INNOVATING TO EVOLVE

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The word innovate is derived from the Latin *innovare* meaning new, renew, incorporate, introduce as new. Innovation is the act of innovating, that is, introducing new ideas. Peter Drucker, who is considered the father of modern business management, refers to innovation as one of the greatest, if not the most important, objectives of any organization. Innovation is what keeps an organization alive and competitive.

Today, innovation is a concept that is much more connected to values and directly associated with the effects of change. However, innovation is not free from risks, uncertainties, and unpredictability of results in these challenging times. Innovation is a strategy for survival and transformation.

The academic journal of the *Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização* – SOBECC Journal – also innovates to evolve.

In 2016, the SOBECC Journal went through many changes. The most important one was its inclusion in the Electronic System of Magazine Publishing (*Sistema Eletrônico de Editoração de Revistas*) – SEER – a management system for electronic publishing of periodicals. This change enabled the open access to the papers published in the journal, providing greater visibility and sustainability for the production of knowledge.

Open access means availability of academic or scientific published content to anyone, via SEER. By means of the open access, all papers published in this journal can be read, downloaded, copied, printed, researched, distributed, referred, saved, and forwarded to friends and professors.

Plenty of work was done behind the scenes for this innovation to occur, such as changing the publishing and submission norms, elaborating verification lists, and training the publishing council so they were capable of conducting the assessment process within the system. All these were accomplished with the support of OJS-SEER operation and assisting technical staff.

Despite the difficulty of this initial process, the journal dared to innovate even more. Those who access the SOBECC online site (https://revista.sobecc.org.br/sobecc) will find the previous collections of the journal uploaded to the system. The collections go as far back as the very first indexing. They have over 10 years of history.

Now, those who no longer have a copy of the journal or their own papers, or those who need to research scientific production in the areas of Surgical Centers, Post-Anesthesia Recovery, Material and Sterilization Center, and Infection Control, will be able to retrieve them from the system. The process is still being implemented.

For this last edition of 2016, another innovation was proposed and you will see that some of the conferences from the 10th International Sterilization and Infection Control Symposium related to health care, held between August 31 and September 2, were published. The authors accepted the invitation to methodologically format their lectures and share them in a scientific journal.

This action aimed at sharing the knowledge of professionals, experts in their fields, and renowned researchers; therefore, knowledge of Nursing may not only grow, but also give more visibility to those who accept this mission.

The title of this editorial is "Innovating to Evolve." It was possible because those who were previously responsible for the magazine also proposed innovations and took risks to put them into effect, with the support of a visionary board of directors.

Developing the journal with the current format was only possible because many nurses dedicated hours – if not days – to the elaboration of papers aimed at sharing their knowledge with the SOBECC community.

Evolving or surviving will depend henceforth on each and every one of us. Thus, we lay out a challenge for nurses, along with their colleagues and multiprofessional staff, to publish their work in order to value their experiences, to occupy the spaces offered to them, such as that of SOBECC journal, and to raise awareness on the important role they play in society.

We approach the end of 2016 hoping that turbulent moments experienced this far have turned into positive experiences and great achievements. And may the New Year find you with peace, health, and knowledge.

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SUSPENSION OF SURGERY AT A UNIVERSITY HOSPITAL

Suspensão de cirurgias em um hospital universitário

Suspensión de la cirugía en un hospital universitario

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ABSTRACT: Objectives: To analyze the incidence of surgery suspension, to categorize surgical cancellations into medical specialties, and to identify its main causes. **Method:** Quantitative, descriptive, and retrospective study carried out in a teaching hospital in the Northeast region of Brazil. The population was composed of 1,600 elective surgeries scheduled from January to September in 2013. Data analysis was performed through descriptive statistics. **Results:** The overall rate of surgical procedure cancellation was 19.5%. The most frequent suspensions occurred in pediatric, oncology, and general surgeries. Twenty-three causes for surgery cancellation were found in the institution, amongst them patients' absence and institutional conditions represented mainly by problems with material, human, and organization service-related resources. **Conclusion:** The rate of surgery cancellation refers to the need of reducing it; for such, it is necessary to monitor this indicator continuously and to implement strategies for its reduction.

Keywords: Surgery department, hospital. General surgery. Perioperative nursing. Quality indicators, health care.

