Healthcare provider implementation

GS1 standards enable an integrated sterilisation management system for University of Fukui Hospital Surgical Centre

Since 2014, the University of Fukui Hospital (Fukui Hospital) had focused on the cost-effective management of its surgical operations by using GS1 standards. The hospital has successfully achieved the traceability of surgical instruments in its surgical centre's sterilisation process by identifying each of 20,000 instruments with the GS1 Global Individual Asset Identifier (GIAI) encoded in a laser-engraved GS1 DataMatrix barcode. To date, Fukui Hospital has reduced the error rate along with the time required when assembling instruments for surgical operations by 2,000 hours per year. Fukui Hospital is the first hospital in Japan to use GS1 Global Location Numbers (GLNs) to identify each of its locations. By using GLNs as part of its surgical container setting system, Fukui Hospital has helped reduce overall operation time by 500 hours per year.

By Kazufumi Sato and Shingo Kasamatsu

UNIVERSITY OF FUKUI
Faculty of Medical Sciences
University Hospital

Aiming to ensure the safe use of instruments

Starting in 1999, the medical device industry began voluntarily marking GS1-128 barcodes on device packages. In 2008, the marking of barcodes had quickly spread after the issuance of the notification by the Ministry of Health, Labour and Welfare (MHLW). Currently, most medical device packages are marked with GS1-128 barcodes. Since then, little progress has been made in using GS1 standards at the unit level when it comes to hospital instruments—standards that are needed for traceability.

"We wanted to prevent surgical instruments from being left in a patient's body as well as eliminate any concerns about infections via contaminated surgical instruments, especially triggered by Creutzfeldt-Jakob disease," explains Kazufumi Sato, M.D., Ph.D., and Deputy Director of the Surgical Centre, University of Fukui Hospital.

There had long been calls for safety management of surgical instruments using two-dimensional barcodes. With the aim of ensuring the safe use and traceability of instruments, the Japan Association of Medical Devices Industries (Jamdi) released the *Guideline for Marking for Two Dimensional Symbol on Steel Instruments* in 2006. This guideline defines the need for direct marking and using GS1 standards for symbol engraving, recommending the use of Global Trade Item Numbers (GTINs) plus serial numbers and direct marking with GS1 DataMatrix barcodes.

Outside Japan, the International Medical Device Regulators Forum (IMDRF) and the U.S. Food and Drug Administration (FDA) issued the UDI

Guidance: *Unique Device Identification of Medical Devices* and the *UDI Final Rules*, respectively, in 2013. Both require the identification of a medical device using the UDI. For surgical instruments, UDI direct marking is expected to improve patient's safety and optimise patient care.

Using GS1 standards to mark instruments

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.

From 2010 to 2014, the hospital was preparing to relocate its wards—the Surgical Centre and the Central Sterilisation Department—to a new building. During this period, the hospital introduced the "integrated sterilisation management system," which through unique identification ensures traceability of steel instruments, for enhancing patient safety and the quality of infection control.

"The system enables the linkage of patient IDs, the surgical schedule and surgical instruments information within a hospital information system," says Shingo Kasamatsu, Technical Officer of the Faculty of Medical Science, University of Fukui. "For identification of surgical instruments and sterilisation-related equipment, the hospital decided to adopt GS1 standards."

Although some guidelines were already in place, such as the practical guidelines for operative medicine released by the Japanese Association for Operative Medicine that recommended the use of UDI for identification of surgical instruments, there were few manufacturers that had actually implemented source marking on their products.

20,000

The hospital has successfully achieved the traceability of surgical instruments in its surgical centre's sterilisation process by identifying each of 20,000 instruments with the GS1 Global Individual Asset Identifier (GIAI) encoded in a laser-engraved GS1 DataMatrix barcode.

Surgical operations require around 20,000 pieces of surgical instruments and marking these instruments must be carried out without affecting the scheduling of surgeries. Due to these factors, it was imperative to conduct direct marking in the hospital for smooth transition to the management of surgical instruments using UDI.

Today, Fukui Hospital has adopted the GS1 DataMatrix barcode as a data carrier for UDI on steel instruments. The hospital obtained the GS1 Company Prefix from GS1 Japan in order to start creating GS1 identification keys. "Because the steel instruments were already in use, we decided to apply the GIAI identification key that is used to mark assets," says Kasamatsu. "We also introduced the GLN to identify the locations of storage and use."

At the beginning of the system, the number of steel instruments marked with GS1 standards totalled approximately 18,000. The hospital spent nearly one year on the direct marking and registration of all instruments in the hospital database.

"Our system has now been in full operation since September 2015 with all 20,000 pieces of steel instruments owned by Surgical Centre identified and marked with GS1 identification keys and barcodes," says Dr. Sato. "Today, our hospital continues to mark about 18,000 pieces of steel instruments for use at outpatient and inpatient wards."

Adoption of the GLN and GIAI

The hospital has also adopted GLNs to identify locations. GLNs are assigned to each operating room, every location in the surgical container storage cabinet that accommodates sterilised containers and items, fixed shelves and storage racks at the hospital wards, and more. In total, more than 1,000 of the hospital's locations have GLNs.

