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To Improving patient safety and Effective traceability of surgical instruments during sterilization process using GS1 standards

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Introduction

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.

Abstract

University of Fukui Hospital launched a new integrated sterilization management system using GS1 identification keys in 2014. Our Hospital succeeded to secure traceability of the sterilization process and the use history for surgical instruments by identifying all 18,000 instruments with GIAI in laser engraved GS1 DataMatrix. Through this journey we have so far achieved reduction of assembling operation time by 2,000 hours per year in addition to the error-rate reduction. Furthermore the surgical container setting system utilizing GLN location information could reduce the operation time by 500 hours per year. This is the first practical use of GLN in a Japanese hospital. With the implementation of GS1 standards achieved cost-effective management of a workflow.

Results

The central supply department has scanned the GS1 DataMatrix more than 2 million times in 3 years. By scanning barcodes, We can obtain various information about their sterilization process which achieves safer and more efficient care.

Background and objectives

The Japan Association of Medical Devices Industries released guidelines on DPM for surgical instruments in 2006. The guidelines showed the need for DPM and symbol marking using GS1 standards. In 2013, IMDRF UDI guidance and U.S. FDA UDI rules were announced. Now, there are great expectations that using DPM for surgical instruments will improve patient safety and the quality of medical care.



University of Fukui Hospital from 2014 **Solution** ✓ **GIAI** (GS1 DataMatrix) In-Hospital Marking ✓ **GTIN** (GS1 DataMatrix) Source Marking ✓ **GLN** Assignment for Theatre, Ward, Shelf, etc. Work flow GLN assigned every GS1 DataMatrix is scanned Shelf in the Surgical twice in the flow Container Storage Cabinet CSD (Central Sterilisation Department) Picking Post operation Assembly

Benefits

- ✓ Scanning GS1 DataMatrix ensured the traceability of instruments
- ✓ Scanning GS1 DataMatrix reduced the working time for retrieving and assembling instruments by 2,000 hrs. per year
- ✓ The entire hospital plans to make further use of GLN, in addition to using in both OR and CSD

Discussion and conclusions

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 unauthorized takeout. In University of Fukui Hospital, assembling steel instruments into containers (assembling operation) used to be conducted by experienced nurses with specialized skills and knowledge. Thanks to the new system, this process can be performed by staff members without these specialized skills and knowledge; therefore the hospital was able to consign the work to outsource staff. The assembling operation under this system is quick and accurate. We estimate that the system has 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 sterilization containers. We estimate the time for such work has been reduced by approximately 500 hours annually. The management of steel instruments directly marked with GIAI 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.

Fig.1 The Assembling Process in CSD







Global Location Number (GLN) http://www.gs1jp.org/2016/pdf/GS1-Handbook_2016-2017.pdf

Global Location Number (GLN) can be used by companies to identify their locations, giving them complete flexibility to identify any type or level of location required.



Picking process of preparation for surgical operations Fig.5



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Next steps:

University of Fukui Hospital aims to introduce a similar system for all of its medical devices and establish a real-time traceability system. In

Fig.3 Post operation scan a surgical instrument





Fig.8 Before Installation

Fig.9 After Installation

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, and take necessary measures to ensure higher medical safety, further increase efficiencies and prevent incomplete reimbursements. 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, We 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. The hospital believes that the GTIN, GIAI, GLN and other GS1 identification keys can be widely used on various scenes in medical institutions.