RESUMO: Objetivos: Analisar a incidência de suspensão de cirurgias, categorizar os cancelamentos cirúrgicos por especialidades médicas e identificar as suas principais causas. **Método:** Estudo quantitativo, descritivo, retrospectivo, realizado em um hospital de ensino do nordeste brasileiro. A população foi constituída por 1.600 cirurgias eletivas programadas no período de janeiro a setembro de 2013. A análise dos dados foi realizada através de estatística descritiva. **Resultados:** A taxa global de cancelamento de procedimento cirúrgico foi de 19,5%. As maiores frequências de suspensão ocorreram nas cirurgias pediátricas, oncológicas e gerais. Foram identificadas 23 causas para o cancelamento de cirurgias na instituição, dentre elas destacaram-se o absenteísmo do paciente e as condições institucionais, representadas principalmente por problemas com recursos materiais, humanos e organização do serviço. **Conclusão:** A taxa de cancelamento de cirurgia remete à necessidade de reduzi-la; para tal, faz-se mister o monitoramento contínuo desse indicador e a implementação de estratégias para sua redução

Palavras-chave: Centro cirúrgico hospitalar. Cirurgia geral. Enfermagem perioperatória. Indicadores de qualidade em assistência à saúde.

RESUMEN: Objetivos: Analizar la incidencia para suspensión de cirugías, categorizar las cancelaciones quirúrgicas por especialidades médicas e identificar sus principales causas. **Método:** Estudio cuantitativo, descriptivo, retrospectivo realizado en un hospital universitario del noreste del Brasil. La población constituida por 1.600 cirugías programadas de enero a septiembre de 2013. El análisis de datos se realizó utilizando estadística descriptiva. **Resultados:** La tasa global para cancelación de cirugías fue de 19,5%. Los mayores porcentajes de suspensión fueron encontrados en las cirugias pediatricas, oncologícas y las generales. Se identificaron 23 causas para cancelación de cirugías en la institución, entre ellas se destacaron la ausencia del paciente y las condiciones institucionales, representadas principalmente por problemas con recursos materiales, humanos y organizacionales. **Conclusión:** Es necesario controlar e implementar estrategias para reducir la taxa de suspension encontrada.

Palabras clave: Servicio de cirugía en hospital. Cirugía general. Enfermería perioperatoria. Indicadores de calidad de la atención de salud.

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INTRODUCTION

A surgical procedure performance involves extensive use of human, material, and technological resources, and promotes alterations in the psychological profile and in the financial resources of patients and their relatives[1].

Costs of these procedures correspond to 40.0% of the total expenses of a hospital[2]; therefore, inappropriate management of the operative block has a significant impact on health services units, mainly on public institutions where resources are scarce[3].

Thus, the surgical unit performance should be measured in order to subsidize managers' decisions and to provide a good care with professional excellence, effective use of resources, low risk for the patient/client, and high level of user's satisfaction[4].

One of the indicators applied for assessing the efficiency of a surgery service is the rate of procedures suspension, which considers all reasons for interruption, whether related to the patient or to the hospital[5].

In the last decade, the theme has received great attention from health-related investigators in all the world[6]. However, we need to open our eyes in order to understand the perspectives of all factors involved in this process and to identify its causes, for improving the quality of the provided service and relieving the patient and family's suffering[7].

We found diverging rates of surgery suspension in the international literature, which vary between 0.37% (found in a Taiwanese hospital[8]) and 28.0% (found in a Nigerian study[6]).

In Brazil, a review study that assessed publications from the years of 1990 to 2010 identified surgery suspension rates that varied between 5.1 and 33.0%, and their main causes referred to clients, due to their lack of clinical conditions or non-attendance to hospitalization[9]. A subsequent investigation, which assessed the reasons for surgery suspension, using the root-cause analysis method, showed as main reasons: improper material (42.0%), dirty material (29.0%), lack of operation room (12.9%), lack of anesthetist (9.7%), and patient's conditions (6.4%)[10]. Due to the repercussions of surgery cancellation to users and hospitals and to the importance of this indicator for managing the operative block, the following questioning was raised: "What is the frequency and main causes of surgery suspension in a university hospital of the Northeast Region of Brazil"?

OBJECTIVE

Therefore, this study aimed at analyzing the incidence of surgery suspension at a university hospital of the northeast region of Brazil, at categorizing the most predominant surgical cancellations into medical specialties, and at identifying the main causes of surgery cancellations in a university hospital.

METHOD

A retrospective study of descriptive nature and quantitative approach was carried out in a medium-sized teaching hospital that provides medical-hospital care of medium complexity, which is a reference in the Brazilian Unified Health System (SUS, acronym in Portuguese).

