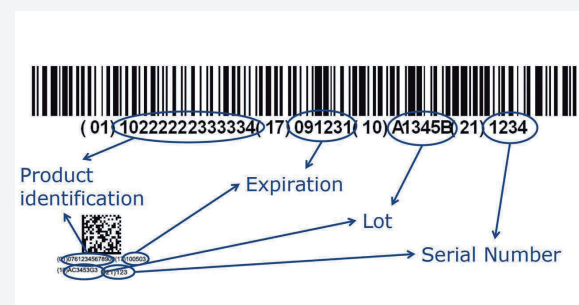
Source: Hospital Israelita Albert Einstein

How the solution works: End-to-end traceability for patient safety

Safer logistics processes were implemented under the direction of the pharmacy—including an electronic ordering system—with barcode scanning each step of the way. The hospital now scans medicine barcodes at the following times:

- **Receipt** – As medicines are received, GS1 DataMatrix barcodes are scanned to register the medicine's type, batch/lot number, expiration date and active ingredients in the hospital's inventory system.
- **Distribution** – The GS1 DataMatrix barcodes are scanned to capture the movement of medicines from the warehouse to the pharmacy.
- **Dispensation** – Whenever a dosage of medicine is scheduled for administration to a patient, the GS1 DataMatrix barcode is scanned as it is dispensed by the pharmacy or at the time of its compounding inside the cleanroom. Compounded medicines are labeled with a unique code generated by the EMR identifying the patient, drug, form, dosage and administration route, as well as with a serial number for traceability purposes. The EMR code is printed in the DataMatrix barcode format for the administration step.

FIGURE 5: EMR UNIQUE CODE ON COMPOUNDED DRUG LABEL
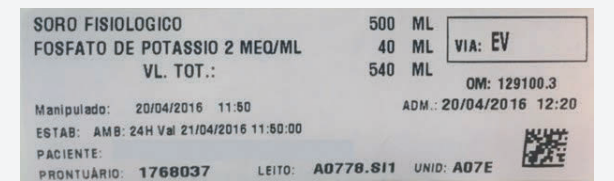
Source: Hospital Israelita Albert Einstein

- Administration – After the caregiver logs into the EMR system, as the dosage of medicine is administered to the patient, its GS1 DataMatrix barcode is scanned along with the patient wristband barcode, registering the type of medicine—drug, dosage and form. The capture of the medication's batch/lot number and expiration date is under development. Drugs that do not carry a GS1 DataMatrix barcode applied by suppliers will carry a customized SAP ERP code, internal product code and batch/lot number in the DataMatrix barcode. This identification is applied in the previously discussed re-labeling processes and the EMR is appropriately configured to identify drug, form and dosage. Pharmacy compounded medicines are also identified by a unique EMR code.

FIGURE 6: TRACEABILITY SYSTEM OF MEDICINES AT HOSPITAL ISRAELITA ALBERT EINSTEIN
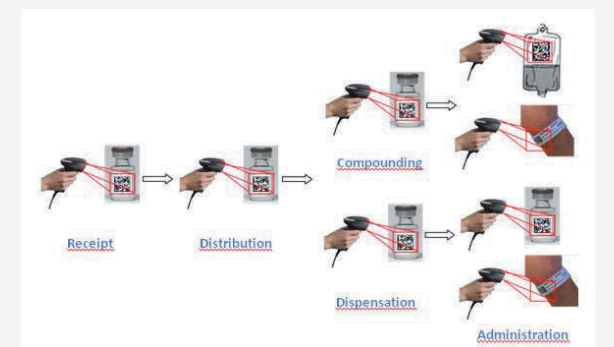
Source: Hospital Israelita Albert Einstein

Further steps: Taking traceability into the OR

The next phase of the traceability project introduced the identification of surgical supplies by means of GS1 DataMatrix barcodes. As products are scanned for use in the OR, the information is captured in the hospital's inventory system as well as the newly implemented electronic medical record system.

Identification information of surgical supplies and products used in the OR for a specific procedure can now be captured for tracking back to the patient's electronic health record.

This new capability has helped HIAE extend traceability to the patient level. The hospital can now analyze and control the materials used for each patient based on their lot information and expiration date.

The results: Focusing on patients

The most important benefit of implementing GS1 standards is patient safety, enabled by medicine traceability up to the final step, when it is administered. One way that HIAE measures the impact of GS1 barcode scanning is by examining the number of errors related to the administration of pharmaceuticals.

HIAE uses a software-based system through which its staff reports the occurrence of errors to the hospital voluntarily and anonymously. HIAE's Risk Management office analyzes the errors reported and, based on its investigations and findings, classifies them according to the National Coordinating Council (NCC) for Medication Error Reporting and Prevention (MERP) Index (Fig. 7).

Figure 8 shows the decline in medication errors based on categories; these errors could have been prevented with adherence to and use of the barcode scanning process.

In 2016, 31 medication administration errors were reported

FIGURE 8: SUMMARY BREAKDOWN OF ADMINISTRATION ERRORS BY CATEGORY

NCC MERP CLASS	2014	2015	2016	2017
B	-	2	1	1
C	45	54	25	2
D	7	4	2	-
E	5	-	2	-
F	-	-	2	-
TOTAL	57	60	31	3

Source: Hospital Israelita Albert Einstein

related to wrong patient, drug or dose. In 2017, only 3 errors were reported, 2 of which classified as C, i.e., clear process violations. If the barcode scanning process had been followed, the violations would have been classified as "B": an error that occurred without reaching the patient.

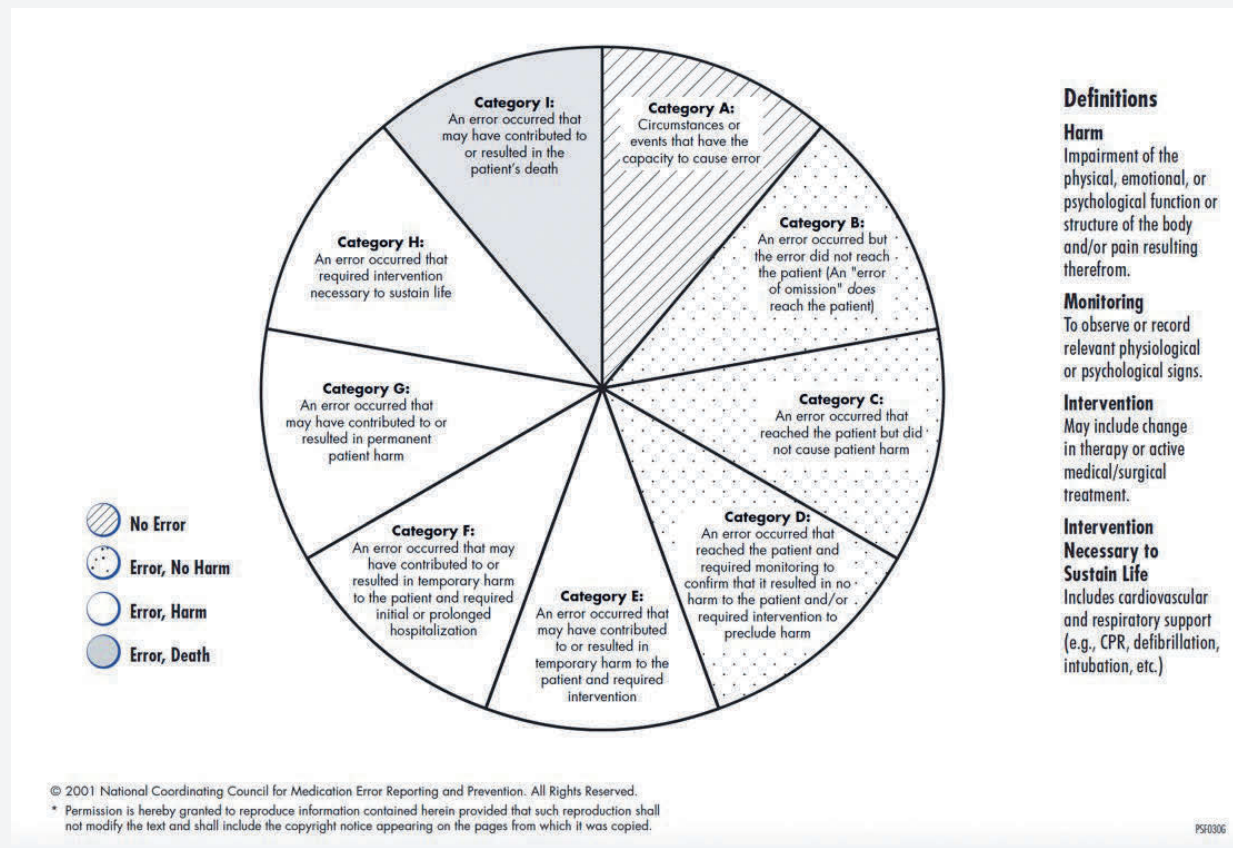The following are positive impacts of traceability with GS1 barcode scanning:

- End-to-end traceability of medicines—inside and outside the hospital—from suppliers' production sites to the hospital's patient bedsides and into the surgical center
- Agility in the dispensation process, with up-to-date online inventory status
- Verification of the medicine dispensed, as ordered
- Confirmation of dispensing drugs that have not expired nor have been recalled
- Ability to quickly locate recalled products and links to the patients they were administered to or used on in a procedure
- Automated bedside check of medication being administered, ensuring control over 7 of 9 administration rights—right patient, drug, dose, time, route, form and documentation
- Essential capability for obtaining quality certifications

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

Biography

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

FIGURE 7: NCC MERP INDEX FOR CATEGORIZING MEDICATION ERRORS

Source: NCC MERP (http://www.nccmerp.org/sites/default/files/indexBW2001-06-12.pdf at http://www.nccmerp.org/types-medication-errors)

References

"Staking Out a Quality Position," video, 1999. Joint Commission International website, www.jointcommissioninternational.org/accreditation/the-jci-difference/

Malcolm Elliott, Yisi Liu; "The nine rights of medication administration: an overview." *British Journal of Nursing*, 2010, Vol 19, No 5.

