

Development of a low-cost automated traceability system for the Sterile Processing Department

Desenvolvimento de sistema de rastreabilidade automatizada de baixo custo para centro de material e esterilização

Desarrollo de un sistema de trazabilidad automatizado de bajo costo para material y centro de esterilización

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ABSTRACT: Objective: To develop a low-cost system that enables the automation of the traceability process in a Sterile Processing Department. **Method:** This is an applied research, focusing on technological production (prototyping), aiming at the development of an automated traceability system for the Sterile Processing Department. The system was developed following the model of the software life cycle for developing prototypes, making use of existing functionalities in the Microsoft Excel 2013[®] software. **Results:** Following the phases of the proposed model, and in accordance with the guidelines of competent bodies, an automated traceability system was developed, with a simple and intuitive design, capable of performing the following functions: registration, by using a barcode; access to information on the processes performed at the Sterile Processing Department, by an automatically fed spreadsheet; and security, with individual login and password. **Conclusions:** This study fulfilled its objective of proposing a low-cost traceability system that would meet the needs of the Sterile Processing Department, which included not only the rules imposed by regulatory bodies, but also the automation of the traceability process. **Keywords:** Nursing informatics. Sterilization. Information systems.

RESUMO: Objetivo: Desenvolver um sistema de baixo custo que possibilite a automatização do processo de rastreabilidade em um centro de material e esterilização. **Método:** Trata-se de pesquisa aplicada, com foco em uma produção tecnológica (prototipação), visando ao desenvolvimento de um sistema automatizado de rastreabilidade para centro de material e esterilização. O desenvolvimento do sistema seguiu o modelo das fases do ciclo de vida de um software para o desenvolvimento de protótipos, utilizando-se para sua construção funcionalidades existentes no *software* Microsoft Excel 2013[®]. **Resultados:** Seguindo as fases do modelo proposto, e de acordo com as diretrizes dos órgãos competentes, desenvolveu-se um sistema de rastreabilidade automatizada, com visual simples e intuitivo, capaz de executar funções: de registro, por meio de código de barras; de acesso às informações dos processos executados no centro de material e esterilização, por meio de planilha alimentada automaticamente; de segurança, com *login* e senha individuais. **Conclusão:** Este trabalho cumpriu seu objetivo de propor um sistema de rastreabilidade de baixo custo que atendesse às necessidades do centro de material e esterilização, necessidades que compreendem não somente as normas impostas por órgãos reguladores, mas também a automatização do processo de rastreabilidade. **Palavras-chave:** Informática em enfermagem. Centro de esterilização. Sistemas de informação.

RESUMEN: Objetivo: Desarrollar un sistema de bajo costo que permita la automatización del proceso de trazabilidad en un CME. **Método:** Se trata de investigación aplicada, con foco en la producción tecnológica (prototipado), con el objetivo de desarrollar un sistema de trazabilidad automatizado para CME. El desarrollo del sistema siguió el modelo de las fases del ciclo de vida de un software para el desarrollo de prototipos, utilizando para su construcción funcionalidades existentes en el software Microsoft Excel 2013[®], en su versión de escritorio. **Resultados:** Siguiendo las fases del modelo propuesto, y de acuerdo con las directrices de los órganos competentes, se desarrolló un sistema de trazabilidad automatizado, de apariencia sencilla e intuitiva, capaz de realizar: funciones de registro, por medio de un código de barras; acceder a la información de los procesos ejecutados en el CME, a través de una hoja de cálculo alimentada automáticamente; y seguridad, con usuario y contraseña individual. **Conclusión:** Este trabajo cumplió con su objetivo de proponer un sistema de trazabilidad de bajo costo que satisficiera las necesidades de los CME, necesidades que incluyen no solo las normas impuestas por los organismos reguladores, sino también la automatización del proceso de trazabilidad. **Palabras clave:** Informática aplicada a la enfermería. Esterilización. Sistemas de información.

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INTRODUCTION

The Sterile Processing Department (SPD) is considered a hospital sector of indirect health care, being responsible for the processing and distribution of various products associated with the provision of health care and diagnostic care. It must ensure a quality process that meets the existing demands in the institution in which the SPD is inserted¹.