The institution is composed of 123 beds, including 5 beds in the Intensive Care Unit (ICU). The surgical center includes 4 operation rooms for elective procedures, working from Mondays to Fridays, since 07 a.m. to 07 p.m. It performs 200 surgical procedures, on average, per month. The surgical specialties are maxillofacial, head and neck, general, digestive system, oncology, pediatric, plastics, breast, gynecology, urology, intestine, rectum, and anus.

The population was composed of elective surgeries, including outpatient surgeries performed in the surgical center, which were scheduled in the period from January to September in 2013. The choice for such time period was made because a systematized printed instrument was implemented in the institution in January of that year, with the purpose of registering information related to surgery suspension.

Medical records whose surgical procedures had been conducted in the surgical outpatient clinic (located therefore out of the surgical center) were excluded.

Every scheduled surgery that by any reasons did not happen in the scheduled date was established as a suspended surgery.

A nursing undergraduate student collected data every week by using an instrument prepared for such purpose, which includes records of performed and suspended surgeries.

Data regarding suspended surgeries are divided into groups of cancellation causes, as follows:

- personal conditions: patient's non-attendance, delay, or abandonment;

- clinical conditions: exams alterations, change or no clinical condition, improvement of clinical situation, respiratory infections, other infections, cardiovascular problems, high systemic blood pressure;
- institutional conditions: surgeon's non-attendance, no anesthetist, problems with material resources, no blood components, no ICU space, no exams, no ward space, scheduling errors, date alteration, hospitalization difficulty, no team communication, no patient's proper preparation;
- other causes and non-mentioned causes.

They are also divided into surgical specialties: pediatric, general, digestive system, oncology, plastic, mammary, colon and rectal, otolaryngology, gynecology, urology, head and neck, among others.

The descriptive statistics of simple frequencies was performed for data analysis. The surgery suspension rate was calculated through the number of suspended surgeries divided by the total amount of surgeries that had been scheduled in a certain period and multiplied by one hundred.

The guidelines of the Health National Council Resolution no. 466/2012 were followed. The University Hospital Ethics Committee from *Universidade Federal de Sergipe* approved the study under CAAE no. 24871014.1.0000.5546, through platform "Brasil".

RESULTS

During the studied period, 1,287 surgeries were performed and 13 were suspended among the 1,600 scheduled surgeries, with a 19.50% surgical cancelation rate.

The surgical specialties presenting the highest frequencies of surgery suspensions were pediatric surgeries (26.8%), followed by oncology surgeries (14.4%), and general surgeries (13.4%). The specialties with the lowest rates were head and neck (1.9%) and urology (1.0%) (Table 1).

After analysis of surgery suspensions causes, we found that 50.8% of the occurrences were associated with institutional conditions and 43.5% with the patient, due to personal (22.4%) or clinical conditions (20.8%) (Table 2).

Among the most frequent reasons due to personal conditions is patient's non-attendance or delay. The causes regarding the patient's clinical conditions mainly include respiratory system infections, followed by systemic blood pressure raise and change or no clinical conditions.

Among the causes related to institutional conditions, the highest and with similar percentages were problems with material resources, no ward space, and surgeon's non-attendance. And the less frequent included no anesthetist, no ICU space, no examinations, and surgery suspension by the anesthetist.

DISCUSSION

The rate of surgery cancellation used for hospital management in this study – this datum translates the efficacy of operation rooms and it is considered a service quality indicator – was similar to those found in national investigations conducted in teaching hospitals of the states of São Paulo, Minas Gerais and Paraná, which identified 17.3, 17.0, and 14.1% rates, respectively[11-13].

Nevertheless, when compared to international research, these rates are quite above those found in foreign university hospitals. We can quote 8.80% in Korea, 4.40% in Lebanon, 0.37% in Taiwan, and 0.21% in China[8,14-16]. This is an unfortunate finding, since it is partially translated by low quality of the provided health services. This happens

Table 1. Frequency distribution of suspended surgeries according to surgical specialties in Aracaju, Sergipe, Brazil, 2013.

Surgical specialty	n	%
Pediatric	84	26.8
Oncology	45	14.4
General	42	13.4
Digestive system	31	9.9
Plastic	28	8.9
Mammary	22	7.0
Colon and rectal	18	5.8
Gynecology	12	3.8
Otolaryngology	11	3.5
Non-mentioned surgery	11	3.5
Head and neck	6	1.9
Urology	3	1.0
Total	313	100.0

because cancellations immediate consequence include non-optimization of operation rooms use, among many other factors.

Table 2. Distribution of surgical suspensions causes according to personal, clinical, and institutional conditions in Aracaju, Sergipe, Brazil, 2013.