The GIAI is used to identify steel instruments that are already in use at the hospital and that were not source marked by manufacturers. The hospital has a laser-marking machine in place, which marks steel instruments with the GS1 DataMatrix barcode. The basic symbol size is 2.5 mm x 2.5 mm, but a rectangle form (1.3 mm x 5.0 mm) is also used depending on the shape of a steel instrument. The GS1 DataMatrix barcode is marked on two places of a steel instrument.

The surgical container storage cabinet (A) and a GLN assigned for a location in the cabinet (B).

GS1 Datamatrix laser-engraved on a steel instrument
C: 2,5 mm. D: 1,3 x 5,0 mm

For those instruments that have been identified and marked by the manufacturers, Fukui Hospital uses the source-provided GTINs and serial numbers instead of marking them with GIAIs encoded in DataMatrix barcodes.

"We mark our instruments in two places since, by repeated washing and sterilisation, the surfaces of these instruments are gradually worn away," explains Dr. Sato. "If the marking was done at only one place, there would be a possibility that the code might become 'unscannable.' In this case, it becomes quite difficult to identify the original code. Secondly, it's easy to scan a DataMatrix barcode when two sides are marked and is very useful, especially when time may be limited during a surgery. Finally, two-place marking has been strongly recommended by the guide of Jamdi based on extensive experience for surgical instruments in Japan."

The integrated sterilisation management system

The workflow of the integrated sterilisation management system is illustrated in Figure 1. By using portable digital devices, the system allows Fukui Hospital to manage information during each step of a surgical operation: the collecting, cleaning, sterilising and storing the surgical instruments along with preparing for operations.

As shown in Figure 1, 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, read GS1 DataMatrix barcodes 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 cleaning instruments, skilled staff members conduct a visual check, read the GSI DataMatrix barcodes again and assemble a surgery set. They ensure that all necessary instruments are in place.
- GS1 standards are used for checking at each step of the registration process of containers before sterilisation, sterilising, storage, placement and picking of sterilised containers, too.

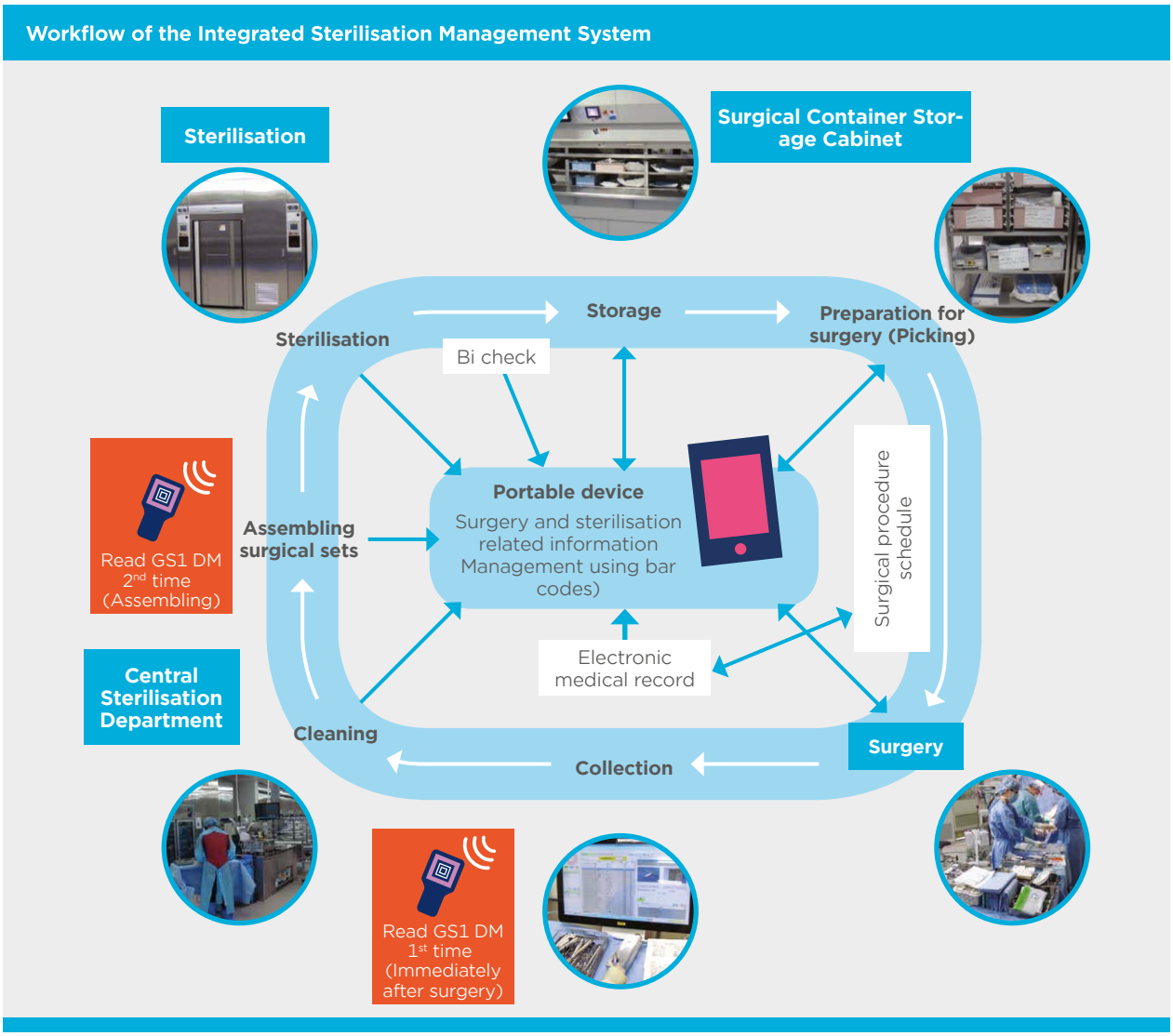
- The hospital's surgical container storage cabinet has been developed specifically for storing containers and sets of sterilised items, and is equipped with a touch-panel monitor for displaying stock status. The monitor displays surgical operation-related information from electronic medical records in real time.
- A staff member reads the surgical operation schedule from electronic medical records using a smartphone-type portable device. By scanning a surgery ID and a barcode on a surgery cart, the shelf inside the cabinet automatically rotates and stops at the position where the necessary container is stored, allowing a staff member to pick it up easily.
- The cabinet has approximately 600 storage locations inside. Each location is assigned a GLN for identification, thereby automatically controlling its "stop" position.

