IMPLEMENTATION AND USE OF AUTOMATED TRACEABILITY SYSTEM IN THE CENTRAL STERILE SUPPLY DEPARTMENT

Implantação e uso de sistema de rastreabilidade automatizado em central de materiais e esterilização

Implantación y uso de sistema de rastreabilidad automatizado en central de materiales y esterilización

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ABSTRACT: Objective: To describe the implementation of the automated traceability system in Central Sterile Supply Department (CSSD). **Method:** Experiment report developed between 2011 and 2014. The traceability system best suited to the profile of the institution was chosen, and its basic license was purchased. The proper infrastructure and training were also adapted. **Results:** We decided to trace cases with barcodes. We began with the database; the cases were registered, and the labels printed. After one month, three cases were registered and 81 traceable units were created; in the third month, 698 units were created; after nine months, 7,669 units were created. Of the total number of stages, 5.0% are omitted; 4.2% are corrected; and 0.8% loose traceability owing to human error. Management is performed through reports and the discussion of results. Total implementation lasted nine months. **Conclusion:** Even with the incipience of the method, this study demonstrates that the automated traceability system benefits the hospital's CSSD.
Keywords: Database management systems; Sterilization; Sterilization center.

RESUMO: Objetivo: Descrever a implantação do sistema de rastreabilidade automatizada no Centro de Material e Esterilização (CME). **Método:** Relato de experiência desenvolvido entre 2011 e 2014. Foi escolhido o sistema de rastreabilidade mais adequado ao perfil da instituição e adquiridas as licenças básicas. Necessária adaptação da infraestrutura e treinamento. **Resultados:** Optou-se por rastrear a caixa por meio de código de barras. Iniciou-se pelo banco de dados. Realizou-se cadastro das caixas e impressão da etiqueta. Após um mês, 3 caixas estavam cadastradas e 81 unidades com rastreabilidade criadas; no terceiro mês, 698 unidades; e após 9 meses, 7.669 unidades foram criadas. São esquecidas 5,0% das etapas; 4,2% são corrigidas; e 0,8% perdem a rastreabilidade por erro humano. A gestão é realizada por meio de relatórios e discussão dos resultados. A implantação total durou nove meses. **Conclusão:** Mesmo com a incipiência do método, este estudo demonstra que o sistema de rastreabilidade automatizado trouxe benefícios ao CME do hospital.
Palavras-chave: Sistema de gerenciamento de base de dados; Esterilização; Centro de esterilização.

RESUMEN: Objetivo: Describir la implantación del sistema de rastreabilidad automatizada en el Centro de Material y Esterilización (CME). **Método:** Relato de experiencia desarrollada entre 2011 y 2014. Fue escogido el sistema de rastreabilidad más adecuado al perfil de la institución y adquiridas las licencias básicas. Necesaria adaptación de la infraestructura y capacitación. **Resultados:** Se optó por rastrear la caja por medio de código de barras. Se empezó por el banco de datos. Se realizó el registro de las cajas e impresión de la etiqueta. Tras un mes, 3 cajas estaban registradas y 81 unidades con rastreabilidad creadas; en el tercer mes, 698 unidades; y tras 9 meses, 7.669 unidades fueron creadas. Son olvidadas un 5,0% de las etapas; un 4,2% son corregidas; y un 0,8% pierden la rastreabilidad por error humano. La gestión es realizada por medio de informes y discusión de los resultados. La implantación total duro nueve meses. **Conclusión:** Incluso con la insipiencia del método, este estudio demuestra que el sistema de rastreabilidad automatizado trajo beneficios al CME del hospital.
Palabras clave: Sistema de administración de base de datos; Esterilización; Central de esterilización.

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INTRODUCTION

Central Sterile Supply Department (CSSD) is the location at the hospital where health products are processed[1]. It is a complex and extremely important process, carried out by a sequence of stages (cleaning, disinfection, preparation, packaging, sterilization, and distribution), which requires both operational and technological capacity to attribute quality to the services provided and ensure patient safety[2,3].