The organizational structure of the SPD underwent several remodeling processes over the years, only reaching the model as it is known nowadays at the end of the 20th century. At the beginning, the SPD was solely and exclusively responsible for the sterilization process of hospital devices, with the other preparation functions being the responsibility of hospitalization units themselves, which occurred until the 1970s, when new technologies and the complexity of surgical equipment began to demand more qualified professionals for their processing².

Currently, the several processes carried out at the SPD, associated with the surgical equipment, attribute to the sector a manufacturing characteristic, operating as a production line, in such a way that it is possible to appropriate industrial management concepts — such as “lean,” which, when applied to the field of health (Lean Healthcare), aims to increase the efficiency of processes and consequently improve the quality of care and reduce costs¹.

Another important factor for the SPD maintenance is the efficient management of expenses. Combining the demands of the institution where it is inserted with the adequate processing cost is an essential function for the nurse manager of the SPD, who must be especially attentive to the reduction of waste of material and time, according to the Lean Healthcare philosophy, improving processes that add value to the final product and eliminating those that add no value, seeking to reduce the burden and increase the quality and productivity of services³.

The SPD process management surpasses the physical boundaries of the sector, because when the performed processes do not meet the expectations, other sectors of the hospital, and the users themselves, are affected, which translates into increased costs with treatments and diagnoses, prolonged hospitalizations, or even irreversible damages to patients. With regard to disease prevention, traceability systems are the most effective measure, as they allow the identification of failures in the processing of products by the validation of the performed processes, in line with what is determined by competent bodies⁴.

According to Resolution RDC No. 15 of the Collegiate Board of Directors of the Brazilian Health Regulatory Agency (ANVISA)⁵, every SPD must have a process and product traceability system, whether manual or automated. The manual traceability process is the most prevalent in Brazil; however, the automated process has several advantages when compared with it — such as productivity gains, information reliability, and facilitation of process management and access to files⁶.

Despite its advantages, few hospital institutions in Brazil use the automated system due to the high cost of the process implementation, which is usually performed by outsourced companies⁷.

The Brazilian Unified Health System (SUS) has an extensive network of hospital services. Nonetheless, the assistance provided is below the national and international minimum standards, due to the archaic nature of practices and methods of resource management, among which the SPD is inserted, which compromises the quality and efficiency of care in addition to raising its costs¹.

The solution towards a more efficient and economical system requires a reformulation in the management. The computerization of management processes is of vital importance as for the modernization of management, considering that it facilitates access to information and processes that, with regard to the SPD, translates into automated and efficient traceability. However, its implementation is never prioritized in relation to the modernization of other activities, mainly aimed at direct care or structural reforms⁸.

It is noteworthy that, in the last two decades, technological development has exponentially occurred, in such a way that, currently, electronic technologies are present both in private life and in work environments. There is a trend for the health area to use this development for improving the quality of the provided care, which includes the SPD⁹.

Taking this into consideration, the research question arises: “Is it possible to develop a low-cost system that meets the traceability requirements recommended by ANVISA and the demands of a large SPD?”, having the “modernization of SPD traceability systems” as the object of the study.

Prototyping is one of the concepts of software engineering that have been recurrently appropriated by the Health Sciences, producing technologies that provide evolution and facilitation of activities performed by professionals in the area. Software development follows conceptual lines that guide projects, such as the life cycle model, which ranges

from the planning of the software objectives to the implementation and evolution of the project¹⁰.

OBJECTIVES

To develop a low-cost system that enables the automation of the traceability process in a SPD.

METHOD

This is an applied research, focused on a technological production (prototyping), aiming at the development of an automated traceability system for implementation in a SPD. Applied research is characterized by the need to produce knowledge and develop products for practical and short-term application¹¹.

The development of the system followed the model proposed by Pressman and Maxim¹⁰ for the development of prototypes, which consists of the application of the phases of a software life cycle: communication, planning, modeling, development, and implementation¹². In line with the proposed model, the development of the system was divided into three stages.

In the first stage, Communication and Planning, the functionalities necessary to the system were defined, according to the literature, as well as the support software for the development of the system.

The functionalities proposed for the system should, at least, follow the criteria established by ANVISA⁵ with regard to the traceability system, and should contain aspects of security, information recording, and access to information. To do so, it is understood that the traceability system must be able to trace the products in the processing phase in the SPD, physically divided into four areas (cleaning, preparation, sterilization, and distribution), and in the sectors for which they were destined, being necessary to record the transfer of the product from one area to another.

