



Healthcare providers

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

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

*By Professor Peter Andreka MD,
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Modern medicine

The Gottsegen György Hungarian Institute of Cardiology (GOKI) was founded in 1977. Today, the institute performs complex cardiovascular examination, non-invasive¹ and invasive² therapies for the entire spectrum of cardiovascular diseases for the pediatric and adult populations in the field of interventional cardiology, electrophysiology, cardiac surgery and heart transplants. Other activities include the prevention of cardiovascular diseases and the monitoring of cardiac conditions.

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

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

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

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

Optimised inventory

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

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

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



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

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

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

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

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

Development challenges

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

- Barcodes based on various standards (and handled by the institute in its financial system) were being gradually replaced by manufacturers with GS1 barcodes. As a result, the institute had to manually enter data concurrently, and in different formats.
- The new GS1 barcodes needed to be assessed to determine how they might be implemented as part of the existing financial system in order to minimise manual data entries.
- It was problematic for the institute when trying to interpret linear and 2D barcodes that appeared in various formats; the human-readable data on 2D barcodes was not always included.
- It took time for GOKI to become acquainted with application identifiers (AIs), group separators and the data sets they marked.
- An additional challenge involved the technological data that determined the structure of GS1 barcodes (e.g., data of fixed and variable lengths).
- The appropriate separation and storage of data in appropriate locations needed to be determined, as well as their alignment with the data that was stored in the current system.
- The separation of the same product in varied collective packaging proved to be a similarly difficult task, because the barcodes differed based on each individual manufacturer. Alignment of the individual and various collective packaging units was an issue that had not been defined at the institute.

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

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

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

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

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

New warehouse processes based on GS1 standards

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

1. Receipt at the consignment warehouse

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

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

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

3. Release from the consignment warehouse for direct use

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

4. Registration of use with a specific patient

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

Benefits of the new system

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

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

- ✓ The workload of employees in charge of data registration has been reduced by 30-40 percent. Employees can now perform additional warehousing activities based on their additional, available time.
- ✓ Wireless barcode scanners can be used during the implementation for more streamlined processes.
- ✓ Users receive requested materials and devices quicker, which is very important for them.
- ✓ Online data registration is now available (unique identifier, serial number, lot number, reference number).
- ✓ A solution has been identified for the multi-level management of GS1 Global Trade Item Numbers (GTINs) on packages. (This will be part of a future software upgrade to the financial system.)
- ✓ Based on the development efforts at the institute, the software module has become available and ready for introduction by other healthcare institutions.

Next steps

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

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

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

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

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

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

- ✓ Improvements of the quality of healthcare services
- ✓ Introduction of a uniform patient identification system
- ✓ Increased safety when administering medicine
- ✓ Safer practice when identifying patients before performing examinations and diagnostic procedures
- ✓ Real-time registration and quantitative record-keeping of devices (trays) used in surgeries and procedures
- ✓ Accurate tracking of implants and high-value devices (trays) used in surgeries and interventions, both for clinical and financial purposes

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

30-40%

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

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

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

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

About the Authors



Professor Peter Andreka graduated from the Semmelweis Medical School in 1993 and is Board certified in internal medicine, cardiology and anesthesiology, and intensive therapy. He completed his cardiology training in the United States. Professor Andreka's main interest is

interventional cardiology and he is among the few international proctors for CoreValve/EvolutR transcatheter valve implantation. As a visiting professor at the University of Aberdeen, he became Chief of the Department of Adult Cardiology in 2006. Besides his clinical duties, Professor Andreka is also responsible for teaching and research activities. He has introduced interventional cardiology procedures in Hungary, including intracoronary stem cell transplantation, transcatheter valve implantation, left atrial appendage closure, assist device therapy and more. He has been the General Director of Gottsegen Hungarian Institute of Cardiology since December 2017.



István Nagy graduated from the Kandó Kálmán College of Electrical Engineering as an electrical engineer, and then earned a degree on Specialised Engineering of Computer Science. He also has degrees as an IT Security Auditor and GDPR Manager. From 1997 to 1999, István worked as

the Project Manager of the World Bank's Hospital IT Program Office at the National Korányi Institute for TB and Pulmonology. Since 1999, he has been the Head of the IT Department at the Gottsegen György Hungarian Institute of Cardiology. He took part in the creation of

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



Balázs Sommer has been working as the warehouse manager at the Material Management Department of the Gottsegen György Hungarian Institute of Cardiology since 2003. He is responsible for the operation of the central and consignment warehouses of large-value cardiac surgery

materials. In recent years, Balázs has participated in the implementation of numerous development projects, such as the establishment and startup of the consignment warehouse with the involvement of 15–20 contracted suppliers and the compilation of a centralised product catalogue for public procurement initiated by the maintainer of the institute. He has created his own stock-taking and evaluation process in cooperation with suppliers, which resulted on outstanding precision and traceability in inventory management in a country-wide comparison.

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

About Gottsegen György Hungarian Institute of Cardiology

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

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