Owing to the need for well-established and validated protocols that comprise all the steps conducted in CSSD, on March 15, 2012, the Brazilian Health Surveillance Agency (ANVISA) published the ANVISA Board Resolution (RDC) No. 15[4], which establishes the requirements for best practices in the processing of health products. Article 26 provides that:

> CSSD must have a manual or automated information system that monitors and controls the records of the cleaning and disinfection or sterilization steps determined in this Resolution as well as of equipment maintenance and monitoring. Records must be archived to ensure traceability for a minimum of five years.

Traceability is defined as the ability to trace and identify the processing of health products and their use through previously recorded information, establishing the requirements for best practices in product processing[5].

The technology advancement, diversity of surgical materials, and growing concern with information management contributed to the development of automated traceability systems that have gained significant importance in recent times[5-7]. By combining technology with quality procedures, automated systems enable rapid information identification and increased productivity[6-8].

Automated traceability is a concept that arose from the need to know where a product is located and which raw materials were used in its production[6]. Widely used in industries and agriculture, these systems have been developed to encompass the processes conducted in CSSD[9]. They provide a multitude of functions and benefits – such as the insertion of results of biological control, preventive maintenance scheduling, and clamp control and productivity reports – which, if fully used, improve quality, streamline work, and reduce the possibilities of human error. Connectivity with other applications in the operating room (OR), which may or may not be purchased, increases operational efficiency by identifying patient or procedure and avoid scheduling conflicts, which brings significant improvements for all the people involved[9].

Six systems that allow automated traceability in CSSD are available in the Brazilian market. It is the responsibility of manager to know the product, its functions and possibilities as well as the necessary infrastructure to choose a supplier.

We chose an easy-to-use automated traceability system that enables access to information on cleaning, preparation, sterilization, and distribution of the health products dispensed by CSSD, which produced quality, safety, productivity, autonomy, and control to the processes performed.

Considering the low number of CSSD Departments that use an automated traceability system, the time required for implementation, the lack of reports in Brazil and the authors' involvement in the process, we share our experience in this article.

OBJECTIVE

To describe the implementation of an automated traceability system for health products in CSSD.

METHOD

This is a descriptive experiment report developed in the CSSD of a large private hospital that specializes in cardiology and heart surgery in the City of São Paulo.

To comply with RDC No. 15, the CSSD purchased an automated traceability system in November 2011.

Three suppliers were selected to present their systems. The retention of traceability applied by system, available tools, usability, possibility of reports, electronic storage of information, necessary infrastructure and connectivity with the available equipment, thermo-disinfectors, and autoclaves were evaluated by the authors (nurse and nurse manager), the information technology (IT) manager, and the clinical engineering manager.

The chosen system, same as the one used in Denmark, enables traceability and control of all process stages by barcode. We decided to track the surgical case, not on a piece-by-piece basis, assessing the possibility of employee's autonomy to replace broken or defective instruments, without the need to record it or interrupt the workflow.

Available features and functions depend on the purchased licenses (modules)[5,6]. The modules acquired by the hospital were administration (item and case registration), batch registration for washing machines and autoclaves, packaging on the screen (list opening on the computer screen at the workstation during preparation), multimedia (inclusion of images and videos), default report (management), and scanner (barcode scanning).

The amount invested in the acquisition of the system and necessary equipment was US$234,000.00 (two hundred and thirty-four thousand U.S. dollars).

After the purchase was completed, there was integration between the supplier and the hospital clinical engineering and IT to verify the physical space in CSSD, necessary adaptations and setup of servers, network, computers, and software. This period of infrastructure adaptation occurred in parallel with the work carried out between January and August 2012, for the renovation and modernization of the CSSD technology park.

The system implementation process is described in Figure 1.

The supplier was monitored during the development of the database and item registration, correcting errors at this stage.

The creation of the database and product database (surgical cases) is the longest stage and is specific to the administrator module, being the responsibility of the CSSD nurse at the institution. Thus, it took about four months, ending in April 2013.