Causes of surgery suspension	n	%
Personal conditions		
Patient's non-attendance or delay	70	22.4
Abandonment	1	0.3
Subtotal	71	22.7
Clinical conditions		
Respiratory system infections	24	7.7
High systemic blood pressure	17	5.4
Change or lack of clinical conditions	10	3.2
Other infections	6	1.9
Clinical condition Improvement	4	1.3
Alterations in exams	3	1.0
Cardiovascular problems	1	0.3
Subtotal	65	20.8
Institutional conditions		
Material resources-related problems	27	8.6
Lack of ward spaces	21	6.8
Surgeon's non-attendance	20	6.3
Scheduling errors	18	5.8
Surgery suspension by surgeon	17	5.4
Lack of patient's proper preparation	14	4.5
Hospitalization difficulty	11	3.5
Date alteration	10	3.2
Lack of blood components	7	2.2
Lack of anesthetist	4	1.3
Lack of ICU space	4	1.3
Lack of exams	3	1.0
Surgery suspension by anesthesiologist	2	0.6
Lack of team communication	1	0.3
Subtotal	159	50.8
Other causes	11	3.5
Non-mentioned causes	7	2.2
Total	313	100.0

With regard to surgical specialties, pediatric procedures presented the highest suspension rate, which is four times higher than studies conducted in the southeast region of the country; for instance, studies of the State of São Paulo presented rates of 14.4 and 6.4%[13,11]. Investigators attribute pediatric surgery suspensions to the ineffective communication between professionals and children's relatives. They also declare that information is superficial and incomplete; therefore, they leave doubts and create feelings like anxiety, fear, insecurity, and distress[11].

Among the causes of surgery suspension, the highest percentage found was related to client's non-attendance or delay. This result is similar to that pointed out by investigations carried out in teaching institutions from the cities of the southeast region of Brazil, which show 18.1% and 18.5%[17,11].

The percentage found in Aracaju (22.4%), a city in the northeast region of Brazil, is relevant because it is expressively lower than the rate found in a study conducted in a hospital of Fortaleza (39.9%)[5]. Such information can be explained because, in the institution under study, surgeries are scheduled a few days before the procedure and, in the other institution, scheduling is done very early.

In the present study, the percentage seen in the client's non-attendance or delay variable is higher than that of studies conducted in the United Kingdom (6.8%), Lebanon (11.1%), and India (4.1%)[18,14,19]. Patient's non-attendance generates waste of material, time and staff, besides the fact that another patient loses the opportunity of scheduling his/her surgery; thus, the service of surgical block and related units is not optimized[20].

Therefore, a better investigation about the reason of client's non-attendance is necessary to plan intervention strategies. A study on user's absenteeism shows the importance of conducting an active search to confirm the presence of an user in the surgery and/or modifications in the surgical procedure scheduling system, because some of the surgeries are scheduled far in advance[11,17].

In the present study, the third cause of cancellations corresponded to clinical conditions, with a rate approximately twice higher than that found in a university hospital of the State of São Paulo, and 1.6 times lower than that found in a large-sized hospital in Taiwan[11,8].

According to literature, many of the cancelled cases could have been recognized earlier and therefore could

have enabled the decision of corrective measures. It is an agreement between the authors that the existence of anesthetic outpatient clinics and preoperative visits reduces the number of surgical suspensions, because they allow the prediction of possible clinical complications[8,20].

The institutional conditions significantly contribute to the suspension of surgery procedures in the studied health unit, and they are the main cause responsible for half of these suspensions and appear as the second most frequent group. Issues related to the organization, scheduling errors, impossibility of surgeon's attendance, and date alteration, explain such fact. The same result was found in a study conducted at a teaching hospital in Paraná, Brazil, which concluded that the lack of specific materials and equipment was also the second cause of surgery cancellation; therefore, it could be a challenge for public institutions[12]. In them, the purchasing process is low and bureaucratic and the lack of interest in the existing resources is increasingly higher[12].

The frequency of surgery suspension causes is different and depends on the reality of each institution; however, the encountered problems are common and should be monitored through indicators that will subsidize planning and evaluation of improvement actions.

Although the item regarding team communication failure presented low percentage, in this study, ineffective communication seems to be the central and subliminal cause of several revealed items, and its impact might be more relevant than the presented numbers.

CONCLUSION

The study found an overall rate of surgery cancellation similar to the national rates and higher than international ones. The highest suspension frequencies occurred in pediatric, oncology, and general surgeries. Twenty-three causes for surgery cancellations were found in the investigated institution, among them patient's absenteeism and institutional conditions received higher attention, mainly represented by problems with material, human, and organization service-related resources.