NCC MERP (http://www.nccmerp.org/sites/default/files/indexBW2001-06-12.pdf at http://www.nccmerp.org/types-medication-errors)

Mercy shows how collaboration and the introduction of global identification standards can lead to increased patient safety in the operating room

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ABSTRACT: Mercy is using GS1 standards to identify medical devices and pharmaceuticals for the automation of its hospital operations. As Mercy's cross-functional team has demonstrated, collaborative relationships within its own institution are enabling the digital transformation of its health system. In fiscal year 2018 (FY18), Mercy reported a 99% reduction in expired products and recalls reaching its operating rooms (ORs) for cases. During FY17 – FY18, charge capture in surgery also improved by 28%, contributing to $909 additional revenue per case. At the same time, there were reductions in the cost of supplies of $123 per case and labor of $29 per case. More accurate charging of supplies has given the clinical team full visibility over the items used in surgery, which has led to a reduction in variation of supplies.

Change requires collaboration

US healthcare providers and suppliers are partnering with GS1 US as well as one another to champion industry initiatives and help government agencies to formulate regulations. The connection between voluntary initiatives and government regulations is increasingly evident as compliance moves from healthcare manufacturers to providers. (Box 1)

In hospitals that are now on the frontlines of compliance, internal partnerships are being formed to collaborate on targeted projects.

When Mercy's perioperative team wanted to increase efficiencies and optimize preference cards in its operating rooms, they turned to the hospital's center of excellence team for assistance to improve the management of product inventory listed on the cards.

Mercy's center of excellence team focuses on driving improvements throughout the hospital's operations, finding new and better ways of helping the work of staff and clinicians and improving processes that deliver better patient outcomes.

At the same time, there was a need to adopt processes surrounding the adoption of unique device identifiers (UDIs) encoded in barcodes that were moving from healthcare manufacturers' production lines into Mercy's operations, specifically in its operating rooms.

System preferences

Mercy's 259 operating rooms within its 45 healthcare facilities

BOX 1: HEALTHCARE PROVIDERS: AT THE CENTER OF COMPLIANCE

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

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

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

Source: Betty Jo Rocchio and Matthew Mentel, Mercy Health System

are governed by preference cards for thousands of cases. Each preference card provides an individual surgeon with a unique set of product requirements for each of the procedures performed.

Operating rooms hold the dual distinction of being among the highest cost centers as well as the highest revenue-generating centers in Mercy. The goal of the project was twofold: to better manage the products used in the ORs and to accurately capture and document the charges per case. This could reduce costs, increase revenues and document precisely how the hospital cared for each patient.

Surgical precision for patient safety

Perioperative services represent from 40% to 50% of any hospital's revenue stream; it is essentially a business within a business. To be successful, perioperative services must deliver quality care, yet, also consider the cost of that care. Currently and in the future, successful health systems will deliver the same or higher quality care—for less cost.

Therefore, being able to accurately identify the exact products that an OR is using in every single case helps establish the cost and reduce patient risk. Furthermore, accurately identifying the cost of delivering care enables Mercy to tie this cost to a quality outcome for comparative effectiveness.

GS1 identification standards and barcodes uniquely identify a product, its origin and attributes, including lot number and expiration date. Before introducing a new product in the OR, the new product's identifier is loaded into the Mercy's ERP system for consumption. At the same time, the staff is fully trained on the new product.

The inventory management system interfaces with the ERP and the electronic health record system. When a product is consumed, a single scan of the barcode "pulls" all product information, including pricing, from the ERP/financial system into the inventory management system and it "pushes" appropriate information into the patient's electronic health record for documentation and billing.

If a product has expired or is recalled, the system will automatically flag it during the front-end process so it will not make its way into the OR for use or implantation in the patient. Via its identifier, the hospital can also link the product to patient outcomes post-surgery.

Exactly what is needed in the OR

However, the true measure of Mercy's success is the widespread *collaboration* it has achieved.

When Mercy first started implementing barcode scanning in its OR, hospital representatives would tell the story of the surgeon who asked to use a product before it was scanned. The circulating nurse stopped the surgery and said, "Doctor, please recognize we're scanning a product to make sure it's been properly identified, to see if it's been recalled or expired before you put it in that patient's body. Do you want to go around that process?" He said, "No, I do not. Scan the product. I can wait."

There are still obstacles to seamless operations, some of which are occurring upstream. Manufacturers may not be applying the proper barcodes to products, or applying multiple barcodes, which can be a source of confusion in the OR. Some manufacturers are using a single identifier for several similar,

but not identical, products. These issues associated with the implementation of GS1 identifiers and barcodes are being corrected throughout the healthcare supply chain and will eventually impact healthcare providers like Mercy.

Yet, even with these challenges, Mercy has high praises for the changes enabled by the use of GS1 identifiers and barcodes. Specifically, there are significant improvements of the preference cards themselves—the roadmap to any surgical procedure.

The charges are taken from the preference card. The OR has a process for keeping preference cards optimized as well as a system for scanning preference card products for each case. The back half of the system checks the OR nurse to make sure that the products brought into the OR are consumed and charged, or products not consumed are returned to inventory. (Fig. 3)

This has been a significantly positive change for the nurses and doctors, since they have exactly what they need in the OR. Mercy verifies in the pre-procedure area that implants and products are available for the patient and then scans barcodes on the products immediately prior to their use in surgery.

The Triple Aim

At Mercy, the Triple Aim of quality, service and cost guides the hospital's strategy, operations and culture. It is about reaching a balance between these three goals to obtain the following:

- Achieve patient safety, reduce risks and ensure comparative effectiveness
- Improve clinical workflow and satisfaction, minimize distractions and increase productivity via standardization
- Control the cost per case and realize charge capture

Based on the Triple Aim of quality, Mercy's SAFE system tracks unusual events related to pre- and post-surgery. Prior to implementing GS1 identifiers and barcodes (FY17), Mercy reported 459 events that were related to recalled or expired implants or products making their way into the operating room. Post implementation of GS1 standards (FY18), only 5 events were reported, yielding a 99% reduction. (Fig. 2)

In the area of service, Mercy is experiencing a 12% reduction in OR turnover times.

When it comes to the financial picture in perioperative services, Mercy has noticed a 28% to 30% improvement in the identification of supply charges being captured per [surgical] case. The charge capture improvements equal $909 in additional revenue per surgical case. Finally, the cost of supplies has decreased by $123 per case with a reduction in labor of $29 per case.

By implementing GS1 standards, Mercy has been able to reduce variations among its surgeons' preferences for the same procedure, which has translated into reduced costs and greater patient safety and throughput. When nurses are trained with the same equipment in the same way, it helps them perform better in surgery and focus more on the patient.

Mercy believes this ultimately leads to improved clinical user satisfaction. With accurate and complete charge capture, the hospital is able to provide the true cost of care for every single procedure.

Inventory management and labor

Mercy stresses how GS1 standards are helping in the

FIGURE 1: THE TRIPLE AIM
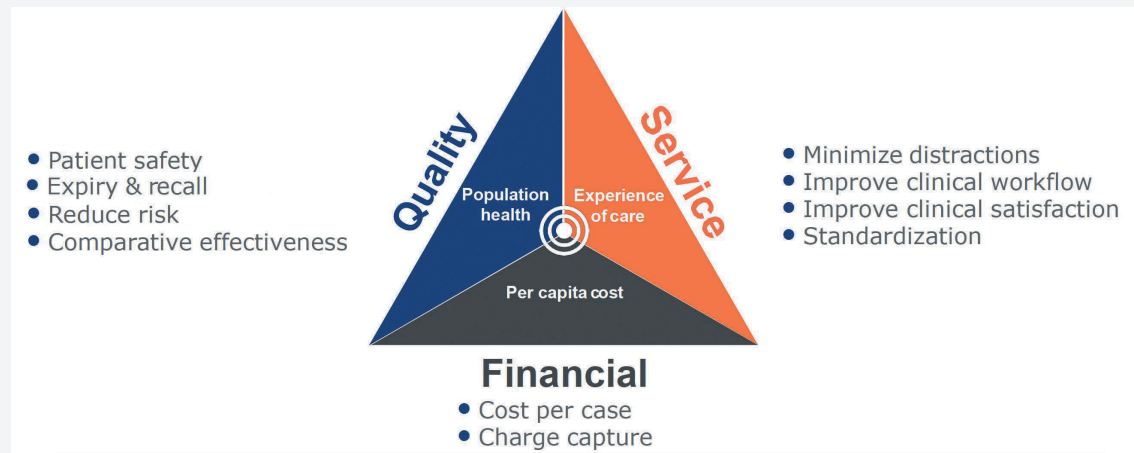
Source: Betty Jo Rocchio and Matthew Mentel, Mercy Health System

FIGURE 2: PERIOPERATIVE SERVICES TRIPLE AIM RESULTS, FY17 – FY18

QUALITY	SERVICE	FINANCIAL		
Reduction in expired products and recalls reaching the Operating Room for a case	Reduction in OR turnover times	Increase in revenue	Reduction in supplies costs	Reduction in labor
99% reduction from FY17 to FY18 459 in FY17 5 in FY18	12% decrease from FY17 to FY18	Increase of $909 per case from FY17 to FY18	Decrease of $123 per case from FY17 to FY18	Decrease of $29 per case from FY17 to FY18

Source: Betty Jo Rocchio and Matthew Mentel, Mercy Health System

important area of inventory management–not expending labor pulling unneeded product that must then be returned to inventory. The hospital realizes that the amount of time spent on a redundant activity increases the risk of inaccuracy, which could impact patient safety.

The hospital has improved its preference card optimization by 284%, reducing the number of products on preference cards and resulting in a one-time savings of US$500,000 in product cost savings.

Collaboration is critical

The partnership between business and clinical operations is clearly one of the keys to Mercy's ongoing success in leveraging GS1 standards in the OR, not just as a means of compliance, but also using them to make vast process improvements.

Mercy advises that its unique product identification and barcodes facilitate data capture and reduce the burden on operations. Healthcare systems cannot afford to ignore GS1 standards, since they provide the foundation for automating healthcare processes.

Biographies

Betty Jo Rocchio, MS, BSN, CRNA, CENP, Chief Nursing Optimization Officer, has more than 26 years of healthcare experience, including 20 years holding various leadership positions in Perioperative Services and Procedural Areas. Within Mercy, she has oversight and leadership accountability for over 45 clinical and procedural areas across four states, including a $2.8 billion revenue stream and $550 million cost structure.

