Japan

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

Challenge

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

Approach

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

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

340 hours per year saved when registering medical devices used in surgeries

Achieved in-hospital traceability of medical devices

70% less time spent when processing reimbursements of catheters

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

Kengo Miyo

Barcodes and EHRs

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

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

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

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

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

Furthermore, current EHR systems are comprised of multiple and various other IT systems in a hospital. Systems related to

medical devices, for instance, include procedural ordering, surgical ordering, surgical, medical accountability, logistics management and more.

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

Flow of information and EHRs

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

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

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

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

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

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

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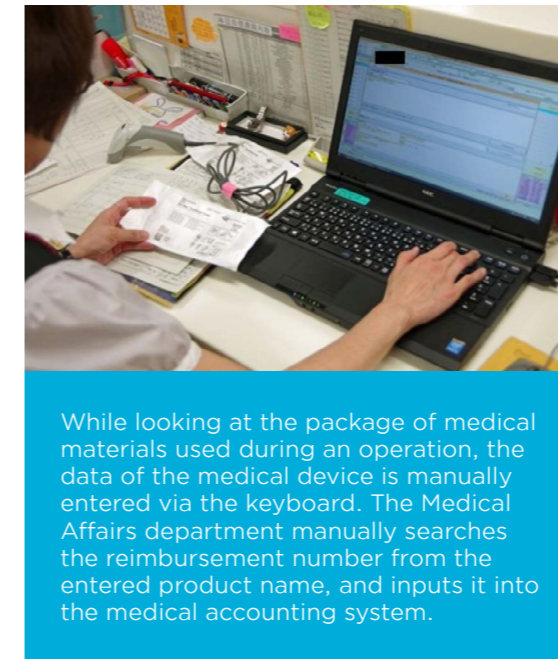

While looking at the package of medical materials used during an operation, the data of the medical device is manually entered via the keyboard. The Medical Affairs department manually searches the reimbursement number from the entered product name, and inputs it into the medical accounting system.

Figure 3a: The manual process

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

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

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

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

Figure 3b: The automated process

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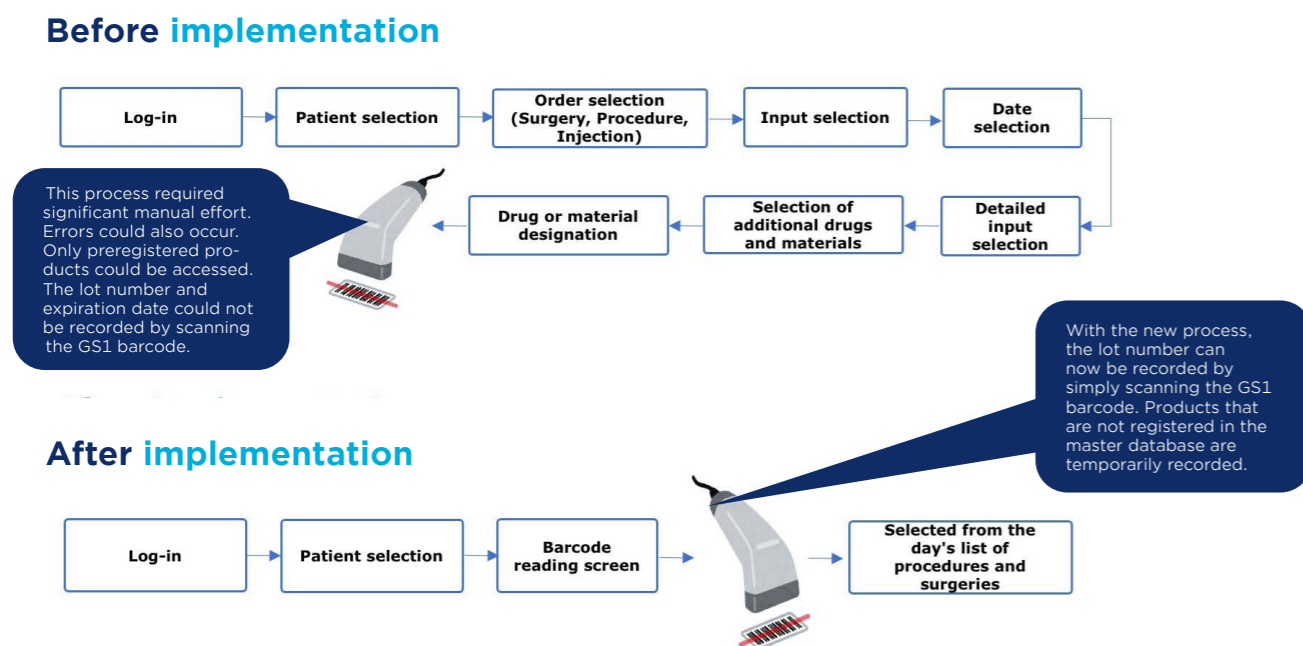
Before implementation

This process required significant manual effort. Errors could also occur. Only preregistered products could be accessed. The lot number and expiration date could not be recorded by scanning the GS1 barcode.