Hence, monitoring the indicators related to surgery suspension should be a continuous action and intervention strategy planning should be subsidized with the aim of decreasing the rate of suspension and consequent minimization of trouble caused for clients, relatives, and institution.

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SAFE SURGERY CHECKLIST APPLICABILITY IN HOSPITAL SURGERY CENTERS

Aplicabilidade do checklist de cirurgia segura em centros cirúrgicos hospitalares

Aplicabilidad de la lista de cirugía segura en centros quirúrgicos de los hospitales

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ABSTRACT: Objective: To identify the safe surgery checklist applicability in hospital surgery centers. **Method:** This is a quantitative research carried out at national level, after approval by the Research Ethics Committee of Universidade Federal de Alagoas. The research was performed using e-mail, and included nurses who were members of Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização (SOBECC) and worked in surgery centers. Data analysis was performed by means of the chi-square test. **Results:** All the participants (100%) were aware of the checklist. Of the 113 research participants who used the checklist, 89 (78.76%) participants observed changes in the surgical team's interpersonal communication, and 94 (83.18%) participants confirmed that after the checklist implementation, there were improvements in professional assistance performance. The main advantages of the checklist implementation were rapid and easy completion and service organization. Team's disengagement was the main difficulty reported by the research subjects. **Conclusion:** The safe surgery checklist application contributes to the quality of care provided to surgical patients.
Keywords: Surgery department, hospital. Checklist. Patient safety.

RESUMO: Objetivo: Identificar a aplicabilidade do *checklist* de cirurgia segura em centros cirúrgicos hospitalares. **Método:** Pesquisa quantitativa, realizada em nível nacional, após aprovação do Comitê de Ética em Pesquisa da Universidade Federal de Alagoas, via correio eletrônico, com enfermeiros associados à SOBECC e que atuam em Centro Cirúrgico. A análise dos dados foi realizada pelo teste do χ^2. **Resultados:** Todos os participantes (100%) conhecem o *checklist*. Dos 113 participantes da pesquisa que o aplicam, 89 (78,76%) observaram mudanças na comunicação interpessoal da equipe cirúrgica e 94 (83,18%) afirmaram que após a aplicação do *checklist* houve melhorias na atuação profissional na área assistencial. As principais facilidades para a aplicação do *checklist* foram o preenchimento rápido e fácil e a organização do serviço. A falta de participação da equipe foi a principal dificuldade referida pelos sujeitos da pesquisa. **Conclusão:** A aplicação do *checklist* de cirurgia segura contribui para a qualidade da assistência prestada ao paciente cirúrgico.
Palavras-chave: Centro cirúrgico hospitalar. Lista de checagem. Segurança do paciente.

RESUMEN: Objetivo: Identificar la aplicabilidad de la lista de cirugía segura en centros quirúrgicos de los hospitales. **Método:** Estudio cuantitativo, llevado a cabo a nivel nacional, después de la aprobación del Comité de Ética en Investigación de la Universidad Federal de Alagoas, vía correo electrónico, con las enfermeras asociadas al CSSD (SOBECC) y que trabajan en un centro quirúrgico. El análisis de los datos se realizó mediante el test de $\chi 2$. **Resultados:** Todos los participantes (100%) conoce la lista de comprobación. De los 113 participantes en el estudio que se aplican, 89 (78.76%) observaron cambios en la comunicación interpersonal del equipo quirúrgico y 94 (83.18%) informó de que, tras la aplicación de la lista de comprobación, ha habido mejoras en la práctica profesional en el área asistencial. Las principales facilidades para la aplicación de la lista de comprobación fueron el llenado rápido y sencillo, y la organización del servicio. La falta de participación del equipo fue la principal dificultad reportadas por los sujetos de la investigación. **Conclusión:** la aplicación de la lista de comprobación de cirugía segura contribuye a la calidad de la atención dada a los pacientes quirúrgicos.
Palabras clave: Servicio de cirurgía en hospital. Lista de verificación. Seguridad del paciente.

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INTRODUCTION

Some mistakes made by health professionals have a strong impact on patients' lives. The most common adverse effects are performing surgeries in the wrong patients or laterality mistakes[1].

The strategy adopted by the World Health Organization (WHO) to promote safety of the surgical patient was the creation and implementation of a standard checklist in health institutions to support surgical teams in decreasing the occurrence of damage to patients[2]. This tool encompasses safety measures during the intraoperative period; however, the pre- and postoperative periods are also highly important to the surgical patient's safety[3].

