Occupational Safety and Hygiene II

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Tracking Surgical Instruments: From a management perspective to safety issues

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ABSTRACT: This paper focuses the importance of tracking Surgical Instruments (SI). Since the goal of healthcare is to be able to deliver necessary quality services, while, reducing healthcare costs, it was necessary to understand the problems related to these particular devices. The aim was to search for research that already tackled these issues and what were their suggestions/solutions to these problems. Therefore the problems of tracking SI in healthcare environments are recognized and analyzed, centered in the facilities through where the instruments flow. To validate the literature review, an investigation on the real context was performed. This was conducted in a participant-observer research in three hospitals to correlate the findings and specify the problem. This investigation shows that, if the primary scope of tracking SI was a way to achieve optimization of the devices process flow, problems of patient safety are also issues that could be addressed trough management control.

1 THE MANAGEMENT PERSPECTIVE

Hospitals are under constant pressure to control health costs (Aguado et al. 2007). In order to cut costs, the optimization of asset management within healthcare appears to be an important issue (Bates et al. 2001). In hospitals, high-value mobile assets (e.g. blood, beds, instruments, surgical devices) are often misplaced, lost, or stolen. It is common for a hospital to loose 10% of its inventory annually (Wicks et al. 2006). This is mainly due to the fact that no one in a hospital has real-time information about where movable assets are because these resources are frequently moved due to emergency necessity responses in different locations. As such, it is a "normal" situation for nurses to spend a great deal of time tracking down appropriate assets so that they are delivered on time. In fact, hospitals have difficulty to locate 15–20% of their assets due to inappropriate and ineffective monitoring procedures (Li et al. 2006). In this context, healthcare organizations are searching for answers to reduce operational costs while, at the same time, facilitating healthcare delivery in order to offer patients with highly reliable care service. Bates et al. (2001) conclude that appropriate use of technology in healthcare could result in process simplification and substantial improvement in patient safety. Establishing a traceability system is a key enabler to enhancing patient safety, improve the quality of care and at the same time reduce operational costs (Tu et al. 2009). In the healthcare sector, one of the environments that are being especially targeted for improvement is the Operating Room (OR). This is due to the fact that the OR is the highest revenue generator within a typical hospital, but at the same time, it is also the one that has the largest costs. Another important fact is that the quantity and complexity of SI, the high cost of equipment and staff time, and the inherent risk involved in many surgeries, makes the OR and all the processes that are involved directly or indirectly with surgeries (e.g. sterilization procedures), the main setting for improvements in patient safety and efficient management operations through technology.

From the stated above, it is clear that the healthcare sector is a multifaceted structure that faces a great demand to reduce operational costs, but at the same time, improve patient care and safety. In the case of patient safety, reducing errors is a required task in all the environments but mostly in the OR. Therefore, it is necessary to further develop the knowledge on the main problems in the OR, and relate them to the management perspective. In other words, investigate the importance of implementing asset management in surgery focused on human-errors to improve patient safety. At the same time, procedures directly linked with surgeries (i.e. sterilization procedures)

will also need to be investigated in order to analyze the general surgical workflow.

1.1 *Operating room safety problems*

Healthcare professionals work under an omnipresent threat of medical errors. Given the increasing complexity of both the modern healthcare environment and the patient population, reducing medical errors is becoming a high priority task for healthcare policy makers and the medical community alike. While the incidence and outcomes of specific types of surgical errors are relatively well described, the knowledge of why these errors occur is incomplete (Gawande et al. 2003).

One of the most perplexing examples of such a medical error is the occurrence of a retained foreign object, following a surgical procedure, such as sponges or SI (Gawande et al. 2003). Retained Foreign Objects (RFO) may cause harm to the patient and can result in serious professional and medicolegal consequences (Imran & Azman 2005). As such, it is a problem that can seriously compromise healthcare quality and patient safety. Despite being theoretically completely preventable, it has been estimated that a foreign object is retained anywhere between 1 in 9000 operations to 2.4 per 10,000 (Greenberg et al. 2008) with one study involving 47 claims resulting in a average cost of 52,581 US dollars in compensation and legal expenses. The most important preventive measure to ensure that foreign objects are not retained in the surgical cavity is to manually count the SI before and after the surgeries and compare the counts (AORN 2008). Nevertheless, in a study of coronary artery bypass surgery, approximately 0.7% of operations were associated with an incorrect count and the cost of each incorrect count was over 900 US dollars. Additionally, the protocols mentioned can account for up to 14% of operative time (Greenberg et al. 2008). In this way, many perioperative nurses question the efficacy of counting SI for every procedure since most hospitals are now concerned with efficiency and decreasing operating times rather than counting (Goldberg 2010). The literature related to the counting of SI (Halvorson 2010) describes error-prone processes and the major issues of performing routine tasks when pressured or distracted. Characteristics that contribute to the error-prone nature of counting include that counting often is highly automatic and prone to unexpected interruptions and that surgeons tend to move to a different task before completing final validation that the count is correct (Gibbs et al. 2005). In summary, when counting practices were first established the OR environment was much different than it is today. Not only has the instrumentation and technology become much more complex, but procedures have also become more sophisticated and complicated. Despite this, no new technology or strategy has emerged to help surgeons and/or nurses ascertain the accuracy of their counts or perform them with more consistency, accuracy, or efficiency (Halvorson 2010). Therefore, it seems that there is a significant need for electronic tagging and detection systems for SI.