Regarding the information deemed relevant for the development of the presentation interface, it was defined that the data to be collected by the system would be related to the products, processes, and professionals of the SPD.

As for the development of the system, it was established that it would occur by coding macros of the Microsoft Visual Basic, a functionality existing in the Microsoft Excel 2013[®] software, in its desktop version, as it is a program widely used

in institutions, which would facilitate the process of implementation in the unit and the reduction of costs.

The second stage, Modeling and Developing, used the information collected in the first stage to build the user interface, using elements considered relevant. At this stage, the functional prototype was developed with the functions deemed essential, as detailed in the Results section.

The third stage, Implementation, is the final stage of prototyping, in which the system is implemented and use barriers are identified, enabling correction. It should be noted that this stage will take place in another phase of the project development, and the present study will only be responsible for prototyping the initial system.

RESULTS

Using the parameters previously determined, we developed the functional prototype presented next.

To record the output and input information of the products in the SPD, the authors created a form containing the basic data to trace the products in the institution (Figure 1), composed of the fields: "Tray Code," referring to the identification code of each type of tray; "Tray Name," identifying the type of tray expressed by the code; "Destination/Origin

Source: author's collection.

Figure 1. Tray registration.

Sector,” referring to the sector from which the tray is coming or to which it will be sent. There are also the buttons: “Register,” to enter information in the system; “Return,” in cases in which the tray is unused and still sterile; “Clear,” to empty the form fields.

All fields are automatically completed after reading the product code, present on the identification label (Figure 2) affixed to all products. The code consists of a barcode identification that will be interpreted by a suitable optical reader.

The registered information is transferred to a spreadsheet (Figure 3) that gathers the information provided with other automatically-generated data. The employee who enters the data (OPERATOR 1) is registered in the system as well as the date and time when the information was entered. The “Return” column identifies products that have returned to the SPD unused.

IDENTIFICAÇÃO DO HOSPITAL: CENTRAL DE MATERIAL E ESTERILIZAÇÃO
CONTROLE INTERNO DE INSTRUMENTAL CIRURGICO 600103

BANDEJA DE PEQUENOS PROCEDIMENTOS - CME

PREPARADO POR: _____
DATA DO PREPARO: / / VALIDADE: _____
AUTOCLAVE: _____ ESTERILIZADO POR: _____
OBSERVAÇÕES: _____

ITEM	DESCRIÇÃO	QUANTIDADE
01	CUBA REDONDA	01
02	PINÇA DISSEÇÃO DENTE DE RATO	01
03	PINÇA DISSEÇÃO ANATOMICA	01
04	PINÇA KELLY CURVA	01
05	PINÇA KELLY RETA	01
06	PORTA AGULHA	01
07	TESOURA METZEMBAUM	01
08	TESOURA DE MAYO	01
TOTAL		08

Source: author's collection.

Figure 2. Identification tag.

Each SPD area has an independent spreadsheet for data entry. All released information is gathered in a specific spreadsheet (Figure 4) that is updated as new information is generated, allowing the product to be traced at the institution. The communication of the spreadsheets occurs through the use of the institution's intranet.

The security of the system is a very important factor and must prevent the release of information by unauthorized personnel as well as access to data already recorded. To prevent unauthorized access and false information, each SPD employee will be assigned a unique username and password.

When opening the spreadsheet, such access will be requested to unlock the previously mentioned functions (Figure 5). For greater security, the system blocks the user after a certain period of inactivity, requesting the login again.

In order to avoid data loss, the system also performs automatic saving in certain periods of time, the creation of a backup copy in a restricted folder, and allows the conversion of all the information in the spreadsheets into a PDF file, for later analysis or other needs.

OPERADOR 1
ÁREA DA CME

CÓDIGO	BANDEJA	DESTINO	OPERADOR	DATA	HORA	DEVOLUÇÃO
401005	CAIXA 05A - INSTRUMENTAL DE PEQUENO FRAGMENTO (TITÂNIO)	CCA	OPERADOR 1	01/11/2021	17:35:07	
401008	CAIXA 07 - INSTRUMENTAL DE GRANDE FRAGMENTO	CCA	OPERADOR 1	01/11/2021	17:35:25	
401015	CAIXA 13 - CAIXA AO DE GRANDE FRAGMENTO	CCB	OPERADOR 1	01/11/2021	19:40:43	
401017	CAIXA 15 - DCS E DHS	AMBULATORIO	OPERADOR 1	01/11/2021	21:16:08	
401005	CAIXA 05A - INSTRUMENTAL DE PEQUENO FRAGMENTO (TITÂNIO)	CCA	OPERADOR 1	01/11/2021	21:38:07	DEVOLUÇÃO

Source: author's collection.