Operational training was started with a few surgical cases registered (simpler in composition and with higher turnover, such as small surgical cases). Training happened between May and July 2013, guided by the IT specialist of the supplier. Only two nurses from CSSD participated in the first stage, which discussed system operation, inclusion of new items, creation of new cases, increase of serial number, label printing, and report issuance. In the second stage, practical training was conducted with the entire staff of nurses, technicians, and nursing assistants in CSSD. All steps (cleaning, preparation, reduction of items on the list, label printing, sterilization, distribution, and reentry) were simulated. Staffs trained during their respective shifts (morning, afternoon, and night) are divided into groups of up to three people so that everyone could participate in and understand this new process.

In July 2013, the use of the system commenced with the entire CSSD staff.

With trained employees and conducting stages correctly, new cases and trays were gradually added.

The inclusion of a new case depends on the assembly of the list and the addition of photos and alerts when necessary. It is a long process that requires the nurse's time and full attention, taking nine months to be completed.

RESULTS

Tracing of surgical cases starts during cleaning. Using a scanner, the employee is identified by the user code affixed to the badge. Through a model (Figure 2), the type of cleaning (manual or automated), equipment, cycle, and included products are selected.

Each barcode affixed to the case or container (Figures 3 and 4) must be scanned individually. At the end, a batch number is generated, and the cleaning cycle starts as per routine.

In the preparation area, the barcode of the case is scanned again, and the list of items that comprise the case is opened on the computer screen so the employee checks it and assembles it. Images, videos, and alerts, when previously inserted in the database, appear at this time. If the instruments are mixed, they are manually separated and identified by colored marking tapes. At the end of the verification, the "OK" button is pressed, and a label with information on packing date, expiration date, employee in charge of assembly and number of pieces is automatically printed (Figure 5).

At this stage, the system automatically generates a unique sequential number, called "unit number," in which it is possible to identify the product and trace the entire process in the administration module. This unit number is also printed on the detachable label, enabling affixation to the patient's medical chart and proper registration on it (Figure 6).

After the preparation stage, the case is released to the sterilization process which, as cleaning, is carried out by selecting the autoclave and the type of cycle using a model; through the label generated in preparation, the cases that will be inserted in the load generate a batch number.

We decided to automatically approve all sterilization batches whose processes were successfully completed. The equipment available at CSSD has all the documents required by current legislation, such as calibration, installation, and performance qualification as well as quarterly preventive maintenance. Parameters can be viewed in real time and are indefinitely stored in the database, enabling automatic approval reliability.