Matthew Mentel, MHA/MBA, CMRP, Executive Director for Business Transformation and Integration, is responsible for identifying and implementing creative solutions as well as leveraging current technology to drive efficiency increase and expense reduction throughout Mercy. He oversees initiatives that seek to optimize the use of tools, technology, processes and metrics across the care continuum, driving more predictive and outcome-based decisions to help enrich the Mercy experience for caregivers and patients.

FIGURE 3: GS1 BARCODE SCANNING IN OPERATIONS ROOM WORKFLOW

Source: Betty Jo Rocchio and Matthew Mentel, Mercy Health System

FIGURE 4: TANGIBLE BENEFITS OF USING GS1 STANDARDS IN MERCY OPERATING ROOMS

Source: Betty Jo Rocchio and Matthew Mentel, Mercy Health System

References

Rocchio, Betty Jo, and Matthew Mentel. Mercy Health System. 2017. "Mercy Cites Collaboration as Best Medicine," Case study presented at GS1 Connect conference. www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=1197&language=en-US&PortalId=0&TabId=134

University of Fukui Hospital Surgical Center creates an integrated sterilization management system for traceability and patient safety

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ABSTRACT: Since 2014, the University of Fukui Hospital (Fukui Hospital) has been focused on the cost-effective management of its surgical operations. The hospital has successfully achieved the traceability of surgical instruments in its surgical center's sterilization process by identifying each of 30,000 instruments with GS1 standards. The error rate in counting was reduced from 3,054 to 175 ppms, and the time required to assemble and check instruments for surgical operation was reduced by 4,000 hours per year. Using GS1 Global Location Numbers as part of its surgical container setting system has helped reduce Fukui Hospital's overall operation time by 4,971 hours per year.

The need: improved safety and efficiencies

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

Fukui Hospital needed to ensure the safe use and traceability of instruments used in surgical procedures. The hospital was experiencing an error rate of 3,054 ppms when counting instruments, which introduced risks associated with leaving surgical instruments in a patient's body. Furthermore, Fukui Hospital wanted to improve efficiencies in its operating rooms and inventory processes.

The hospital's Surgical Center and Central Sterilization department decided to research the concept of "marking" instruments directly with unique identifiers (UDIs) encoded in barcodes.

In 2006, the Japan Association of Medical Devices Industries (Jamdi) released the *Guideline for Two Dimensional Symbol Marking on Steel Instruments*. This guideline defines the need for direct marking and using GS1 standards for symbol engraving, recommending the use of GS1 Global Trade Item Numbers GTIN®[1] plus serial numbers, together with direct marking by means of GS1 DataMatrix barcodes.

1 The GTIN® is a trademark registered of GS1 AISBL

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

The solution: Integrated Sterilization Management System

From 2010 to 2014, the Surgical Center and Central Sterilization Department introduced the Integrated Sterilization Management System (ISMS), which ensures the traceability of steel instruments by means of unique identification.

The system enables the linkage of patient identification, surgical schedule and surgical instruments information within a hospital information system. For the identification of surgical instruments and sterilization-related equipment, the hospital decided to adopt GS1 standards.

Some guidelines were already in place, such as the one by Jamdi, previously mentioned, and the *Practical Guideline for Operative Medicine*, released by the Japanese Association for Operative Medicine, which recommended using UDI for the identification of surgical instruments. However, there were few manufacturers who had actually implemented direct barcode markings on their products.

Uniquely identifying surgical instruments and locations

Surgical operations require around 20,000 pieces of surgical instruments whose marking must be performed without affecting scheduling. Due to these factors, it was imperative to conduct direct marking in the hospital, for a smooth transition to the management of surgical instruments using unique identification.

To do this, Fukui Hospital used the GS1 DataMatrix barcode as a data carrier for the unique identifier on steel instruments.

The initial number of steel instruments marked with GS1 identifiers encoded in DataMatrix barcodes totaled approximately 18,000. The hospital spent nearly one year on the direct marking and registration of all the instruments in its database.

The Integrated Sterilization Management System has been in operation since September 2015. As of June 2018, the hospital has in total about 31,000 pieces of steel instruments marked with GS1 identifiers and barcodes.

The hospital has also adopted another GS1 standard, called Global Location Numbers (GLNs), to identify locations. A GLN is assigned to each operating room, every location in the surgical container storage cabinet that accommodates sterilized containers and items, fixed shelves and storage racks in the hospital wards and more. In total, more than 1,000 of the hospital's locations have GLNs.

### Applying barcodes on surgical instruments

The hospital has a laser-marking machine that marks steel instruments with the GS1 unique identifier encoded in a DataMatrix barcode.

For those instruments that have been identified and marked by the manufacturers, Fukui Hospital uses the manufacturer-provided GS1 unique identifiers and serial numbers encoded in DataMatrix barcodes, instead of marking them internally.

The hospital marks instruments in two places for several reasons:

▌ By repeated washing and sterilization, the surfaces of these instruments are gradually worn away.

▌ If marked in only one place, there would be a possibility that the code might become "un-scannable", making it quite difficult to identify the original identification

FIGURE 1: MARKING INSTRUMENTS, CABINETS AND LOCATIONS FOR TRACEABILITY
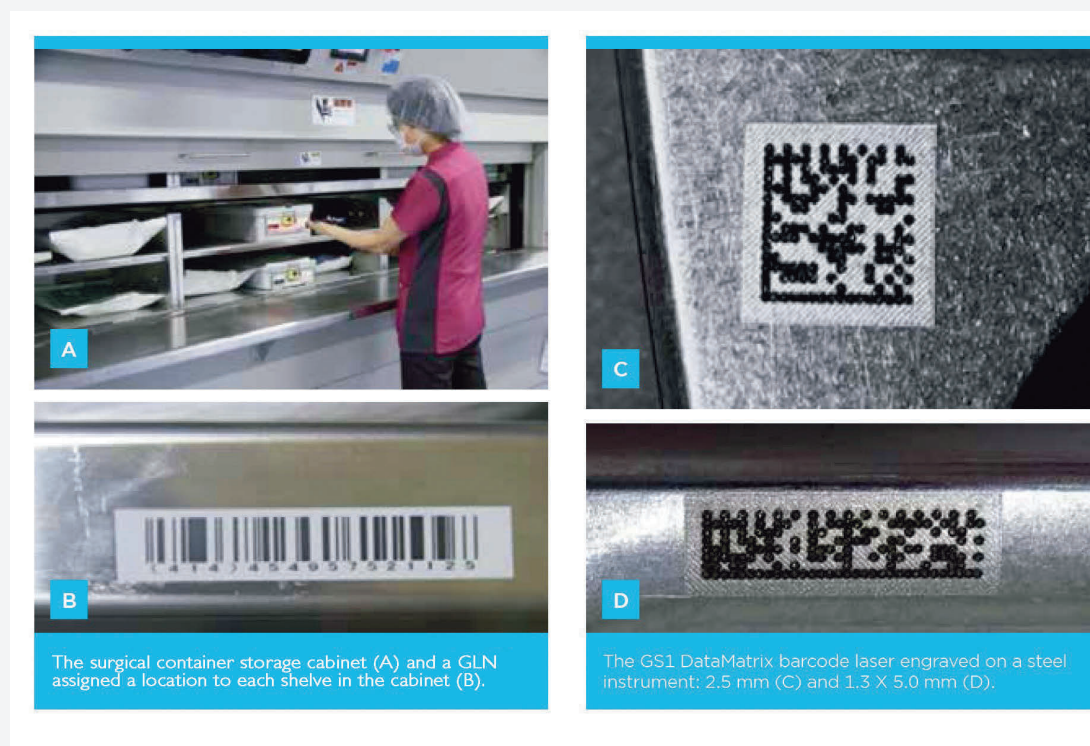
The surgical container storage cabinet (A) and a GLN assigned a location to each shelve in the cabinet (B).

The GS1 DataMatrix barcode laser engraved on a steel instrument: 2.5 mm (C) and 1.3 X 5.0 mm (D).

The hospital's surgical container storage cabinet (A) and a GLN assigned a location to each shelve in the cabinet (B). The GS1 DataMatrix barcode laser engraved on a steel instrument: 2.5 mm X 2.5 mm (C) and 1.3 X 5.0 mm (D).

Source: University of Fukui Hospital Surgical Center

code.

▮ It is easier to scan a DataMatrix barcode when two sides are marked; this is also very useful when time is limited during a surgery.

▮ Based on extensive experience, two-place marking has been strongly recommended by the Jamdi guide for surgical instruments in Japan.

How the ISMS works

By using portable digital devices, the system allows Fukui Hospital to manage information during each step of a surgical operation: collecting, cleaning, sterilizing and storing surgical instruments, along with preparing for operations (Fig. 2).

The GS1 DataMatrix barcode that is directly marked on each steel instrument is read twice—during the collection step after a surgical operation and during assembly.

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

▮ Immediately after the completion of a surgical operation, GS1 DataMatrix barcodes are scanned on the steel instruments used during the operation, counting all of them before the patient leaves the operating room. This ensures that all prepared instruments have been collected.

▮ After the instruments are cleaned, skilled staff members conduct a visual check, scan the GS1 DataMatrix barcodes again and assemble a surgery set. They thus ensure that all necessary instruments are in place.

▮ GS1 barcodes are used for checking at each step of the containers' registration process: before and during sterilization and upon storing, placing and selecting the sterilized containers.

▮ The hospital's surgical container storage cabinet has been developed specifically for storing containers and sets of sterilized items and is equipped with a touch-panel monitor to display stock status. The monitor displays real-time surgical operation-related information based on electronic medical records.

▮ A staff member reads the surgical operation schedule from electronic medical records using a smartphone-like portable device. By scanning a surgery ID and a barcode on a surgery cart, the shelf inside the cabinet automatically rotates and stops on the position where the necessary container is stored, allowing staff members to select it with ease.

FIGURE 2: WORKFLOW OF THE INTEGRATED STERILIZATION MANAGEMENT SYSTEM

Source: University of Fukui Hospital Surgical Center

▮ There are approximately 600 storage locations inside the cabinet. Each of them is assigned a GLN for identification, thereby automatically controlling its "stop" position.

The tangible results

Specific benefits of the new system using GS1 standards include improved medical safety measures by ensuring traceability on individual steel instruments (Fig. 3). This includes preventing surgical instruments from being left inside a patient's body, preventing errors in counting, surgical sets being assembled more precisely, preventing loss and unauthorized takeout.