1.2 *General sterilization problematic*

As stated, one of the most important objectives of healthcare facilities is improving quality of care and patient safety, which is to a high extent related to hygiene conditions. At this level, one of the major challenges is to prevent nosocomial infections (Rutala & Weber 2008).

In general, SI are seen as a high-risk item since it penetrates sterile tissues such as body cavities. These items are called critical items because of the risk of infection. As such, they must be sterilized. The use of inadequately sterilized SI represents a high risk of transmitting pathogens (Rutala & Weber 2008). Inadequate destruction or inactivation of pathogens (e.g. bacteria, fungi, viruses, spores and other microorganisms) left on an instrument by one patient can result in serious adverse clinical outcomes in the next patient. Improperly sterilized SI can promote the development of Surgical Site Infections (SSI).

SSI is a dangerous infection that has been associated with mortality and healthcare costs with huge economic impact. As stated by Alexander et al. (2011) the large increases in healthcare costs may be related to the increased incidence of SSI, which may lead to an annual increase of 900 million US dollars in healthcare costs. Although SSI is the most commonly reported nosocomial infection and accounts for 14–16% of all infections among hospital inpatients, published data on SSI may be underestimated because many SSI that are developed after patient discharged are not recorded (Smyth & Emmerson 2000). Therefore, the sterilization of SI is an imperative to prevent SSI.

For the sterilization of instruments there are several methods (e.g. Ethylene Oxide, Hydrogen Peroxide Gas Plasma, Dry Heat, Ozone). The oldest and most commonly used is steam sterilization under pressure—also called autoclaving (Goldberg 2010). Mainly because it is the most reliable in destroying prions, that are associated with the Creutzfeldt-Jacob disease and other degenerative neurologic syndromes, although some cases still exist (Brown et al. 2000). As such, sterilization processes are able to overcome the common microorganisms, but uncertainties about efficacy towards prions destruction subsist. Therefore, the identification of instruments that were involved in patients with degenerative neurologic syndromes

would be an important achievement regarding patient safety. Therefore, the optimization of the sterilization process flow is an imperative. As the changing context of healthcare structures encourages hospitals to improve the quality of services while reducing the associated costs, the sterilization process is a potential area for important cost savings. The sterilization activity stands as a major focus to improve efficient management of the instrumentation. SI should be accurately traced in all their movements. From the different OR to the SU, and at the same time it must be possible to identify them individually in the SU.

2 UNDERSTANDING THE PROBLEM IN REAL CONTEXT

Although the main findings of the problem of tracking SI have been already acknowledge, these were at a theoretical level. In order to understand the actual problem that SI pose in healthcare, an investigation of the current situation in the real context was seen as a way to corroborate the previous findings and to acquire a better knowledge of what really was important.

2.1 *Understanding the problem*

As stated this research began with the problem of understanding the importance of tracking the SI. In this scope several questions arose. Namely, if tracking SI were necessary because instruments were stolen? Loose? Mixed? Damaged? Or the main scope was on improving productivity? Faster and simpler management? Patient safety? Therefore, after these general questions, specific questions were developed as a guide to the overall aim of stating and specifying the problem (Tab. 1).

These questions were divided in pre-operative, surgery and post-operative groups. This was done to understand the overall cycle with the specific knowledge of each phase.

2.2 *Participants*

This research was developed in three hospitals (Two public and one private) located in northern Portugal. All the hospitals in this research are general hospitals that offer clinical care, with an emergency room open 24 hours per day and 7 days per week, perform surgeries in a regular basis (every weekday with more than four operating rooms), and have an indoor SU.

2.3 *Procedure*

The research was implemented and conducted in a participant-observation strategy as prescribed by Zenios (2009), in three major hospitals for the same surgical procedure (hernias). All surgeries were performed in the traditional way (no laparoscopes). The research began by sending authorization letters to the clinical directors of the three hospitals, explaining the aim of the research and the need to visualize surgical procedures. The main aim was not in the surgical procedures by themselves but in following the SI through all the steps, and spaces in order to understand and close the cycle. The focus was on the cycle that involved surgical procedures in the OR; therefore, the cycle that involves the emergency room had no part in this research.

