RFID and barcode based management of surgical instruments in a theatre sterile supply unit

ABSTRACT
To effectively use surgical instruments Kanto Medical Centre NTT EC in Tokyo has introduced automatic identification and data capture (AIDC) technologies in the Theatre sterile supply unit. Both two-dimensional barcode (DataMatrix, 3–5mm square in size) and RFID tag are used for verification of surgical instruments and their containers, respectively. Although statistically meaningful data has not yet been drawn, effectiveness of AIDC technologies has already been well recognized among the staff in the operating room (OR) because accuracy and fluency of the sterile and supply unit (SSU) after the introduction of AIDC technologies are apparently improving.

Introduction
Kanto Medical Centre NTT EC (Nippon Telegraph and Telephone East Corporation) is located in the south of Tokyo. It was remodelled at the end of 2000 as a 606-bed general hospital fully equipped with modern information communication technologies (ICT) including an electronic medical record (EMR) system. Barcode scanning for verification of patient identity via a wrist band was also introduced in 2008. The hospital treats 2,300 outpatients daily and more than 15,000 admissions annually. Surgical case volume is reaching 6,000 a year.

In order to overcome a shortage of operating rooms caused by unexpected increase of surgery, we have started to implement AIDC technologies in the Theatre sterile supply unit. We report here how we utilise radio frequency identification (RFID) and barcode for maximising the operating room facility (OR).

Process improvement in the Sterile Surgical Unit (SSU)
Standardisation of surgical procedure and outsourcing of non-specific tasks of medical staff are essential issues for increasing efficiency of the OR. In the past, most surgeons used to require their own surgical instruments and materials for performing surgery in their own way. Today, however, if a surgical procedure is the same, common surgical instruments and materials should be used regardless of surgeons. Standardisation of surgical procedure is essential not only for simplifying workflow in the Sterile Supply Unit (SSU) but also for saving cost in the OR. Outsourcing is very effective as proven in all aspects of hospital management. Freeing surgical nurses from such tasks as cleaning operating rooms and washing surgical instruments enables them to play their own roles in their original field.

Where outsourcing of tasks has taken place, outsourced staff, who work in the SSU, are often not familiar with the tasks. Declining efficiency in the SSU due to outsourcing might affect the entire efficacy of the OR. Process improvements in the following areas in the SSU were mandatory:

- Simplification of tasks
- Standardisation of workflow
- Improvement of safety and reliability
- Traceability of instruments (Frequency of use, sterilisation, repair, storage, event history etc.)
- Reduction of sets

Workflow of the SSU forms a loop composed of retrieve, sort, washing/decontamination, assembly, sterilisation, supply and storage. These processes, instruments going back and forth between OR and SSU, are very suitable situations...
for applying AIDC technologies; data capture can provide information as follows:

- When the surgery started and ended
- When and by whom instruments were retrieved and washed
- Which instruments are in each container
- How often instruments are being used
- When and which instruments have been repaired
- When, how and by whom the container were set, sterilized and stored
- Which patient the instruments were used upon (AIDS, Creutzfeldt-Jakob disease, etc)

Not only simplification of the task but also recording of event history will become possible with using barcodes and RFID.

**Introducing Unique Device Identification and Traceability**

As a unique device identification (UDI) for metal instruments we have employed DataMatrix, two-dimensional bar code, 3–5mm square in size, according to the guideline of JAMEI (Japan Association of Medical Equipment Industries).

Direct part marking to each instrument was carried out on its flat mirror–like surface by laser printing in cooperation with Mizuho Ika Kogyo Co. Ltd. Durability of barcode printing to rust and friction had already been proven through five-year tests. Reversed reading was chosen for increased legibility of barcodes.
Instruments are grouped together into a set by surgical procedure and housed in a container. For identifying the container an RFID tag was applied to it.

In Kanto Medical Center NTT EC the OR is located on the third floor and the SSU on the B2 floor. Both floors are connected with two elevators (EV) specific for surgical instruments. Automated guided vehicles carry used instruments in their containers to the entrance of the SSU.

After here, used instruments proceed along the arrows shown in figure 2.

A total of five RFID antennas are in place in the SSU:
- One at the entrance of the SSU
  Retrieval of multiple containers is simultaneously verified while they are passing in front of the antenna. Name of the set, which department used it and when it was retrieved are automatically recorded.
- One on the table for assembly
- Two at the exit of high pressure steam sterilizer
  Multiple containers are put into the sterilizer with the tagged face directed left. When sterilisation is completed and the containers are pulled out from the opposite side, tags are simultaneously recognised by the antenna at the exit. Data relating to sterilisation are recorded, namely which sterilizer was used, when sterilisation started and ended, completeness of process, name of the set and method of sterilisation.
- One at the exit of the SSU
  Finally containers are sent to the OR via EV for storage. The RFID antenna set here collects date of supply and name of the set.

Following the process of washing/decontamination via washer disinfector instruments are sent for assembly, where a barcode reader is installed to support tasks of assembly. Staff are requested to hold each instrument over the barcode reader before grouping it together into a set. A green light on the display indicates the instrument belongs correctly to that set. If a red lights appears this indicates the instrument is in the wrong set. Staff not familiar with assembly, while holding the instrument over the bar code reader, can refer to the name of the instrument and its photograph displayed on screen. The display also shows the number of individual
instruments that comprise the set. During this process if an instrument that needs to be repaired is found, it can be replaced with a new one.

We started the introduction of barcode and RFID in April 2008. Management error of surgical instruments relating to the SSU occurred in 108 out of 5,712 surgical cases (1.89%) from April 2007 to March 2008. 58 errors were in assembly (53.7%), 13 in retrieve (12.0%), 13 in washing/decontamination (12.0%), 10 in supply (9.3%) and 4 in storage (3.7%), with the remainder in other areas. Among the 58 assembly errors one third of them was due to poor inspection and one fifth of them due to lack of devices. During the first four months from April to July 2008, we experienced 31 errors among 1,913 cases (1.62%). However, only three errors occurred among 2,729 surgical cases (0.11%) from August 2008 to January 2009. Regular use of barcode and RFID possibly decreased the errors during these six months.

**Conclusion**

We have not yet obtained enough data. However, every staff member in the SSU believes that workflow of assembly has become simple and accurate.

At present, we have accomplished barcode printing on approximately 6,800 instruments. In 141 out of 208 sets an RFID tag has been installed on their containers. Printing on 8,000 instruments is the goal. Recently, printing on both sides of the instrument has been started to make barcode reading more convenient. Direct part marking to each instrument, however, is too costly for end users to do themselves. To increase the utilization of AIDC technology in OR and SSU, globally standardized UDI, such as GS1 DataMatrix barcode, should be marked on every product by the manufacturer. If such an identification system for instruments is built, in the near future, all sorting and distribution of surgical instruments and sets could be done automatically and more accurately using a robotic distributor, avoiding human error and saving manpower. Similar problems occur in the field of medication administration.

If AIDC technologies are applied to everything used, spent and wasted in the hospital, we will be able to track forward and trace back every care and every event for each patient as a link to records, composed of 5W1H, along the time line from his/her admission to discharge. It should ultimately assure patient safety and enable cost management in the field of health care.

**REFERENCE**

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