FIGURE 3: PREVENTING ERRORS IN COUNTING			
	# of errors	# of surgeries per year	Error rate (ppm)
2013: Before ISMS	15	4,911	3,054
2015: After initial implementation	2	5,025	398
2017: After full implementation of ISMS	1	5,715	175

Source: University of Fukui Hospital Surgical Center

The system enables the hospital to analyze more easily the instruments' frequency of use, turnover and stock status at specified piece and set levels. This leads to a highly efficient stock management system and a 1.5% reduction of surplus stock, resulting in $20,000 USD cost savings.

Furthermore, frequency of use by surgical method type analysis can help the hospital optimize the number and content of surgical sets. In the past, an experienced nurse with specialized knowledge was needed to assemble the steel instruments into containers. Now, with the new system, this process can be performed by staff members without these specialized skills and knowledge.

Under this system, the assembly operation is quick and accurate. One of the major benefits of the system is that labor costs are lower than before in spite of the increased number of surgical cases during the past four years.

The hospital estimates that in 2017 the system has also contributed to a reduction of approximately 4,000 hours in overall operation time, including the confirmation of steel instruments after surgery.

Container storage and selection tasks, part of the preparation process for surgical operations, have become automated, paperless processes based on the real-time stock status of sterilization containers. Fukui Hospital estimates the time for such work has been reduced by approximately 1,000 hours annually.

The management of steel surgical instruments directly marked with GIAIs and the management of locations using GLNs have saved a total of nearly 5,000 hours and more than $200,000 USD annually (Fig. 4). This allows nurses to concentrate on other duties; furthermore, it can contribute to a reduction of their overtime work.

For medical washer disinfectors and sterilizers, Fukui Hospital has a system in place that provides the real-time operation status of each piece of equipment through a monitor. This means that the cleaning and sterilization history of each instrument can be easily checked, as well as its location and utilization history, thereby enabling the hospital to swiftly respond to a lack of instruments during surgery and recalls. It is expected that the analysis of instrument turnover in addition to their usage rate would further improve the efficiency of the operations.

Next steps

Fukui Hospital plans to introduce a similar system for all of its medical devices and establish a real-time traceability system. The hospital will expand the scope of its traceability management to single-use medical devices and materials using GS1 identifiers marked by manufacturers on packaging.

The hospital will adopt this kind of traceability scheme to loan instruments, as well. A new system is under development to collect real-time location information on carts being prepared for a surgical operation in. Using this system,

FIGURE 4: REDUCTION IN OPERATION TIME AND ASSOCIATED LABOR COSTS (ANNUAL)					
Timeframe	Number of surgical cases	Number of operation hours	Labor costs (USD$)	Estimated reduction in labor costs (USD)*	Estimated reduction in total department work hours*
2013: Before ISMS	4,911	24,400	$700,058	n.a.	n.a.
2015: After initial implementation	5,025	22,842	$589,385	$126,923	2,124
2017: After full implementation of ISMS	5,715	23,424	$613,105	$201,562	4,971

Source: University of Fukui Hospital Surgical Center
*Correction for number of surgical cases, adjusted based on increased number of surgical cases

5,000 hours time and $200,000 USD cost savings annually for the overall operation, including post-surgery confirmation of steel instruments for increased patient safety
- 1,000 hours time and $40,000 USD cost savings annually, based on automated, real-time stock status of sterilization containers
- 4,000 hours time and USD $160,000 cost savings annually, based on the improved management of steel surgical instruments

1.5% reduction of steel instruments surplus stock and $20,000 USD cost savings

Source: University of Fukui Hospital Surgical Center, "Improving patient safety and effective traceability of surgical instruments during the sterilization process using GS1 standards," Prepared for the 6th World Congress of Clinical Safety Conference, September 2017.

Fukui Hospital will further improve the existing workflow so that it can confirm that carts are transported to and from an operating room and respond to an urgent change of surgery procedure and/or operating room.

The hospital believes that the GS1 identification system can be widely used for a variety of reasons in the future.

Biographies

Shingo Kasamatsu is the Technical Officer of Faculty of Medical Science at the University of Fukui. He introduced GS1 standards into the University of Fukui Hospital. He is one of the key people who spread the adoption of GS1 standards in the medical field. His interest in GS1 standards is now expanding to other GS1 identification standards beyond the Global Trade Item Number®, Global Individual Asset Identifier and Global Location Number.

Yoko Ishimoto is the Deputy Head Nurse of the Sterilization Management Department at University of Fukui Hospital. As a nurse for the surgical center and also a certified sterilization specialist, she has played a key role in the design of the current central sterilization chamber and has led the implementation of the Integrated Sterilization Management System.

Dr. Kazufumi Sato, M.D., Ph.D., is the Associate Professor of the Surgical Center at the University of Fukui. He graduated from the Kanazawa University Medical Department in 1980. Since 2003, Dr. Sato has served as Deputy Director for the Surgical Center at University of Fukui Hospital. He is leading the implementation of GS1 standards in the Surgical Center for secure traceability of the sterilization process and cost-effective management.

References

Japan Association of Medical Devices Industries and Japanese Society of Medical Instrumentation. 2017. *Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments, Version 1.3.* http://www.jamdi.org/business/data/Technical_Guideline_on_Direct_Marking_for_Two-Dimensional_Symbol_on_Steel_Instruments(Ver.1.3).pdf

Japan Association of Medical Devices Industries. 2017. *Standard Guideline for Two dimensional (2D) Symbol Marking on Steel Instruments, Version 3.* http://www.jamdi.org/business/data/Standard_Guideline_for_Two_dimensional(2D)Symbol_MarkingV3.0.pdf

International Medical Device Regulators Forum and United States Food and Drug Administration. 2013. *UDI Guidance: Unique Device Identification of Medical Devices* and the UDI Final Rules. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452262.pdf

Japanese Association for Operative Medicine. 2013. "Practical Guideline for *Journal of Japanese Association for Operating Room Technology,"* *Journal of Japanese Association for Operating Room Technology.* 34. (in Japanese)

NHS trusts demonstrate benefits of implementing standards

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ABSTRACT: GS1 standards are increasingly being adopted across acute trusts in England, with a number of government reports recommending their use to increase patient safety, reduce clinical variation and drive operational efficiencies. The trusts currently using standards are diverse: some are large, metropolitan centers and others include hospitals serving mostly rural populations. Learnings from each trust have provided a wealth of knowledge to help future National Health Service (NHS) implementations. By applying standards to people, products and places, they are quantifying costs and benefits across their organizations. This article highlights the achievements of two trusts.

Leeds Teaching Hospitals NHS Trust

Leeds Teaching Hospitals (LTHT) is one of the largest trusts in England with more than 2,000 beds across eight hospitals. The two main hospitals, the Leeds General Infirmary and St James' University Hospital, have over 17,000 staff, 1.1 million out-patient appointments annually and deliver regional specialist care for up 5.4 million people.

Based on the need for greater efficiencies, improved patient safety and lower costs, LTHT decided to focus on standardizing the way it captured data. They implemented GS1 standards and barcodes to identify and track patients, products and locations.

LTHT implemented an inventory management solution that today captures product data, and also *patient* identification data. This data is used to link each product administered back to the patient.

LTHT then decided to extend its use of GS1 barcodes, rolling out mobile barcode scanners into their operating theaters. Clinical staff can now scan a patient's barcode on the wristband to identify the patient, the theater's barcode that identifies its location and barcodes on products administered at the point of care.

With the GS1 identification and barcode system in place, the trust has achieved end-to-end traceability of products as they travel from manufacturing sites to the hospitals and throughout their operations to the administration to patients.

Since 2017, LTHT has been able to track all Class III implantable medical devices by batch-level information, simply by scanning GS1 barcodes. This enables the trust to better manage inventory levels, expiration dates and, if needed, recalls of products. As a result, the trust has been able to reduce inventory on hand by more than £1.5 million.

The hospitals have also automated their order and receipt processes and helped reduce online requisitions to 11% of total orders.

In turn, this has released valuable staff time and reduced the cost of ordering, while also saving approximately £75,000 per year

based on increased productivity through the use of automated quoting systems.

Real-time patient tracking

To achieve full traceability throughout its hospitals, LTHT needed to deploy GS1 Global Location Numbers (GLNs) encoded in barcode labels to 22,303 locations. The initial rollout prioritized clinical areas (the most logistically complex) and, at the same time, encouraged clinical staff to engage with the program and consider different ways of working.

The trust combined the GLN-provided data with the development of a mobile application that links directly to the patient's electronic health record. In this way, the trust has been able to explore real-time patient tracking.

In fact, LTHT has delivered a successful prototype that allows nursing staff to scan a patient's barcode on the wristband and either open the record or scan the location, down to the bed level. The electronic whiteboard on each ward is then updated with this information, showing the exact location of the patient.

One look at the electronic board enables hospital staff to see if the patient has gone to another department (for pre-operating theater procedures), and at what time, as well as what time they actually went to the theater, or how long they have been out of the theater and in the recovery area.

Thanks to these changes, LTHT have already seen a decrease in the number of telephone calls between the ward and departments such as Nuclear Medicine and Breast Imaging. They can now check where the patient is and know that the information is accurate. This means they're able to give better information to relatives if they call, rather than putting them on hold or calling them back. It saves their staff time and offers peace of mind for the patient's family.

Much faster recalls

For the next area of focus, LTHT centered on improvements in

FIGURE 1: PATIENT WRISTBAND BARCODE INVENTORY MANAGEMENT

Source: Leeds Teaching Hospitals NHS Trust

FIGURE 2: ROOM BARCODE FOR PATIENT TRACKING

Source: Leeds Teaching Hospitals NHS Trust

product recalls. Previously, any information about used implants was captured manually—hand-written in a book.

Now, with standards, the trust can electronically store this information with a simple barcode scan. A product recall that once could take days, now only takes minutes, with an estimated savings of over £80,000 annually based on saving nurses' time.

Patients are safer, too. With implantable products recorded electronically, if a recall is needed, patients who are affected can be more quickly identified and brought back into the LTHT with urgency.

LTHT ran a product recall test in Ophthalmology, to see where the real savings were being made. With its former manual system, the recall process would have cost a minimum of £173, based on 8.33 hours of time for a theater team leader. Now, with barcode scanning, the process takes only 35 minutes and a maximum of £9, since a less senior staff member is able to perform these duties.