In the observations, several records were taken on a notebook, and with a photo camera. Additionally, seven performance measures of routine tasks were also recorded in terms of time.

Table 1. Guide questions for the research.

Pre-operative	Surgery	Post-operative
What steps are required?	How many people were in the OR?	What steps are required?
Who is involved?	How many people are involved directly with the SI?	Who is involved?
How were the SI taken to the surgery? From where?	How are they been used/handled?	Are the SI "clean" just before the procedure?
How are they prepared?	Was it necessary for more/different SI during the procedure? Why?	How are they been handle/ used?
What are the safety measures?		How is the sterilization done?

General
How long did the overall cycle take (SI)?
How many people are involved in the overall cycle? In what steps? What are their various roles?
What are the limitations or difficulties associated with the current cycle?
How is the device used? In all the steps?

2.4 *Main findings*

From the observations done, it was possible to see that the overall cycle (Fig. 1) is not so different between hospitals. All hospitals have the cycle divided in eleven zones (A to K), been those zones identical for all hospitals. Another thing in common is the type of people involved (1 to 4). All observations show that there are four types of participants in the overall cycle. Although operational assistants work on this cycle, the only responsibility that they have is transporting SI from the SU to the OR and vice-versa. The sterilization technicians are responsible for the maintenance of the

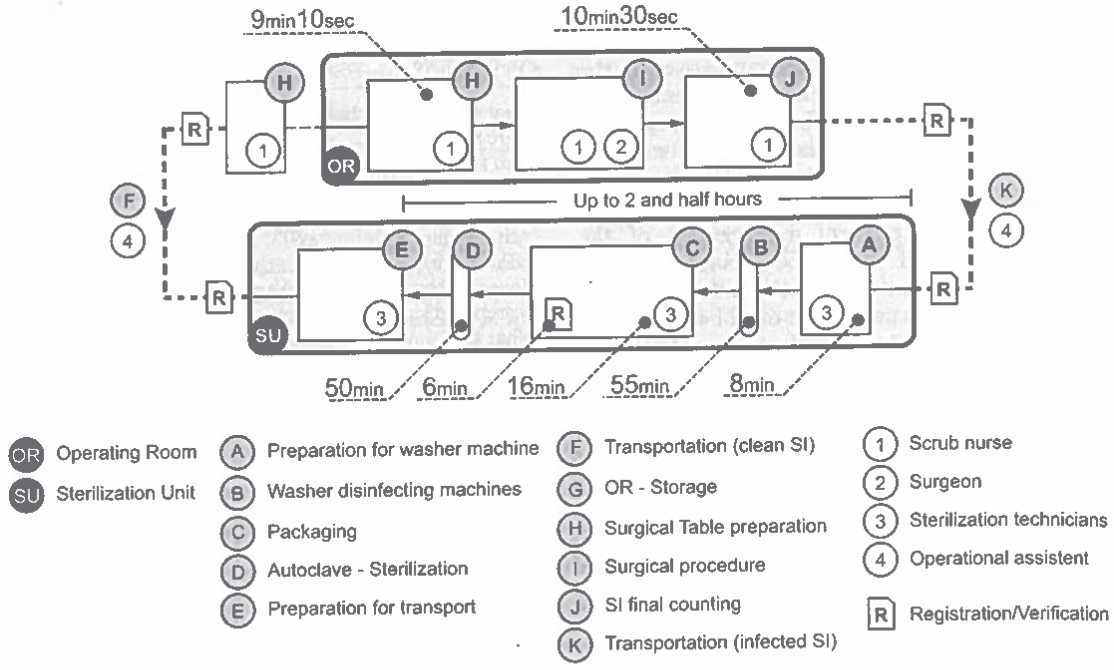

Figure 1. Overall cycle of surgical instrument (people involved, tasks per zone, average task-time measures).

SI. There work is concerned with operational and technical procedures focused on the SI. They clean, wash, verify, pack and sterilize the instruments. Their work relates to the safety of the main procedures of the product (surgeries), from a patient, scrub nurse and surgeons perspective. They are the basis of the SI cycle. Working in the background in order to maintain the proper functions of the instruments. They are responsible for the management of the SI.

Scrub nurses are responsible for the preparation of surgeries. In the OR the SI are their responsibility.

They assist the procedure but the issues of safety are their major concern; this is why they count the SI before (Zone H) and after the surgery (Zone J), assuring that no SI is left behind.