With the new process, the lot number can now be recorded by simply scanning the GS1 barcode. Products that are not registered in the master database are temporarily recorded.

After implementation

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

Before implementation

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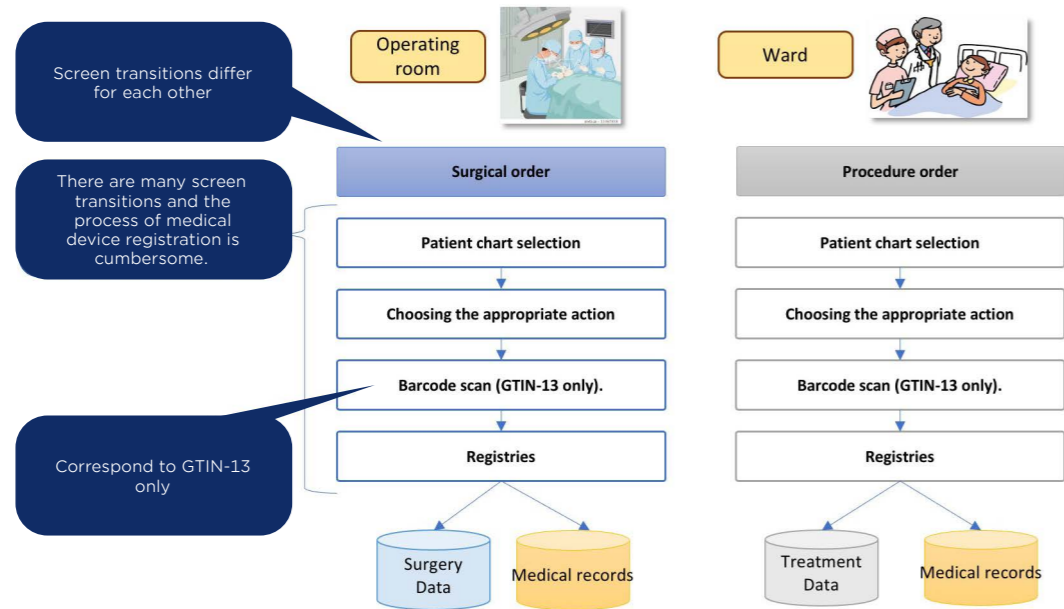

Figure 2a: Integration of use recording flow of medical devices in EHR (before)

After implementation

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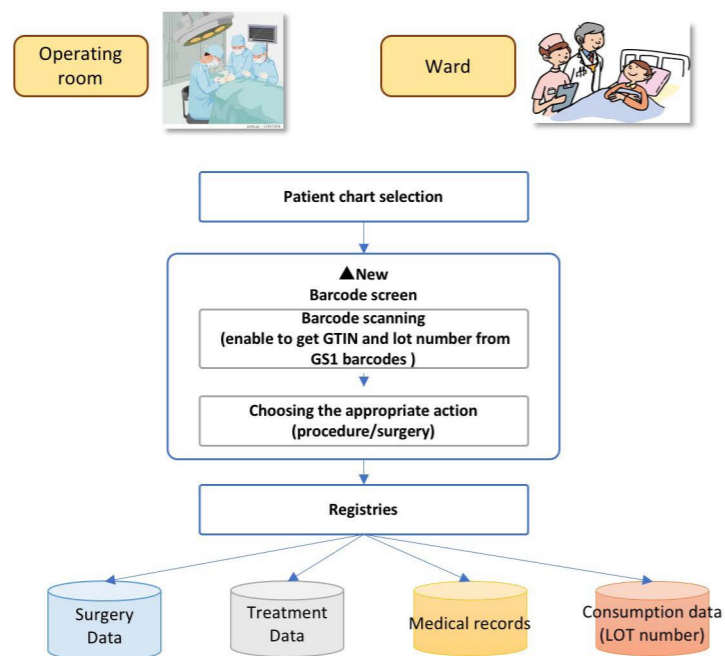

Figure 2b: Integration of recording flow of medical devices in EHR (after)

Catheter management

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

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

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

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

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

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

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New system

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

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

Integration of master data

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

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

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

Medical device traceability

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

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

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

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

Future perspectives

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

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

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

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

About the author

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

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

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

About the organisation

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

www.ncgm.go.jp