Improved data management

To support these use cases, product management has been key. LTHT has worked directly with suppliers and other trusts to lead the largest work of its kind in the NHS, producing a singular, transparent source of product information for all products purchased by the trust. The catalog now holds over 130,000 product identifiers and has integrated this data throughout all points in the demand systems.

Now, LTHT can scan products efficiently at points of care and automate the process of re-ordering products, all because of GS1 barcodes on suppliers' packages.

Significant benefits for LTHT and its patients include the following:
- Reduced inventory to 21 days across the trust.
- Reduced inventory by more than £1.5 million across operating theaters, wards and pharmacies.
- Saved more than £80,000 annually based on saving nurses' time through more efficient product recalls.
- Saved approximately £75,000 annually on implementing automated quoting systems.
- Several rooms were cleared of stock for re-utilization.
- Improved reliability and increased visibility of the trust's supply chain.

- Minimized stock wastage.
- Improved accuracy in patient-level costing.
- Freed up clinical staff's time to spend caring for patients.

Derby Teaching Hospitals NHS Foundation Trust

Derby Teaching Hospitals NHS Foundation Trust (DTH) provides both acute hospital and community- based health services, serving a population of over 600,000 people in and around Southern Derbyshire. The trust runs two hospitals: the Royal Derby Hospital is a busy acute teaching hospital and London Road is the trust's community hospital.

Optimizing without compromise

Royal Derby was built more than 10 years ago, with 35 theaters that operate at maximum capacity. Rather than build more, the hospital needed a solution that would optimize its existing theaters' efficiency and use without compromising patient safety.

They wanted a solution that would not only work in theaters, but could eventually work in their wards and clinics. Derby Teaching Hospitals were also challenged with the need to efficiently and effectively manage product safety recalls. The hospitals used a manual, paper-based process that was time-consuming for clinicians and inadequate for patient safety.

Scanning barcodes at each step

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

Basically, everything and everyone involved in a procedure is now identified with a GS1 identifier encoded in a barcode that is scanned and can be traced back to the related patient.

Clinicians scan barcodes that identify the patient and the times during which the procedure starts and progresses—from administering the anesthetic through to recovery—and then at

the time when the patient is out of recovery. Location barcodes are scanned as well as barcodes that identify who is present and what job they are performing, the type of anesthesia used and any procedure that is performed on the patient, especially when a medical device is implanted.

By scanning barcodes each step of the way, Derby hospitals are confident that these new processes are safer for their patients.

In addition, their inventory management, product catalog and financial systems have all been integrated so that data captured from scanning barcodes can be used across all hospitals—such as automating the creation of orders to suppliers triggered by the actual usage of products and supplies.

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

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

Analyzing patient outcomes

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

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

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

Realizing benefits at multiple levels

- Derby hospitals now have full traceability in their theaters. When a recall is needed, they can identify all patients that may have been impacted and if any of the recalled products are still in inventory. Before GS1 standards, the recall process took on average 50 hours per patient to trace the affected products and/or medical devices used. Now, it takes 30 minutes at most—a dramatic saving in time and improvement in patient safety.
- The hospitals have increased the recording accuracy of their OPCS codes—used to classify procedures that are encoded in GS1 barcodes—and are now capturing all data and costs at points of care. This improvement has enabled Derby hospitals to earn more than £1 million in additional revenue per year from commissioners.
- Complete and accurate procedure costs are now captured for each patient due to the recording of scanned data from barcodes on all implants, equipment and products.
- Derby hospitals have recorded more than 150,000 theater episodes, giving them an expansive database to identify

patient outcomes and variances in clinical treatments and outcomes.
- Efficiencies in the hospitals' processes are expected to reach £2.8 million in savings during the hospitals' 2017 - 2018 fiscal year—and that's just from the implementation of standards in theaters, endoscopy and cardiac catheterization labs.

Conclusion

GS1 standards have only just begun to demonstrate some of the potential improvements barcode technology can make within the NHS. As NHS healthcare systems face increasing pressure to improve safety and efficiency and to be a world leader in delivering care, technology will be key. In the UK, an increasing number of national programs, mandates and initiatives—whether from NHS England, NHS Improvement or the Department of Health and Social Care's Scan4Safety program—are pushing trusts to stay ahead of the game in their use of data and technology. GS1 standards will be key to help achieve both.

Biography

Glen Hodgson is Head of Healthcare at GS1 UK. He is charged with supporting the NHS and the healthcare industry to deliver greater efficiency and a more robust approach to patient safety.

With over 15 years of national and international experience, Mr. Hodgson has served at board level in a variety of operational and commercial roles within complex organizational structures inside the pharmaceutical/ healthcare arena.

References

GS1 UK. 2018. "Leeds Teaching Hospitals NHS Trust uses GS1 standards to track patients." April 30, 2018. www.gs1uk.org/our-industries/news/2018/04/30/leeds-teaching-hospitals-nhs-trust-uses-gs1-standards-to-track-patients

Downs, Kevin. "Product safety recall – the view from the theatre." September 2015. www.gs1uk.org/our-industries/healthcare/demonstrating-success-in-healthcare/product-safety-recall

GS1 UK. "The eProcurement strategy: GS1 and PEPPOL standards in healthcare." www.gs1uk.org/our-industries/healthcare/gs1-standards-for-nhs-acute-trusts/the-eprocurement-strategy-for-trusts

NHS. Scan4Safety website. https://www.scan4safety.nhs.uk/

GS1 UK. "Demonstrating success in healthcare: See how GS1 standards are delivering benefits in the UK and globally." www.gs1uk.org/our-industries/healthcare/demonstrating-success-in-healthcare

GS1 UK. "Industry news: Read industry news and watch the latest videos," www.gs1uk.org/our-industries/news

Transparency on a foundation of standards

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With standards in place, Aarhus University can now easily locate the people and assets it needs to provide patients with timely and safe care.

ABSTRACT: Enhancing information levels and expertise combined with reducing costs are some of the basic drivers designing the new University Hospital in Aarhus. The focus is on the supply chain, service and raising information levels without adding labor costs. Transparency throughout hospital processes allows for better decision making and planning. Introducing an automated tracking system based on global standards allows the hospital to strengthen internal processes, enhance transparency, raise system interoperability levels and extend the overall information model for object identification to suppliers and partners. A key benefit is the ability to ensure a safe and repeatable patient experience, built on reliable methods with a high level of information and quality assurance based on automatically produced data.

Background

Background
As part of a nationwide reorganization of the Healthcare System in Denmark, Aarhus University Hospital was created by merging five medium sized hospitals in the Central Denmark Region. The vision was to create fewer, more efficient hospitals, each with a greater level of expertise.

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

Building a hospital this large takes a considerable amount of time. The technology available at the inception of the building project was generally expected to be outdated by the time the hospital would be ready to take in patients. Guessing which technologies would be available in the future was not a viable solution. Creating a technological foundation to support an efficient hospital with a high level of technological automation and patient empowerment needed a change in focus away from current day technology.

Accountability: a key factor in Aarhus University Hospital's design

A key design concept of Aarhus University Hospital is a high level of accountability and traceability to ensure high quality, efficiency and patient safety. These concepts are not unique to healthcare, even though some of the markers are a bit different from other sectors. Many of a hospital's operations are similar to businesses in other industries. Building and running a large hospital requires a focus on supply chain efficiency and a just-in-time delivery model. An analysis of the just-in-time delivery concept showed a general mistrust among staff that goods would truly be available on time—an issue that is addressed by the science of logistics management. Creating transparency in the supply chain, allowing access to information on goods in transit and showing the whereabouts of goods reassure staff that supplies will be ready on time. This mitigates the mistrust.

Research into potential focus areas produced different results. Some of the significant challenges to overcome included the following:

- Every employee in patient wards, surgery and outpatient clinics spent, on average, at least 12 minutes a day searching for items or personnel. Newer data suggest an even higher amount of time spent searching (1).
- The time needed to order new hospital beds and clean beds in patient wards put a heavy load on both nurses and service personnel.
- Several transports were made without goods due to a tight split between service personnel responsibilities and organization.
- Much of the medical technical equipment appeared to have a very low utilization rate.

To turn this strategy into future systems, obvious gaps had to be bridged. For example:

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

The basic concept of "What - Where - When"

Early in the physical design of the hospital, just-in-time delivery was evaluated as an enabler, resulting in the following strategic design decisions:

- Reducing the number of storage rooms reduces the amount of floor space built.
- Better utilization of hospital equipment reduces procurement.
- Knowledge of staff whereabouts could ensure that the nearest employee will handle a task, reducing waiting time.

Combining "Just-in-time" with "Accountability" and "Transparency" leads to an overall system that automatically registers the **location** and **identity** of a mobile object at a known **time**. This again leads to the basic concept of "What-Where-When".

Methods and foundation

Initially (in 2010-2012), this concept was adopted into a reference architecture in the Central Denmark Region, unfolding the perceived effect of 40+ use cases (2). The reference architecture was upgraded and co-released amongst all Danish Healthcare Regions[1] (3). Since 2016, the reference architecture has been governed in its third generation by the Danish Ministry of Health (5)(6), as a joint methodology to share tracking information between all Actors in the Danish Health Systems. The National reference architecture (4) unfolds the principles and requirements that create the foundation for Aarhus University Hospital's use of standards and implementation of tracking and tracing in both generalized and specialized systems.

Information backbone

Automated tracking poses many challenges:

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

Introducing a generalized information model and underpinning the model with a generalized tracking infrastructure was chosen as the best solution to support hospital requirements.

GS1 standards were found to be the best fit for many of the model's requirements: GS1 identification keys like the Global Location Number (GLN), which identify locations, and the Global Trade Item Number® (GTIN®[2]), Global Individual Asset Identifier (GIAI) and Global Returnable Asset Identifier (GRAI). which identify objects, were used along with the Electronic Product Code Information Service (EPCIS) to share data about the physical movement and status of objects and products as they transit throughout the hospital and supply chain.

In combination with the Core Business Vocabulary (CBV), EPCIS enables the creation of an event-based infrastructure. An EPCIS integration system has been implemented, making event data available to multiple actors at the same time. Business applications subscribe to events through EPCIS query interfaces and handle the supplied information to cover the needs of the individual processes supported by the applications[3].