It is possible to say that, as sterilization technicians are responsible for the SI in the SU, in the OR that responsibility is of the scrub nurse. In turn, surgeons are only responsible for the surgical procedure. They are not concerned with any other task other than performing the surgical operation and they just work in zone I. Although the number of zones is the same, the tasks in zones with the same letter are different from hospitals. It is possible to say that, the major differences can be seen in SU area. Divergences are seen in the private hospital, as they do not have the task of cleaning (Zone A) the SI before washing machine process (Zone B), and do not store surgical sets in the SU (Zone E). The absence of cleaning is due to the notion that the washing machine process (Zone B) as already a pre-cleaning, so doing it by hand is not necessary (although the other two hospitals perform this task). The lack of storing the SI in the SU is due to the reduced number of sets that the private hospital has opposed to the other two. In this way, their OR-Storage is sufficient for storing all instruments. The private hospital is also different from the other two in the case of preparing the sets, since they don't mix instruments. In other words, they perform the cycle in the SU for each instruments set. The inner cycle of the SU is done separately—a cycle for each set.

Another major difference can be seen in the number and place of the documentation/verification process. The hospital relies on written documents to manage the SI cycle. There are two types of documents: the documents that follow the SI set and the delivery and pick-up registrations. The first one is a document that lists all the SI contained in that set (by name and number of SI). The main purpose of this document is to make it possible for the scrub nurse to know exactly what SI the set has. The registrations are performed in order to track the sets and assign a worker to the delivery and picking-up tasks.

In the case of the two public hospitals the management of the SI/Sets are done in the same way. The main document is performed in each cycle, by

) Scrub nurse
) Surgeon
) Sterilization technicians
) Operational assistent
] Registration/Verification

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a sterilization technician (Zone C), and the document follows the set through all zones till reaching zone A. This is how they control that a set has completed a cycle. The registrations are done when entering and leaving the OR and SU areas and the OR-Storage. In the case of the private hospital, the main document is the same for several cycles. Outside the OR the registrations are the same as the other two hospitals.

What could be concluded from the observations is that SI requires significant attention inside a healthcare provider organization such as hospitals. Aside from the typically large number of SI that a hospital has, they represent an asset normally associated to the most difficult procedures. These devices, far from their general use, have a very distinct cycle that involves lots of people. If, from a general point of view, it can be said that a major preoccupation is centered in the number of people that interact directly with these instruments and the different places where they are used, other problems such as leaving instruments inside the human body, makes the task of tracking SI a complex but necessary approach. Nowadays there is no consensus regarding the documentation/verifications tasks. Nevertheless what is worth saying is that this constant need to track the SI and the way that is done are very time-consuming. Another important fact is that in order to prevent accidents in the OR, strict protocols are implemented in healthcare providers, since the scrub nurse needs to perform the counting of the SI before and after surgical procedures. This task is, obviously, difficult, error prone, and also very time-consuming. Another aspect is that currently, it is near-impossible to tell how many times a SI has been used. For security reasons, individual management of the SI need to be performed, so the issue of tracking becomes much more than just a question of preventing accidents; it is also a way to reduce task times, optimize nurse efforts, and manage the number of uses of each instrument.

3 CONCLUSION

Asset management in healthcare is an imperative if hospitals hope to reduce costs. These costs have different causes and are of different types. What is seen as an obvious cause to raising costs is the particular structure of hospitals. Given the increasing complexity of modern healthcare environment issues related to whether the assets move and are found and, the number of assets available pose a challenge to improve management control. In this way, one system that healthcare providers are considering is the integration of tracking technologies. Although tracking technologies is seen as an important system in the management of assets that leads to a reduction of costs, several other problems exist where these technologies could be preventive. In this paper it was stated that in hospitals medical errors might lead to adverse events, some with irreversible consequences. This was what it was acknowledged from the analysis of the problems concerning the surgical procedures and the sterilization process. These two main facilities that involve any surgery were investigated for three different, but at the same time cumulative, reasons. First, the OR, as this is the facility with the highest costs in any hospital but at the same time the one that involves the most difficult procedures, second the sterilization unit as this is the facility that assures the integrity of the instruments used in the surgery and, third the instruments as they are the main focus of this problem. As such, in the OR, the major problems identified were the occurrence of RFO after surgery. Although the existence of preventive measures, these procedures were seen as an error-prone practice.

In the SU the facility responsible for the prevention of SSI, the problems were associated with the need to identify instruments that were in contact with patients with degenerative neurologic syndromes, since sterilization processes do not always achieve the sterility assurance level.

The analysis of the problems of these two facilities has demonstrated the need to incorporate electronic tagging in SI, which could permit tracking and identification of the instruments in their working cycle. In the OR it would be much easier to count instruments and to prevent the occurrence of RFO and in the SU the identification of SI would be possible and the efficient management of instruments improved.

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