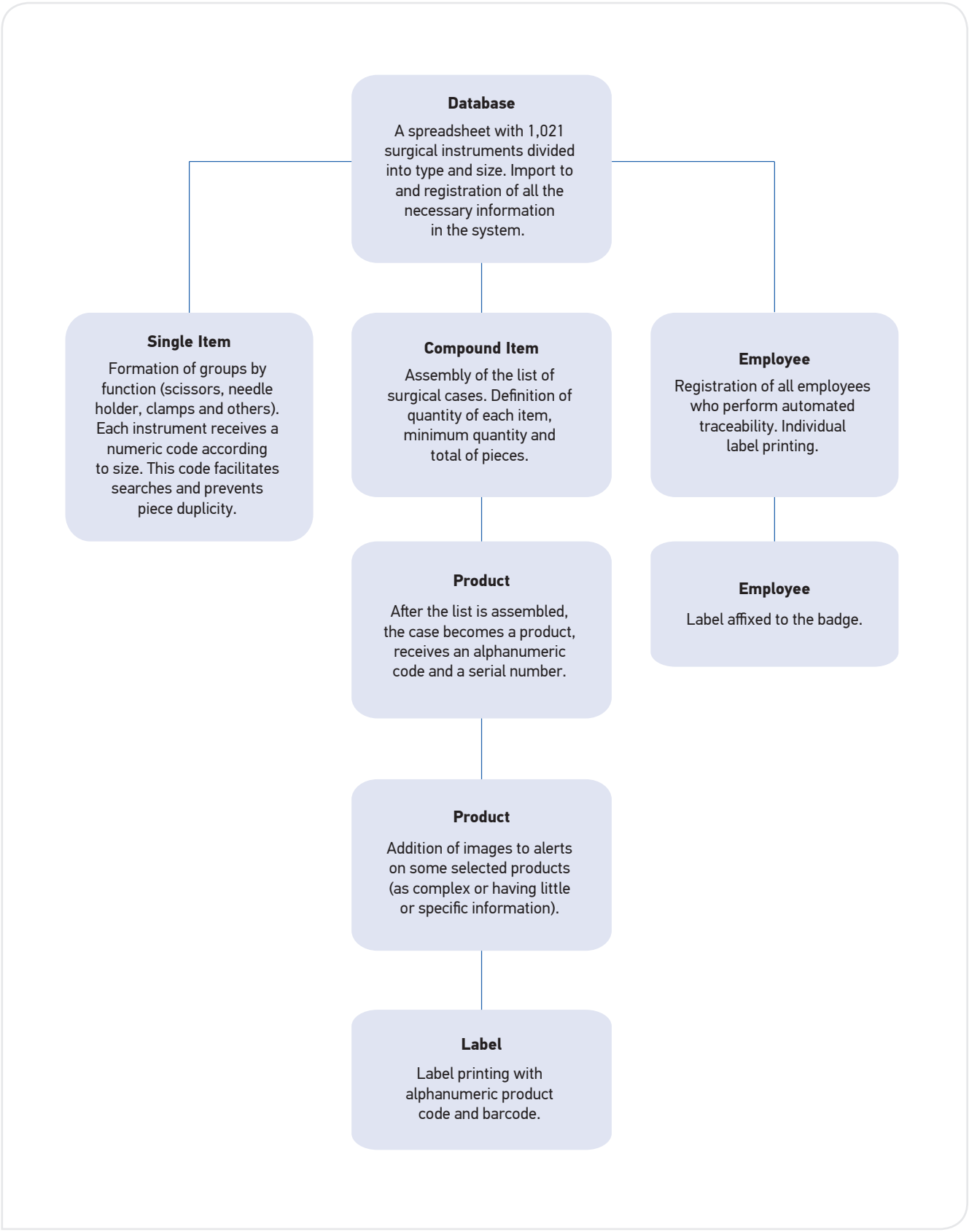

Figure 1. Implementation process for the automated traceability system.

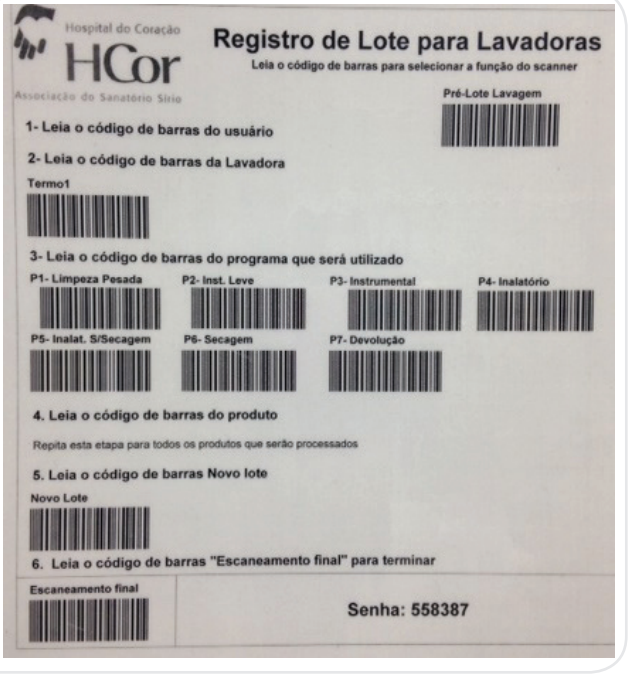

Figure 2. Model used in the automated traceability in the cleaning area.

Figure 3. Barcode affixed to the surgical case.

Figure 4. Barcode affixed to the container.

The case then becomes available in stock for distribution.

CSSD is responsible for the preparation of instrumentation carts for surgeries, according to the daily schedule. By dispensing surgical cases, a new reading is performed (also by scanner), in which the receiving client is selected, for example, the OR. New clients can be inserted at any time, expanding dispensing possibilities for all hospital units.