The tool is characterized as a standard checklist that needs to be observed by the entire surgical team, i.e. anesthesiologist, surgeon, assistants, and nursing professionals. It is composed of three stages: the first checking (Sign In) takes place before induction of anesthesia, with the patient's presence in the operating room. The second checking (Time Out) is performed before the surgical incision, and the last checking (Sign Out) is carried out by the end of the procedure, before the patient leaves the operating room to the recovery room[4].

The checklist implementation can be fast and cost-effective. In addition, only one person is recommended to be in charge of the application. Although the nurse is the most indicated professional to coordinate the checking process, any professional participating in the surgical procedure can play this role. If needed, such professional should have the authority to interrupt or impede the surgical process advancement, as small details may be unnoticed[5].

The need to deepen the research on this theme supported this study. Consequently, hospital's teams and health professionals may acquire more knowledge of the importance of safe care processes; therefore, it is relevant for ensuring excellence and quality to the care provided to the surgical patient.

OBJECTIVE

To identify the safe surgery checklist applicability in hospital Surgery Centers.

METHODS

This is a quantitative research approved by the Research Ethics Committee of *Universidade Federal de Alagoas*, CAAE: 42024315.9.0000.5013. The study included professors and nurses from five Brazilian regions. These professionals worked in surgery service management and assistance, and their e-mails were provided by the *Sociedade Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização* (SOBECC). The inclusion criteria adopted to build the sample of this study were working as a nurse in surgery centers. The exclusion criteria were working in the Central Sterile Supply Department (CSSD) and Post-anesthesia Care Unit (PACU) and not being a SOBECC member.

Data was collected from September to November 2015. We maintained all data as private and confidential. The invitation to participate in the research was sent via e-mail, including guidelines and rationale of this study, as well as the Free Informed Consent and the questionnaire.

The data collection tool applied in this research was an adaptation of the questionnaire used in the study *"Checklist de cirurgia segura: análise da segurança e comunicação das equipes de um hospital escola,"* which was carried out in the countryside of the state of São Paulo[5].

The data collected were organized in tables, and then analyzed in statistical software used in research (Statistical Package for the Social Sciences – SPSS). Data analysis was carried out by means of the chi-square test. If the p-value was less than 0.05, results were considered statistically significant.

RESULTS

The study participants were 147 nurses who worked in all the regions of Brazil. The Southeast region of Brazil had the highest representativeness in the sample with 67 participants (45.57%), followed by the South region with 36 (24.48%) participants (Table 1). The importance of including all the Brazilian regions in this study should be highlighted, as it enabled to verify the checklist applicability at a national level.

The age range with higher prevalence among the research participants was 30–39 years. This age range included 60 (40.82%) participants, and was followed by the age range of 40–49 years, with 39 (26.53%) participants. Participants older than 50 years corresponded to 29 (19.73%) respondents, and 19 participants were aged 22 and 29 years (12.92%). The sex distribution was different: 132 participants (89.80%) were female and 15 participants (10.20%) were male.

Table 2 shows the predominance of specialization in the educational level of the subjects – 78 (53.06%) participants. Nurses with a master's degree totaled 37 participants (25.18%).

The analysis of length of professional experience in surgery centers showed that 37 participants (25.17%) had professional experience equal or higher than 16 years; 31 participants (21.08%) had 6–10 years of experience; 27 professionals (18.37%) had 3–5 years or 11–15 years; and 25 professionals had 0–2 years (17.00%) of professional experience in surgery centers.

Of the 147 participants, 138 (93.87%) of them worked in assistance or management of surgery centers, 8 (5.44%) were nursing professors in the studied field, and only 1 (0.68%) was a nursing resident.

Among the 147 participants, 100.00% are aware of the safe surgery checklist; 113 (76.87%) declared that the safe surgery checklist is applied in the surgery center where they work; and 34 (23.12%) do not use it. The 34 (23.12%) subjects that do not use the checklist reported that they would like it to be applied if they had been working as nurses in an operating room.

Table 1. Geographic distribution of the research subjects (Maceió, Alagoas, Brazil, 2015).

Variable	n	%
Geographic distribution of participants		
North region	8	5.44
Northeast region	25	17.00
South region	36	24.49
Southeast region	67	45.58
Central West region	11	7.49
Total	147	100.00

n: number of participants; %: frequency.

Table 2. Distribution of the educational level of the participants (Maceió, Alagoas, Brazil, 2015).

Variable	n	%
Educational level		
Undergraduate	13	8.84
Graduate	78	53.06
Master's Degree	37	25.18
Doctor's Degree	18	12.24
Post-doctor's Degree	01	0.68
Total	147	100.00

n: number of participants; %: frequency.

