



Healthcare providers

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

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

By Nilson Gonçalves Malta



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Commitment to patient care

Hospital Israelita Albert Einstein is an integrated healthcare system in São Paulo, Brazil with more than 13,000 employees, including over 1,200 physicians. In 1999, HIAE 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 traceability system to ensure quality services and safety for all of its patients.

Pharmacy leads the way

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

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

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

Relabelling in the pharmacy

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

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

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

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

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

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

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

Nilson Gonçalves Malta, Hospital Automation Manager, Hospital Israelita Albert Einstein

Suppliers join in

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

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

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

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

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

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

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Lots of data in a small space

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

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

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

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



Ampoules labelled with GS1 DataMatrix barcodes

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

End-to-end traceability for patient safety

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

- **Receiving** – As medicines are received, GS1 DataMatrix barcodes are scanned to register the type of medicine, batch/lot number, expiration date and active ingredients in the hospital's inventory system.
- **Distribution** – As medicines move from the warehouse to the pharmacy, the GS1 DataMatrix barcodes are scanned to capture the movement of the medicines from one site to the other.
- **Dispensing** – When a dosage of medicine is scheduled for administration to a patient, the GS1 DataMatrix barcode is scanned as it is dispensed by the pharmacy or at the time of

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

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

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

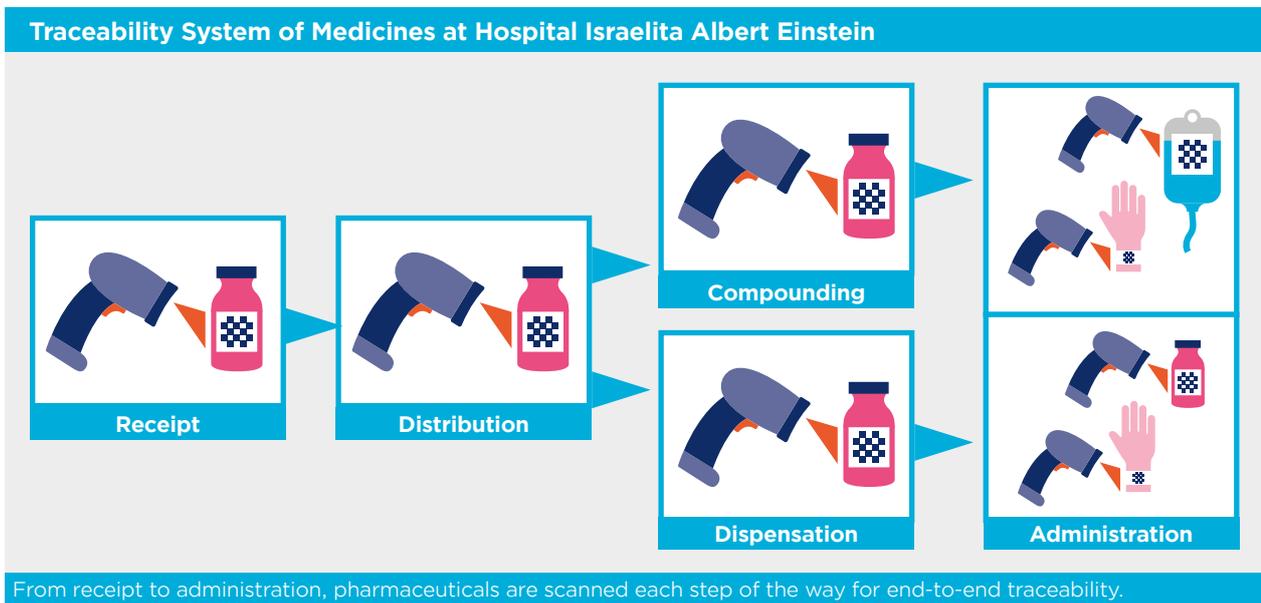
Taking traceability into the operating room

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

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

Benefits centre on patients

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



Positive impacts of traceability with GS1 barcode scanning includes:

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

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

About the Author



Nilson Gonçalves Malta is

Hospital Automation Manager at Hospital Israelita Albert Einstein. For 18 years, he has led multiple automation projects in hospital pharmacy logistics and clinical processes. Nilson graduated as a Pharmacist-Biochemist with a

post-graduate degree in Hospital and Healthcare Systems Administration. He is a member of the ANVISA (Brazilian Regulatory Agency for Drugs) committee for the National System of Drug Control. Nilson is a former member of the GS1 Healthcare Providers Advisory Council.

About the Hospital Israelita Albert Einstein

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

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