If the case dispensed is not used and returns to CSSD in perfect storage conditions, that is, with the full package, in a sealed and intact container, with its identification label, without humidity or visible dirtiness and dispensed to a clean OR, it reentries stock.

Figure 5. Model printed label.

Figure 6. Barcodes affixed to the patient's medical chart, ensuring traceability.

In case they are opened and/or used, the case is returned to the sluice room, also by means of a model and barcode scanning. Therefore, a case cycle ends. In preparation, a new cycle is started with a new unit number and a new history.

If there is any error in or out-of-sequence scanning, the user is notified by a sound and an alert, which are triggered on the scanner and the computer to prevent failure or skipped stages.

After one month of training and use of the system in CSSD, three minor surgery cases were registered, and 81 units were created, that is, 81 histories traced by the automated system. In the third month, 13 cases were registered, and 698 new units with the possibility of history were traced. In the sixth month, 52 cases were registered, and 3,031 units were traced; in the ninth month, 112 cases were registered, and 7,669 units were traced.

In May 2014, all the cases, containers, urethral catheterization trays, central venous accesses, phlebotomies and asepses as well as critical independent items (such as saws, optics, and batteries) were registered in the system.

There are operational failures related to the nursing staff. Approximately 5.0% of cleaning, sterilization, and dispatch stages are not performed by the automated system. Of these, 4.2% are corrected in the administration module by the nurse, who adds the missing information, enabling process continuity. Only 0.8% loose automated traceability due to human error. Consequently, manual traceability was maintained.

Management is carried out monthly by the head nurse, using general productivity reports, both on individuals and the equipment, failure reports, and cause analyses as well as result discussions and presentations with the nursing and clinical engineering staffs.

Support is performed by the supplier's IT specialist, either in person or from a distance, whenever necessary.

Thus far, there have been no failures of any kind in the system.

DISCUSSION

Resolution No. 15, from March 15, 2012, on the requirements for best practices in the processing of health products, establishes traceability as the ability to trace the processing history of health products and its use through previously registered information, using a manual or automated information system, with a monitoring record and control of the cleaning and disinfection or sterilization stages[4].

The application of traceability systems is very common in the food, pharmaceutical, automotive, aviation, and aerospace industries[11].

In the Brazilian literature, there are no reports on the use of automated systems in CSSD. In the international literature, few authors describe it, all of them emphasizing their benefits in comparison to manual traceability. Rapid information, reduction in instrument loss, maintenance signs, employee productivity monitoring, inventory control, and report issuance are some of the benefits found that support the literature[5,7,9].

The implementation time is not mentioned in any reference. As the second hospital to install this system in Brazil, there is insufficient comparative data to assess whether the nine-month period was good, regular, or bad. According to the supplier's installation checklist, one week is required for technical installation and setup, in addition to one week for staff training. The database varies according to each institution.

We observed implementation depends on the purchased modules and required resources. The most important factor is completing and detailing the database. The more people available to execute this stage, the faster the process is. We conducted the assessment during nine months, including installation, database, registration of all surgical cases, and training; this is a good period considering only one nurse was available, who was also responsible for CSSD.

Training is also not an issue addressed in any of the cited references. We noted that the application of the traceability system was easy. The stages with the greatest difficulty of assimilation and, therefore, errors refer to cleaning and sterilization batches, in which the case barcode is not read, thus not being available for the next stage. To minimize these failures, new trainings were requested and performed.

The involvement of the CSSD nursing staff is paramount to the implementation process and the use of the automated system. Knowledge is vital so that no steps are skipped, ensuring the authenticity of the recorded information. The OR nursing staff also plays a key role as it is responsible for affixing the barcode to the patient's medical chart.

National and international visits are constantly conducted to present and preview the practical use of the system, making CSSD a reference.

CONCLUSION

Even with the incipience of the method, this study demonstrates that the automated traceability system benefits the hospital's CSSD.

It is a gradual and thorough process that requires time and adjustments even after implementation.

Investment cost is high, but the automated traceability system adds quality and standardization to the processes performed, enabling more active management.

This article is expected to open the way for new reports that promote the inclusion of this technology for the benefit of CSSD.

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