There was a predominance of checklist use in private health services – 47 (41.59%) participants. However, the discrepancy in relation to the public system, that is, 42 (37.16%) subjects who used the checklist, were not strong. Research subjects who work both in the public and private systems represent 24 (21.23%) of the participants.

Of the 113 participants who used the checklist in the surgery center where they work, 89 (78.76%) declared that such use caused changes in the surgical team's interpersonal communication, and 24 (21.24%) did not observe these changes. There was a statistically significant difference (p=0.013) in the association of interpersonal communication changes with hospitals public or private systems, considering that among the 47 participants working in the private system, 42 (89.4%) observed changes in communication, whereas only 5 (10.6%) did not observe these changes (Table 3). Changes in the surgical team interpersonal communication after the checklist implementation were more frequently observed by participants who worked in private health services.

When the participants listed the difficulties and advantages of using the safe surgery checklist, they mentioned more than one reason. Among the 113 subjects who applied the checklist in the surgery center, 59 (52.21%) mentioned easy and rapid completion and 44 (38.94%) mentioned service organization. These were the most referred advantages, followed by low cost — 42 (37.17%) — and care agility — 22 (19.46%).

The health institution system (public or private) also showed statistical difference associated with care agility (p=0.006) (Table 4). Of the 113 participants who used the checklist, 91 (80.53%) did not refer care agility as an advantage. Of these 91 subjects, 42 (46.15%) worked in the private system, whereas 35 (38.47%) worked in the public system.

Table 3. Changes in the surgical team's interpersonal communication after checklist implementation (Maceió, Alagoas, Brazil, 2015).

Variable	Yes		No		p-value
	n	%	n	%	
Type of health institution					
Public	27	64.3	15	35.7	0.013
Private	42	89.4	5	10.6	
Both	20	83.3	4	16.7	

n: number of participants; %: frequency; p<0.05: statistically significant difference.

There was a statistically significant difference (p=0.003) for rapid and easy completion, according to public or private hospital systems. Of the 113 participants who used the checklist in the surgery center where they work, 54 (47.79%) declared that its completion was rapid and easy. Among them, 30 (55.55%) worked in public health institutions.

The reasons proposed as difficulties in using the checklist were team's disengagement, difficult comprehension of some items, lack of checklist guidelines, long completion, and no difficulties in applying the checklist, among others. Team's disengagement was referred as the main difficulty by 88 (77.88%) of the 113 participants who used the checklist in the Surgery Center (SC) where they work.

Table 5 shows a statistically significant difference (p=0.016) related to the perception of improvements in the nurse's performance after the checklist implementation, according to the participant's educational level. Among the participants, 94 of them (83.19%) declared that there were improvements in the performance of the health care team and 19 (16.81%) of them declared no improvements. Of these 94 participants, the higher frequency of those who reported improvements in the nursing care were among professionals with graduation degree — 46 (48.93%) — and master's degree — 25 (26.60%).

Of the total amount of participants, 91 (80.53%) stated that the checklist did not contribute to agility in the surgical patient's care. For subjects with professional experience greater than six years, the comprehension of the checklist items was not a difficulty, as only 7 (6.20%) of the 113 participants mentioned such difficulty. The regions where the checklist was most applied were the Southeast and South, represented by 55 (48.68%) and 27 (23.90%) respondents, respectively.

Table 4. Assistance agility as an advantage of the checklist implementation in public and/or private systems (Maceió, Alagoas, Brazil, 2015).

Variable	Yes		No		p-value
	n	%	n	%	
Type of health institution					
Public	7	16.7	35	83.3	0.006
Private	5	10.6	42	89.4	
Both	10	41.7	14	58.3	

n: number of participants; %: frequency; p<0.05: statistically significant difference.

Table 5. Improvements in nurse's assistance performance in surgery center after checklist implementation, according to the professional educational level of the research subjects (Maceió, Alagoas, Brazil, 2015).

Variable	Yes		No		p-value
	n	%	n	%	
Educational level					
Undergraduate	10	100	0	0.0	0.016
Graduate	46	75.4	15	7.4	
Master's Degree	25	92.6	2	7.1	
Doctor's Degree	13	92.9	1	100.0	
Post-doctor's Degree	0	0.0	1	100.0	

n: number of participants; %: frequency; p<0.05: statistically significant difference.

DISCUSSION

In the majority of Brazilian public hospitals, professionals are subject to work overload, low salaries, inappropriate working conditions, and absence of safety protocols. These characteristics certainly increase the probability of mistakes[6].