Saving significant time

Specific benefits of the new system using GS1 standards include improved medical safety measures by ensuring traceability on individual steel instruments. This includes the prevention of leaving surgical instruments in a patient's body, the prevention of errors in counting, the more precise assembly of surgical sets, and the prevention of loss and unauthorised takeout. "The system enables the hospital to more easily analyse the frequency of use or turnover as well as the status of stock instruments at specified piece and set levels," says Dr. Sato. "This leads to a highly efficient stock management system and a reduction of surplus stock."

Furthermore, the analysis regarding the frequency of use by type of surgical method can help the hospital optimise the number and content of surgical sets. "Experienced nurse with

Workflow of the Integrated Sterilisation Management System



specilialised knowledge once assembled the steel instruments into containers," adds Kasamatsu. "Now, thanks to the new system, this process can be performed by staff members without these specilialised skills and knowledge. The assembly operation under this system is quick and accurate.

2,000

The hospital estimates the system has also contributed to a reduction of approximately 2,000 hours annually for the overall operation time, including the confirmation of steel instruments after surgery."

In addition, container storage and picking tasks, part of the preparation process for surgical operations, have become automated, paperless processes based on the real-time status of stock of sterilisation containers. Fukui Hospital estimates the time for such work has been reduced by approximately 500 hours annually. The management of steel instruments directly marked with GIAI identifiers and the management of locations using GLNs have saved a total of 2,500 hours annually. This allows nurses to concentrate on other duties, and furthermore, can contribute to a reduction of their overtime work.

For cleaners, driers and sterilisers, Fukui Hospital has a system in place that provides the operation status of each piece of equipment in real time through a monitor. This means that the cleaning and sterilisation history along with the location and utilisation history of instruments can be easily checked, thereby enabling the hospital to swiftly respond to a lack of instruments during surgery and recalls. It is expected that the analysis on instrument turnover in addition to their usage rate would further improve the efficiency of the operations.

Next steps

Fukui Hospital aims to introduce a similar system for all of its medical devices and establish a real-time traceability system. In addition, the hospital will expand the scope of traceability management to single-use medical devices and materials using GTINs that are source-marked on packaging. "We plan to take the necessary measures to ensure higher medical safety, further increase efficiencies and prevent incomplete reimbursements," says Dr. Sato.

The hospital will adopt this kind of traceability scheme to loan instruments, as well. A new system is under development to collect location information of carts in preparation for a surgical operation in real time. Using this system, Fukui Hospital will further improve the existing workflow so that it can confirm the transportation of carts in an operating room and respond to an urgent change of surgery procedure and/or operating room. "We believe that the GTIN, GIAI, GLN and other GS1 identification keys can be widely used for a variety of reasons," concludes Kasamatsu.

About the Authors

***Kazufumi Sato**, M.D., Ph.D., is the Associate Professor of the Surgical Centre, University of Fukui. In 1980, he graduated from the medical department of Kanazawa University. Since 2003, Dr. Sato has served as Deputy Director for the Surgical Centre, University of Fukui Hospital. He is leading the implementation of GS1 standards in the Surgical Centre for secure traceability of the sterilisation process and cost-effective management.*

***Shingo Kasamatsu** is the Technical Officer of Faculty of Medical Science, 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 keys beyond the GTIN, GIAI and GLN.*

About the University of Fukui Hospital

***The University of Fukui Hospital** was founded in Yoshida County, Fukui Prefecture in 1983. With 600 beds, the total number of inpatients served in 2015 was 12,551, and 5,245 surgical operations were performed by the Surgical Centre.*

http://www.hosp.u-fukui.ac.jp