Multiple tracking technologies are also used. These technologies supply tracking information through an EPCIS-capture interface within the integration system. Wi-Fi is used for devices like smartphones and computers, while EPC-enabled RFID is applied for more accurate, low-cost tracking applications. Additionally Infrared-, Ultrasound- and Bluetooth Beacon systems are being tested and implemented in this Hybrid tracking model. Replacing and upgrading hardware can be done without affecting business applications.

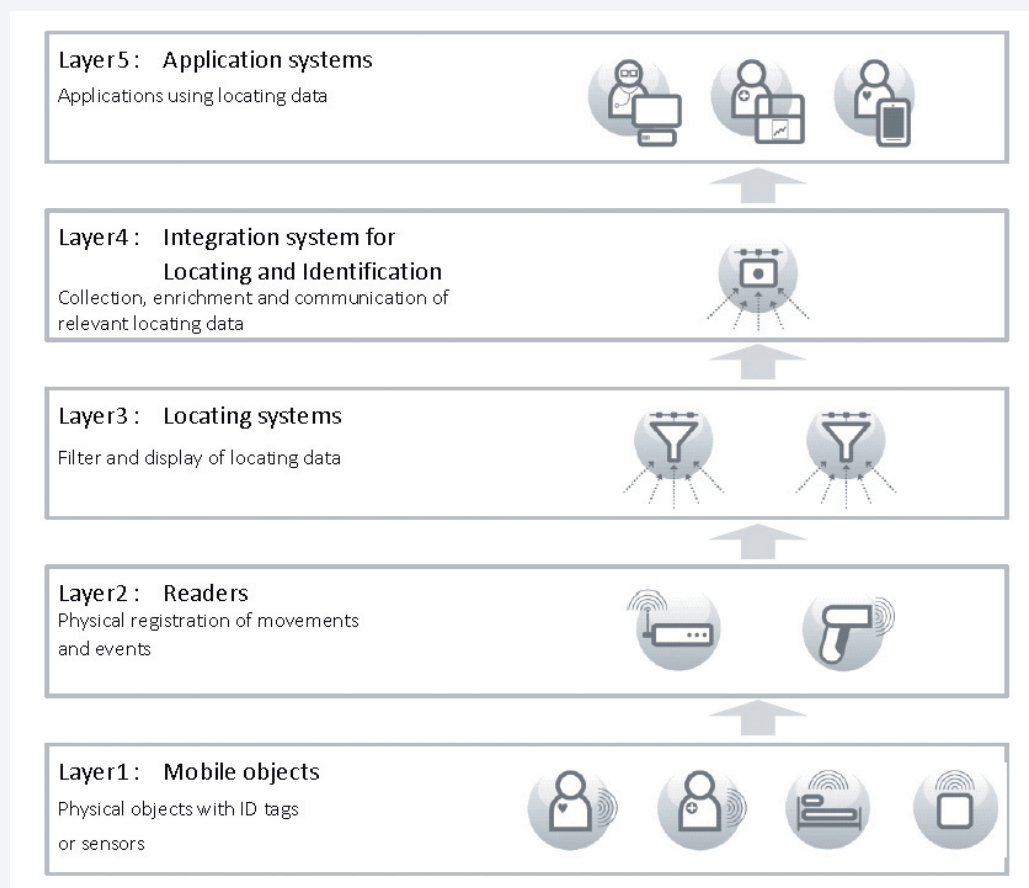## Scalability and interoperability on a global level

Today, a GLN identifies each location inside the hospital. A minimum level of usage is the exchange of GLN information between systems, yet, a high level of metadata and location context information is available for systems. The general availability to systems of the 25,000+ registered locations creates a uniform data set. Previously, these were split into more than 11 known location models, not counting system specific location models. Now, users have the ability to communicate about locations, thus minimizing the risk of misunderstandings.

An example is planning a patient encounter. It is now done in a way which ensures that the planner and the patient have access to a strictly managed data set. For all systems used in the process, now the data need to be entered only once. Since the identification of a location is based on GLN, multiple levels of information such as GPS coordinates and addresses can be provided tailored to the user's needs. This gives the hospital the possibility to give an Ambulance Driver, who uses a high-level system to consume and provide information, the same data that are converted into written text in a letter to a patient. Inside the hospital, a patient can use the automated tracking systems for guidance through wayfinding apps on their smartphone, again by transferring data to a new platform that can enhance the patient experience.

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1 The document was deprecated in 2014 and is not available in English.

2 The GTIN ® is a trademark registered of GS1 AISBL
3 https://www.gs1.org/standards/epcis

Layer 5 : Application systems
Applications using locating data

Layer 4 : Integration system for Locating and Identification
Collection, enrichment and communication of relevant locating data

Layer 3 : Locating systems
Filter and display of locating data

Layer 2 : Readers
Physical registration of movements and events

Layer 1 : Mobile objects
Physical objects with ID tags or sensors

By layering the architecture, the model supports multiple tracking technologies that can be replaced at any time without affecting the business applications subscribing to the tracking data.

Source: Resource 4

EPC/RFID was chosen to introduce a general traceability method. A hospital-wide EPC/RFID infrastructure with more than 2,400 gates has been placed in doorways of both old and new buildings. This investment has reduced the cost of adding traceability to an object, since EPC/RFID tags can be very cost-effective and durable. More than 20 different tag types are in use with plans to tag more than 250,000 objects over the next two years. The first 10,000 tags are already in use. Combined with barcodes, EPC/RFID allows the hospital to share and consume data from any supplier that can deliver GS1 compliant data, allowing end-to-end traceability from manufacturer to consumer and automating tracking at key steps of the process.

Right now, the focus is on getting a real-time overview of

carts and goods transported inside the hospital. The aim is to support decision-making and allow for a rapid change of transportation flows to reduce the internal costs of logistics. The produced data highlights poor utilization of capacity and identifies bottlenecks. All of this is achieved without staff performing manual registrations.

Tracking and searchability of personnel

A pilot project within a Ward was conducted to identify the effect of making co-worker locations available in real-time. Location data are available at two levels, both through overview screens and a search engine available on multiple platforms. Adding a location to a co-worker is translated into context information. For example, staff in a patient room is probably

attending to the patient in the room. This context allows the employee to make an informed decision on whether to contact that co-worker, risking a counterproductive disturbance, or seek help or guidance from someone else. The general ability to search for equipment also shows a reduction in the time used to find it.

Conclusion

Ensuring the general availability of master data like location and object data can create a robust foundation for business development. Several systems, which were not part of the original project, consume tracking and location data just by using the general services available from the EPCIS service and the location database.

Overall traceability sustains the staff's and patients' ability to make informed decisions. However, the higher level of information made available to users is only a benefit if maintained with a high level of integrity. As opposed to deterministic task distribution or routine behavior, information based decisions reduce the time spent on tasks and allow the user to avoid seeking help from coworkers who have more important tasks to tend to.

Aarhus University Hospital is looking into the possibility of extending the use of automated traceability based on GS1 standards to more clinical processes in conjunction with the

current focus on supply chain, logistics and services.

Sharing the standardized data with other Healthcare Suppliers and Business Partners has a high priority. A use of the GDSN network (https://www.gs1.org/healthcare/share-data-gdsn) to share data on a global level is seen as a key means of delivering transparency to actors outside the company.

Biography

Henrik Stilling, an engineer by trade specialized in IT design focused on process management and technology adaption, is an Information Technology Architect at Central Denmark Region. He is the Lead Architect for item identification and tracking and is part of the Danish national initiative on identification and traceability in healthcare.

References

1) GS1 UK. 2009. *Leeds Teaching Hospitals NHS Trust.* Case study. https://www.gs1uk.org/~/media/documents/case-studies/92950_casestudy_leedsteachinghospitalstechnical_2014.pdf?la=en

2) Central Denmark Region. 2012: "Reference architecture for Item identification and Traceability". http://www.dnu.rm.dk/siteassets/dnudnu/it/sporbarhed/referencearkitektur-for-sporbarhed-og-emneidentifikation-2-2_en.pdf

3) Danish Ministry of Health. 2016. *Structure of Danish Healthcare - Overview.* Ministry of Health, Denmark. https://www.sum.dk/English/~/media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx

4) Danish Ministry of Health. 2017. *The Danish Health Data Authority: Reference Architecture for object locating and identification.* Danish Health Data Authority, Denmark. https://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referenceaktitektur-og-it-standarder/referencearkitektur/object-locating-and-identification-1,-d-,0,-d-,4,-d-,3_en-public.pdf?la=da

5) The Danish Health Data Authority can approve standards according to an executive order. Read more here: https://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referenceaktitektur-og-it-standarder/standardkatalog/engelsk-version-af-bekendtgoerelse-af-standarder.pdf?la=da

6) Ministry of Health. 2013. *Executive Order no. 160 of 12 February 2013 on Standards for IT application in the Health Sector.* Translation of Danish executive order. https://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referenceaktitektur-og-it-standarder/standardkatalog/engelsk-version-af-bekendtgoerelse-af-standarder.pdf

7) Henrik Stilling and GS1 Healthcare Provider Advisory Council 2017. 2018. "GS1 Healthcare Reference Book 2017-2018, State-of-the-art hospital relies on GS1 standards for highly efficient and safe ways to work and care for patients". GS1 AISBL, Belgium. https://www.gs1.org/sites/default/files/docs/healthcare/gs1_hcreferencebook_17-18.pdf

The Canberra Hospital uses positive patient identification to significantly reduce errors when collecting pathology samples

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ABSTRACT: To provide greater patient safety and deliver better outcomes, today's healthcare providers need to "capture" the identification of their patients and clinicians at the points of care. Positive patient identification is especially important in busy clinical areas and where mis-identification could lead to adverse events. Using GS1 standards as the needed foundation, ACT Health and The Canberra Hospital are identifying their patients, lab and pathology samples in addition to care providers to ensure accuracy in patient-care processes throughout each patient's journey within their hospital. As a result, there has been more than a 40% reduction in wrong-blood-in-tube incidents based on clinicians scanning GS1 barcodes when collecting pathology samples.

Digitization of healthcare

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

The healthcare system needed to develop a framework to support its digitization of clinical processes across ACT Health and The Canberra Hospital campus. Part of the framework was implementing GS1 identifiers that would enable the hospital to scan barcodes in order to accurately identify patients, caregivers, locations and instances of patient care. This also needed to be scalable for implementation at the new University of Canberra Hospital and Calvary Public Hospital Bruce.