Figure 3. Information spreadsheet.

ATUALIZAR

Buscar saída da bandeja por código ou nome

Buscar entrada da bandeja por código ou nome

DISTRIBUIÇÃO							LIMPEZA					
CÓDIGO	BANDEJA	DESTINO	OPERADOR	DATA	HORA	DEVOLUÇÃO	CÓDIGO	BANDEJA	DESTINO	OPERADOR	DATA	HORA
401005	CAIXA 05A - INSTRUMENTAL DE PEQUENO FRAGMENTO (TITÂNIO)	CCA	OPERADOR 1	01/11/2021	17:35:07		401008	CAIXA 07 - INSTRUMENTAL DE GRANDE FRAGMENTO	CCA	OPERADOR 1	01/11/2021	22:05:25
401008	CAIXA 07 - INSTRUMENTAL DE GRANDE FRAGMENTO	CCA	OPERADOR 1	01/11/2021	17:35:25		401015	CAIXA 13 - CAIXA AO DE GRANDE FRAGMENTO	CCB	OPERADOR 1	01/11/2021	22:07:40
401015	CAIXA 13 - CAIXA AO DE GRANDE FRAGMENTO	CCB	OPERADOR 1	01/11/2021	19:40:43		401017	CAIXA 15 - DCS E DHS	AMBULATORIO	OPERADOR 1	01/11/2021	22:10:20
401017	CAIXA 15 - DCS E DHS	AMBULATORIO	OPERADOR 1	01/11/2021	21:16:08							
401005	CAIXA 05A - INSTRUMENTAL DE PEQUENO FRAGMENTO (TITÂNIO)	CCA	OPERADOR 1	01/11/2021	21:38:07	DEVOLUÇÃO						

Source: author's collection.

Figure 4. Traceability spreadsheet.

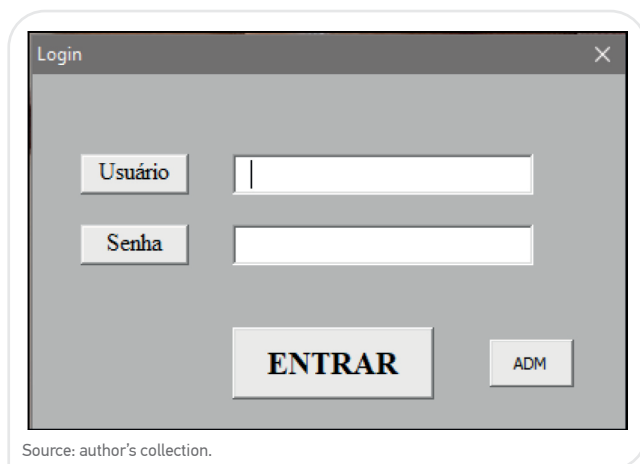


Figure 5. Login.

DISCUSSION

The technological advance present in several health sectors, especially in the SPD, is undeniable. Nevertheless, the acquisition of these technologies often presents financial and logistical obstacles, which makes this process unfeasible. The automated traceability system is one of these technologies in question, as few intuitions acquire outsourced software capable of providing the automation of this process⁸.

The added value of the automated traceability system is the main constraint on the acquisition of this technology. Taking this into consideration, a prototype was developed based on operating systems and programs compatible with the reality of various institutions, including public ones.

The developed prototype aimed at maintaining the cost of development and implementation at negligible values, meeting, as minimum prerequisites, what is determined by Resolution RDC No. 15, of ANVISA⁵, according to which there must be a registration of all products in all processing stages of the SPD, as well as of those responsible for its execution, and accessibility to information, allowing the traceability of products within the institutions.

All the developed functionalities meet the established prerequisites, presenting the user with a simplified interface that is easy to use, in addition to being effective and compatible with the needs of a large SPD.

Studies carried out in different institutions have shown that the implementation of computerized management systems, such as the automated traceability reported in this research, presents a series of benefits to hospital intuitions, of a managerial, financial, and patient-safety nature.

