Japan

Medical device management using GS1 barcodes at Tokyo Yamate Medical Center

**Challenge**

Medical device management was a manual process, medical staff checked the labels and made an entry every time the devices were sent out or returned. This manual process made it difficult to monitor the usage histories of all devices.

**Approach**

A medical device management system was developed using barcode scanning. All medical devices were scanned every time they were taken out or returned to the store room, as well as when they were used at an operation venue. By linking all the scanned data, the use and maintenance histories of over 1,000 devices in the hospital are captured and verified in real time.

Tokyo Yamate Medical Center began their GS1 journey by scanning barcodes on medical devices, such as infusion and syringe pumps. This scanning simplified the management of device use histories and reduced the workload of medical staff. It also meant that the use status of devices could be captured easily and accurately. Tokyo Yamate Medical Center is planning to expand GS1 barcode scanning to device monitoring during surgical operations and to the remote (home) monitoring of patients with implantable devices.

**Management of medical devices for patient safety**

To ensure patient safety, it is crucial to manage and maintain medical devices properly. In many hospitals, medical devices, such as infusion pumps and syringe pumps, are managed by a centralised unit and are used when necessary, at multiple places, such as theatres, wards, ICUs etc. To facilitate the smooth management of a medical device, a management label with in-hospital product name and/or number is attached to it. The medical staff checked the labels and made an entry every time the devices were sent out of the control room or returned; however, this manual process made it difficult to monitor the usage histories of all devices.

Aware of the inaccuracy of usage records and the growing workload, Kento Watanabe, a clinical engineer at Tokyo Yamate Medical Center, developed a medical device management system in 2013 using in-hospital barcode scanning. All medical devices managed by the unit carried a barcode label containing the in-hospital code; they were scanned every time they were taken out or returned to the store room, as well as when they were used at an operation venue. By linking all the scanned data, the use and maintenance histories of over 1,000 devices in the hospital are captured and verified in real time (Fig. 1).
GS1 barcodes lead to more accurate and efficient procedures

In 2017, Kento noticed that most of their recently purchased devices had a source-marked barcode, GS1-128, on their body. He also saw that the barcode label contained the GTIN and serial number of the product. “If the code, GTIN, and serial number are unique, we can use GS1-128 instead of in-hospital barcode. Using the source-labeled barcode, device management would become much easier and more accurate. By switching from the use of in-hospital barcodes to GS1-128, we would avoid the task of sticking barcodes on devices and the problem of mislabeling.”

In Japan, the medical device industry started using GS1-128 labeling voluntarily in 1999. After the Ministry of Health, Welfare and Labour announced barcode labeling with GS1-128 in 2008, the rate of GS1-128 marking increased rapidly. For the last several years, the Japan Federation of Medical Devices has been recommending the marking of GS1 barcodes on the body of devices, especially on those that are portable. Based on these circumstances and the progress in Unique Device Identification (UDI) regulations in the US and EU, almost every medical device sold in Japanese market today now has a GS1 barcode.

Workload reduction by using GS1 barcodes

There are many old devices in the hospital that do not have a GS1 barcode. As per 2018 data, the centralised management unit had 211 types of medical devices and 1,150 in total; only 20% of the devices had source-marked GS1 barcodes. Despite this, Tokyo Yamate Medical Center decided to start using the source-marked GS1-128; this is because most medical devices purchased in the future are expected to have GS1 barcodes on their bodies. Their current system can scan GS1 barcodes, as well as the in-hospital barcodes.

By scanning GS1 barcodes on the devices, the hospital is now able to smoothly transfer device information to their management system.

“A GTIN is very convenient for getting information about medical devices. Product information can easily be taken from medical device databases supplied by MEDIS-DC (Medical Information System Development Centre), an organisation for standards, and/or other commercial databases. All we need to do is scan the GS1 barcodes on the devices.”

Even though they need to arrange and adjust the data to make it compatible with their system, the registration time for devices was still drastically shortened by using GS1 barcodes (Fig. 3). And now, there is no need to apply in-hospital barcodes.

Thanks to the internal system, hours spent on record keeping reduced drastically. Compared to manual recording, the processing time per device was reduced from 23s to 11s for lending procedure; from 31s to 5s for the returning procedure; and from 26s to 12s for periodic checks. (Fig. 2).
Problem of source-marked GS1 barcodes

Fig. 4 shows some examples of problems encountered in the hospital. Because of these problems, they sometimes have to print a new barcode, stick a printed barcode at a suitable place to read, or check the barcode that should be scanned. Proper source-marking of GS1 barcodes at a user-friendly location is essential for the efficient use in healthcare institutes.

Defective printing  In-accessible location  Multiple barcodes

Fig. 4 Unreadable GS1 barcodes

Toward further improvement in medical device management

Although many medical devices are used in surgical operations and information about their usage gets accumulated, most of it is currently erased after the operation is completed. Very little information is stored as records of operations. The hospital is now planning to establish a database system to store various types of information connected with patient number and GTIN. The goal is that medical staff can access information derived from life support machines such as anesthesia apparatus and artificial heart lung apparatus, and also monitoring equipment to get patients’ biometric information. In addition to using the accumulated information for increased patient safety in theatres, they expect the continuously generated biometric data to provide new information for making improvements in medical care. In the proposed database, the GTIN is the indispensable key for linking patient information with medical device information.

Going beyond management within the hospital

Recently, the hospital developed another new system for remote (home) monitoring of patients. The system can automatically collect the monitoring data from implantable devices, such as pacemakers, from patients in remote locations.
To effectively collect and manage the data, the system links monitoring data with the GTIN and serial number obtained from a GS1 barcode. The hospital expects the new system to facilitate early detection of arrhythmia and the malfunction of devices. By enabling early intervention to cure patients, it will greatly contribute to the improvement in life prognosis and their quality of life. By shortening the duration of medical care and the frequency of consultation, remote monitoring will also reduce the burden imposed on outpatients.

Kento pointed out the importance of understanding GS1 standards by not only manufacturers, but also healthcare providers. “Currently our hospitals use GS1 barcodes for the management and traceability of devices, however, if we were able to capture safety-related information, such as recall information from government databases automatically, patient safety would improve significantly. GTIN and GS1 barcodes should play a more important rule in the identifying of medical devices. Proper understanding of GS1 standards by healthcare providers will expand the use of GS1 barcodes. This, in turn, will contribute to the improvement of patient safety and provide economic benefits.”

About the organisation

Tokyo Yamate Medical Center was established in 1947 and shifted to its current location—Shinjuku, Tokyo—in 1987. The hospital provides advanced medical care with a capacity of 418 beds. In 2017, the total number of inpatients was 107,231 and 4,646 surgical operations were performed. The hospital is working on a project to establish a regional comprehensive medical care system that provides healthcare services, ranging from emergency care to regional and home healthcare.

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