The challenge: room for errors

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

The hospital was experiencing a continuation of possible preventable incidents despite its efforts to implement policies to prevent them, like signaling (near-) incidents and discussions about process improvements. For example, its wrong-blood-in-tube occurrences were above the national average. Based on an error-prone process when collecting pathology samples, there was an elevated risk of people getting the wrong treatments. Simply put, the situation was unacceptable.

Paper-based policies were not making a big enough difference, as compliance by staff proved to be low. To increase compliance, a better understanding of the source of resistance to change was needed. The need was identified to use technology to create standardized, automated processes to support error-free patient care. To address this, the ACT Health team established the Location Based Services Steering Committee in 2013 and set off on its multi-year journey to transform patient care processes across many areas—starting specifically with the collection of pathology samples.

The hospital needed to implement a more robust method to ensure the identification of patients and caregivers in the process of collecting pathology samples and enable "positive patient identification" (PPID), in line with Australia's National Safety and Quality Health Service (NSQHS) standards for patient identification and procedure matching. In addition, this method needed to be able to support other patient care interactions within the hospital where PPID was required.

GS1 Australia introduced the team to the ISO Technical Standard 18530:2014, which provided detailed workflows to assist them with pathology samples. The ISO technical specification outlines how GS1 identifiers, specifically the Global Service Reference Number (GSRN) and Service Relation Instance Number (SRIN), can be used for patient and care provider identification across many processes. The document also illustrates how these can be applied along with several other international standards to support good practices within a series of 30 use cases.

The solution: building a foundation

The first step taken by the team was to implement GS1 identifiers in the hospital's IT-system as the building blocks for the PPID solution. ACT Health initially implemented GS1 identifiers with minimal integration and then derived value through integrating the standards with its systems.

In an integrated world, the hospital knew well how hard it would be to make a change without it having a widespread impact on everything else. The team soon realized that they needed to contain the impact and make the right changes with the greatest risk reduction and benefit. This meant focusing on patient identification. It also meant facilitating the safest processes, leading to staff "automatically" following these.

The team needed to ensure positive patient identification could only occur at the bedside by scanning the patient's wristband. To achieve this, the patient wristband's two identifiers (one identified the patient and the other the "instance" of patient care, such as taking a blood sample) were electronically distinct from any other forms of patient identification, such as the identifiers on the clinical notes labels.

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

Planning was underway for a multi-year, major project to upgrade to a Patient Administration System (PAS). Rather than wait on the new PAS, the hospital developed a middleware solution to generate the GS1 patient wristbands. By doing this, the roll-out of the wristbands would not be reliant on the upgrade and could avoid the delays that the process would have introduced.

Today, each patient wristband includes the GSRN and SRIN identifiers encoded in a GS1 DataMatrix barcode to uniquely identify the patient and the instance of patient care. Labels associated with a patient's clinical notes and specimens also include the same identifiers with subtle yet technically significant differences.

The team also worked with its existing vendors to modify the hospital's security system and print staff identification cards that used the GS1 identifier in a GS1 barcode. (Figure 3)

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

Perhaps the biggest push back occurred when implementing GS1 standards on patient wristbands. It pertained to the cost of upgrading the hospital's barcode scanners to support 2-dimensional DataMatrix barcodes. However, this soon became a non-issue when put into the context of patient safety. It was a small price to pay to ensure the hospital was always working with the right patient.

FIGURE 1: GS1 STANDARDS PROVIDE THE IDENTIFICATION FRAMEWORK FOR PPID

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

Source: ACT Health

FIGURE 2: SAMPLE PATIENT ID WITH GS1 IDENTIFICATION IN GS1 DATAMATRIX BARCODE

Source: ACT Health

FIGURE 3: SAMPLE STAFF ID WITH GS1 IDENTIFICATION IN A GS1 BARCODE
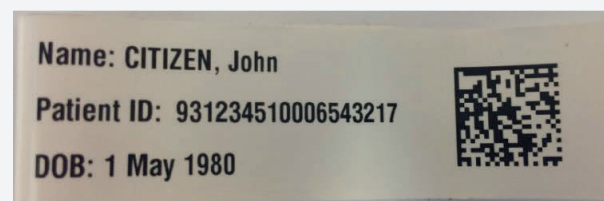
Source: ACT Health

How the solution works: PPID solution in action

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

Here's how the new process works:

▮ The collector (doctor, nurse, or phlebotomist) selects a patient from a pending collections list. Using the ACT Health Clinical Portal displaying the specimen collection screen, the collector first verbally confirms the patient's identity with the patient, using their name, date of birth and address. (Figure 4)

Preventing possible errors/incidents

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

▮ With the right patient identified and verbally confirmed, the collector needs to scan the patient wristband. If instead the collector scans the patient's GSRN identifier on the clinical notes label (which may be away from the patient bedside), the PPID system will not accept the patient identifier, because it is not the same as the one on the patient wristband; as a result, the collector cannot proceed until the wristband is correctly scanned. (Figure 5)

▮ Once again, patient safety has been preserved, and the details of the incorrect identifier scanned have been recorded.
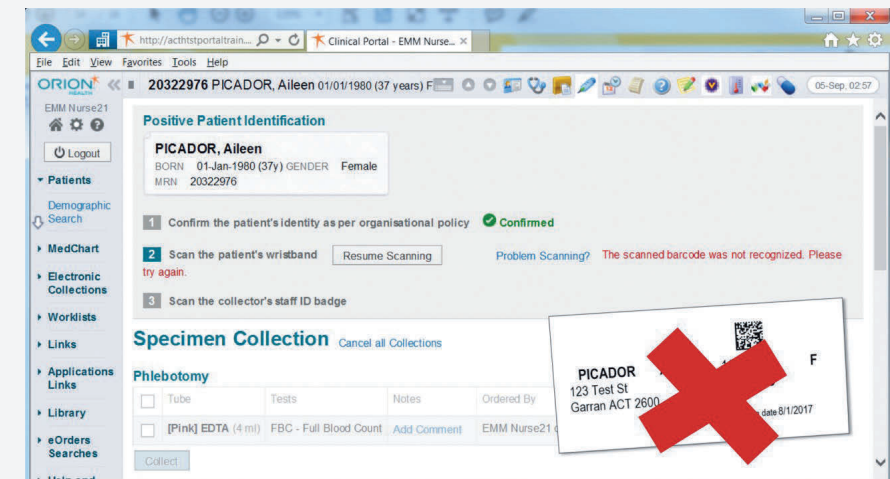
FIGURE 4: POSITIVE PATIENT IDENTIFICATION DISPLAYED IN THE ACT HEALTH CLINICAL PORTAL
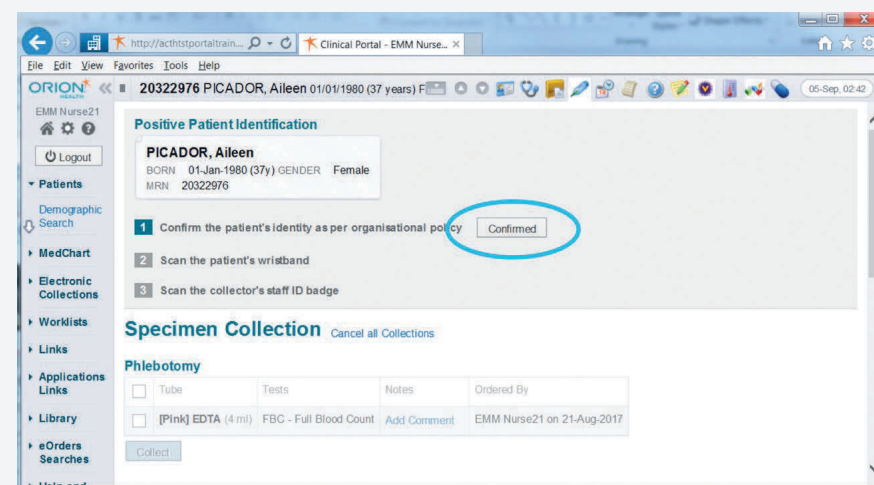
Source: ACT Health

FIGURE 5: SYSTEM ALERTING COLLECTOR: SCANNED BARCODES DO NOT MATCH

Source: ACT Health

This is perhaps the most significant point of differentiation for the PPID solution driving patient safety. The wrong-blood-in-tube incidents were typically a result of blood collections being taken from the correct patient, only to then become inadvertently switched with another patient's specimen before being submitted to the lab. This could happen when order handling and labeling is performed away from the patient for a batch of collections. With the new identification system, order handling and labeling are all done at the point of care.

A safe process

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

▮ Now that the patient wristband identifier has been successfully scanned and matched with the clinical notes label, the order is confirmed for this patient. The collector can proceed by scanning the staff identification card. Only a valid staff card with a barcode is accepted. The PPID system checks the unique identifier against the ACT Government Active Directory before allowing the collector to continue. This allows for only correctly qualified and trained staff to proceed.

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

FIGURE 6: ACT HEALTH CLINICAL PORTAL SHOWS PPID EACH STEP OF COLLECTION PROCESS
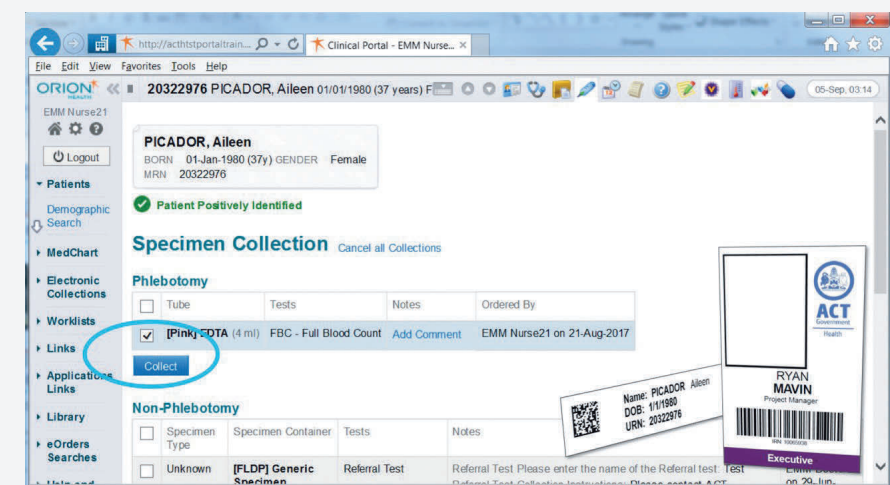
Source: ACT Health

The results: error prevention is a priority

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

Patients benefit from needing to take only a single sample. Without errors, there are no delays in results and treatments. In addition, the PPID solution eliminates risks associated with the wrong results and incorrect diagnoses.