The computerized traceability system is a management tool of great value in health institutions, both in the public system and in the private network, for facilitating the audit of internal processes, assisting to identify failures and waste and, thus, proposing more efficient models¹³.

A study conducted at a university hospital in the city of Porto Alegre (state of Rio Grande do Sul, Brazil)¹⁴ on the use of surgical instruments contained in trays used in the operating room, employing the Lean Healthcare methodology, indicated that the use of a computerized traceability system allows the optimization of SPD processes with consequent reduction in operating costs. The system would enable to identify and resolve situations that are burdensome to institutions in an uncomplicated way, such as reducing the number of “re-sterilizations” of expired trays and the reallocation of surgical instruments from unused trays to those with greater rotation, in addition to serving as a basis for acquiring new instruments. The optimization of the SPD promotes more agility in the delivery of sterile material, which, indirectly, increases the efficiency of the operating room, allowing the performance of more procedures.

The importance of using a computerized traceability system was also mentioned in a study conducted in the state of São Paulo (Brazil), in a private hospital¹⁵. The authors state that, from a managerial point of view, health institutions should be seen as a company, where nurses, especially those from the SPD, must assume a strategic posture to reduce waste and costs related to the execution of processes, without harming the provision of health care, and point to the computerized traceability system as a vital tool. The study also points out the SPD responsibility in distributing, managing, and gathering surgical instruments in other sectors.

The surgical instruments dispensed to other sectors are also under the responsibility of the institution’s SPD, which is responsible for supervising the quantity, packaging, and conditions of the material. A study on this matter, carried out in hospitals in the state of Minas Gerais (Brazil)¹⁶, indicated several nonconformities in relation to the ideal packaging of sterile instruments, as, overall, healthcare sectors do not have the physical structure to maintain the parameters that ensure the shelf life of the instrument sterility. Aiming at the efficiency of the management of these resources, and avoiding waste and compromising the safety of health care, the SPD must regulate the dispensing of materials to the sectors, in such way to avoid unnecessary accumulation of sterile instruments in the healthcare sectors. The information

obtained from the computerized traceability system would be of great value, as they enable to visualize the demands of each sector, allowing greater control over the quantity dispensed, and facilitating the location of products with an upcoming expiration date.

The information collected by the computerized traceability system can also be useful in managing the SPD human resources. According to a study on the workload in the sector¹⁷, SPDs tend to have little control over daily production, which makes it difficult to request employees for the sector, as they are unable to base their demand. The computerized traceability system allows easy access to productions by period, employees, and products, serving as reliable data to justify employee requests.

The development of technologies that improve SPD process management, which includes traceability, affects the entire organizational structure of the hospital institution. Automated systems produce more reliable information, by increasing the quality and reliability of processes, benefiting not only the institution, but also the user, contributing to patient safety, similar to other digital technologies focused on health^{18,19}.

Despite the great value for the improvement and modernization of SPD processes, the development of technological productions aimed at the sector, such as the presented system, still lacks scientific studies in Brazil.

As a limitation of the present study, the authors mention the fact that the developed system is a prototype not yet implemented. When implementing the program, one or more functions will probably have to be reformulated, in such a way that the program is functional and fulfills its intended purpose.

CONCLUSION

This study fulfilled its objective of proposing an automated traceability system that meets the needs of the SPD, being a

powerful management tool. Its implementation will enable to reduce failures in processes and facilitate access to information, making the services of the sector more efficient, economical, and safe.

The low cost of development and implementation of the system is also in accordance with the proposed objective, thus enabling its use in different institutions as an alternative to systems already on the market and provided at high costs.

All in all, it is expected that the present study will serve as a basis for further research and that more authors will be inspired by such a proposition and produce more content on the subject.

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None.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

AUTHORS' CONTRIBUTIONS

LCSB: Project Management, Formal Analysis, Conceptualization, Data Curation, Investigation, Methodology, Resources, Writing — original draft, Writing — review and editing, Software, Supervision, Validation, Visualization. YCD: Project Management, Formal Analysis, Conceptualization, Data Curation, Investigation, Methodology, Resources, Writing — original draft, Writing — review and editing, Software, Supervision, Validation, Visualization. CRLS: Project Management, Formal Analysis, Conceptualization, Data Curation, Investigation, Methodology, Resources, Writing — original draft, Writing — review and editing, Software, Supervision, Validation, Visualization.

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