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

GS1 standards and barcode scanning applied at the point of printing the specimen labels ensures that the physician or medical staff collecting the sample will perform precisely the steps set by the organizational policy.

ACT Health reports obtaining 100% compliance with the adjusted process and that its policy will preserve patient safety. To date, more than a 40% reduction in wrong-blood-in-tube incidents has been achieved, with remaining incidents only occurring during system maintenance periods, or with orders that have remained on paper due to patient transfers.

FIGURE 7: REDUCTION IN WBIT INCIDENTS
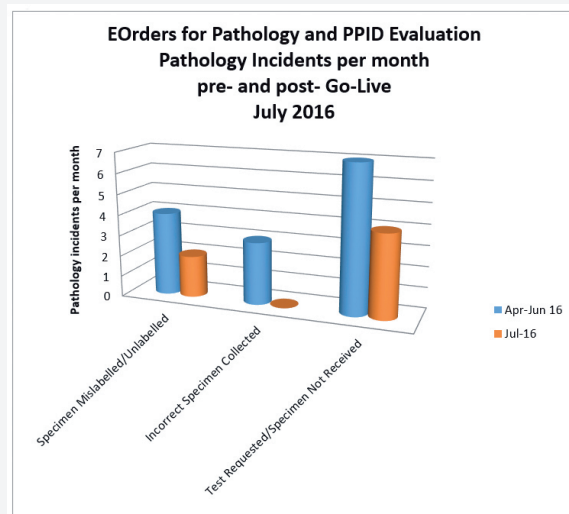
Source: ACT Health

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

The Canberra Hospital has been able to significantly reduce the number of pathology collection related errors, repeated processes and pathology costs, while also securing better patient care. The hospital also notes that its staff members are finding out that the easiest way to do their jobs is now the correct way, scanning GS1 barcodes each step of the way; thus supporting the needed management change and policy compliance.

Scalable solution

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

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

There is an overall transformation of systems and processes happening at ACT Health and The Canberra Hospital with patient safety and outcomes as a priority.

Biographies

Ryan Mavin is Manager of the Enterprise Architecture Office at ACT Health and has been working in the IT Industry for more than 20 years. For the past six years, Ryan's focus has been on Healthcare, implementing electronic systems to streamline clinical interactions and information capture for ACT Health. Ryan is passionate about IT interoperability, delivering better patient outcomes and enabling the industry to adapt to the challenges posed by an aging population.

Sandra Cook is the Director of Future Capability and Governance at ACT Health, a role that incorporates development of and adherence to the Digital Health Strategy as well as oversight over the delivery of ICT Work Projects and Programs. Sandra has been working for ACT Health for the last 14 years, with over 10 years experience in implementing health information technology projects in the public health environment. She was trained as an Exercise Physiologist.

Peter O'Halloran was appointed Chief Information Officer (CIO) of ACT Health in September 2016 and has been a CIO in the healthcare sector for over a decade. Peter is a transformational CIO with a proven track record of delivering ICT solutions quickly, using agile methodologies that are on-time, on-budget, meet or exceed user expectations/requirements and make a real-world difference both in improving the quality of life and saving tax-payers' funds.

References

Australian Commission on Safety and Quality in Health Care. 2012. *National Safety and Quality Health Service Standards*. Sydney. ACSQHC.

International Organization for Standardization. ISO/TS 18530:2014: *Health Informatics-Automatic identification and data capture marking and labelling – Subject of care and individual provider identification*. https://www.iso.org/standard/62805.html

Healthcare regulations: driving opportunities for hospitals

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ABSTRACT: In today's global healthcare landscape, more and more healthcare regulations are being developed and/or implemented. For example, in Argentina, Europe, Turkey, India, South Korea and the U.S.A., regulations aim to put practices in place to better protect patients as consumers of healthcare services, pharmaceuticals and/or medical devices. Some of the main regulatory objectives include combating falsified medicines, improving recalls, reducing medication errors, improving supply chain efficiency and reducing reimbursement fraud. While specific objectives and timelines may differ from country to country, manufacturers are complying with regulations, delivering medical devices and pharmaceuticals with barcodes that hospitals can use for the benefit of their operations and patients.

Taking a closer look.

What has sparked this heightened activity of healthcare-related regulations? One doesn't need to look too far to find troubling patient safety incidents in the news.

Released in the late 1950's, Thalidomide was prescribed to treat morning sickness in pregnant women. What followed was a man-made medical disaster; over 10,000 children were born with a range of severe and debilitating malformations. One of the world's largest selling drugs, Thalidomide was distributed in 46 countries and advertised as completely safe right up until the time it was banned, in November 1961. We will never know precisely how many women were given the drug, because 'the world was still on paper' at that time, with limited traceability possibilities.

In 2010, breast implants manufactured by the French company PIP were found to contain industrial-grade silicone. This had worldwide implications, affecting about 300,000 women in 65 countries who had received implants made by this company. Since accurate records were not kept, the total number of women affected can only be an estimate; no one really knows exactly how many women received a PIP implant.

In 2017, pharmaceutical counterfeiting involved falsified batches of the cancer drug Velcade, which were found in the European supply chain. Interestingly, the active ingredient in the vials from these batches matched the levels and specifications indicated on the label, suggesting that the counterfeiters had taken lengths to source the drug and cover up their activities.

How are regulations addressing issues like these? When examining regulations related to medical devices as compared to pharmaceuticals, different pictures emerge. Falsi-fied medicines entering the supply chain appear to be the driving force for pharmaceutical regulations, requiring that products be serialized to authenticate their sources and effectively enable product traceability and visibility throughout the supply chain, and ultimately to the patient.

On the other hand, medical device regulations are focused on making the link between a device (including implants) and a patient to enable precise and highly efficient recalls and post-market corrective measures. Their purpose is global identification—to uniquely identify medical devices around the world and, ultimately, to be able to trace each device's identification data back to its patient via the healthcare provider's electronic health record system. Furthermore, more and more countries are developing medical device and implant registries where globally unique identifiers are stored. Such registries can facilitate recalls and enable healthcare providers to contact possibly affected patients.

Good news and challenges

While hospitals are typically not targeted with these regulations, they can certainly benefit from them.

Consider that manufacturers from around the globe are labelling or marking their medical devices and pharmaceuticals with globally unique and harmonized identifiers encoded in barcodes; additional data is also available, like batch/lot number, serial number and expiry date. Currently, manufacturers are using GS1 standards on healthcare products for regulatory implementation in about 65 countries.

As manufacturers' products arrive at their warehouses, hospitals are starting to leverage the value of information provided by regulatory requirements. More and more, hos-

pitals are automating processes that are mostly manual and paper-based, resulting in cost and time savings, productivity gains, lower risks and, ultimately, safer environments for patients.

The unique identification of medical devices and related products like surgical instruments is helping hospitals to optimize operating room processes for improved inventory management and better patient outcomes via post-procedure surveillance and monitoring; it is also facilitating recalls down to the patient level.

Still, hospitals may find regulation-driven changes to be burdensome. Not all manufacturers comply in the same way; for example, barcodes may differ in quality and "read-ability" and multiple barcodes may appear on packages, causing confusion and errors. In addition, they have to deal with changes in administrative procedures and the need for investments in software, systems, scanners and training.

Furthermore, regulatory-driven actions result in manufacturers labelling pharmaceuticals with barcodes at the secondary package level. Yet, hospitals need medicines to be identified and labelled as single dosages for administration to patients, thus preventing medication errors. As hospitals take on this responsibility to add labels at the single-unit dose level, they are investing in what they believe is improved patient safety.

Even though more and more hospitals are starting to take advantage of what regulatory compliance has delivered to them, there is still a lot of work to be done…and it takes time.

Simply start scanning

What can hospitals do? Hospitals can begin to realize the benefits of global standards-based barcodes already applied on products by manufacturers…by simply starting to use them.

Consider that many hospitals of all sizes and all around the world are already using barcodes. In the UK, the Scan4Safety programme is showcasing the scanning practices and tangible benefits of six different NHS hospital trusts as demonstrator sites. In Australia, Brazil, Colombia, Japan, several European countries and the U.S.A., to name just a few, hospitals are scanning barcodes in operating rooms, pharmacies, supply rooms and at patient bedsides. They are starting to experience the value of barcodes and the information they carry—data that can be collected, managed and ultimately used for the benefit of their operations and patients.

Healthcare environments are quickly evolving with regulations as major drivers of change. It's time to get started and help build a better and safer healthcare future for everyone.

Biography

Géraldine Lissalde-Bonnet is the Director of Public Policy for Healthcare at GS1 Global Office. She leads the GS1 Healthcare Global Public Policy Work Team, whose mission is to interact with decision makers globally and provide strategic leadership on the use of GS1 standards in the healthcare sector, with the goal of enhancing patient safety and supply chain efficiencies worldwide. Based in Brussels, Belgium, Géraldine works with her local GS1 colleagues in 112 countries across the world.

References

Vargesson, Neil. June 4, 2015. "Thalidomide-induced teratogenesis: History and mechanisms." Wiley Birth Defects Research. 105 (2): 140–156.

Jones, Bryony. January 27, 2012. "Breast implant scandal: What went wrong?" CNN website.

Taylor, Phil. September 8, 2017. "More falsified Velcade discovered in Europe." Securing Industry website.

Berry, MG and Jan Stanek. June 2012. "The PIP mammary prosthesis: A product recall study." *Journal of Plastic, Reconstructive and Aesthetic Surgery.* 65 (6): 697-704.

Kessel, Lily. 19 April 2012. "Nog meer kapotte PIP-borstimplantaten." *Journal of Plastic, Reconstructive and Aesthetic Surgery.* doi: 10.1016/j.bjps.2012.02.019

GS1, January 2018. "GS1 General Specifications: The foundational GS1 standard that defines how identification keys, data attributes and barcodes must be used in business applications." Release 18.

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