The optimization of safety of the surgical patient should be implemented in all health institutions, whether they are public or private, by means of trainings and lectures about its importance for patients and health professionals. The safer the surgical procedure, the better the quality of care, safety, and recovery both for the patient and the multidisciplinary team. However, many team members working in public and private hospitals show resistance to the checklist implementation, relying on their memories, without taking into account the fatigue resulting from long working hours[6].

Checklist use is also necessary as a means of improving interpersonal communication, that is, as a facilitator to patient's care. The checklist contributes to minimize conflicts caused by unexpected situations, and the team members' contributions before the surgical procedure improves surgical patient's safety[5]. By means of the checklist, communication among team members occurs, and the team also confirms items and reports their action and concerns to all professionals in the operating room.

When health team communication is not effective, events such as suspension of surgeries, procedures, and exams become very common. Furthermore, patients may undergo long periods without food and they may not receive a proper diet owing to these failures, which generate delays and failures in patient's health care[1].

Many errors caused by failures in the communication process may be irreversible. Communication processes are very complex and dynamic in health services. High flow of

information, large number of professionals from different health teams, and high demand of activities, lead to necessary updates and information exchange with patients, family, and teams. The lack of integrated communication processes between the different health teams and services is a factor that contributes to failures in the care process[1].

In this context, it is worth mentioning that the surgical team is composed of surgeons, anesthesiologists, nursing team, technicians, and other professionals of the operating room involved in the surgery. The team is the most critical resource for the surgical procedure success. Thus, if a team effectively works together to use their knowledge and abilities in favor of the surgical patient, a considerable proportion of life-threatening complications can be avoided[1]. More than only completing the checklist, professionals involved in the anesthesia and surgical procedures should rescue the origins of their humanistic and ethic development[7].

The main difficulty reported in this study concerning the checklist use was the disengagement of the surgical team, which proves that this tool is properly used when professionals understand its importance; therefore, the participation of all team members is necessary[8]. Educative actions directed to paradigm shift, such as surgeon's hierarchy, are a strategy to avoid problems associated with the checklist use and lack of surgical team's commitment[9]. Efforts from managers and professionals should aim at awareness and full knowledge of the importance and correct use of the safe surgery checklist to ensure the safety of patient and surgical team[10].

Therefore, in order to properly implement the "Safe Surgery Saves Lives" program from WHO in a health organization that provides surgical assistance, much more should be done than only implementing a checklist of the flow and stages of the anesthesia and surgical procedure. To promote a change in the patient's safety culture is imperative to enable all professionals of the surgical team and organization management to understand the need and the advantages of this protocol for all those people involved[11].

Rapid and easy completion of the checklist was the characteristic most frequently reported by the study participants. It is estimated that the three phases of the checklist take three minutes to complete, and it is recommended that only one person guide its implementation[5].

Nurses are the most indicated professionals to guide the checklist implementation; however, any professional who participates in the surgical procedure can play this role. On the basis of the presented results, it can be assumed that the nurse became more participative and active in the operating room.

The checklist intends to provide an efficient and simple set of priority verifications to promote effective work processes and communication among the team members. The checklist purpose is not to pronounce something that was memorized or to prevent the workflow. Thus, to properly implement the checklist in the operating room and for the teams to learn how to use it effectively, it is necessary to put the checklist into practice[4].

Verifying the checklist applicability in many regions of the country, in public and private hospitals, collaborates to understanding the challenges of the implementation process. The importance of an organizational culture change involving health managers and professionals should be highlighted. By means of this change, teams can comprehend the patient's safety as essential to prevent adverse effects.

This study had important limitations involving the population and sample, because data collection was conducted via e-mail. Results are limited to the investigated sample of nurses who are SOBECC members; therefore, they do not enable generalizations to the general population of nurses working in Surgery Centers in the country.

CONCLUSION

All the research participants are aware of the safe surgery checklist, which is more frequently used in the Southeast and South regions and in private health services.

The checklist implementation led to some changes in the surgical team's interpersonal communication and to improvements in the nurse's assistance work.

The advantages found regarding the checklist use were easy and rapid completion, service organization, and assistance agility. Team's disengagement was the main difficulty found in the checklist use, followed by difficult comprehension of some items, long completion, and absence of checklist guidelines.

Although all participants of this study were aware of the checklist, they did not know how to use it correctly. Training sessions with professionals who work in the operating room are essential to raise awareness of the importance and correct use of this instrument.

Thus, it is necessary to improve teamwork, considering that the safe surgery checklist use aims at promoting the surgical patient's safety, thus providing a safe environment and efficient interpersonal communication among the surgical team members.

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ROBOTIC SURGERY TRAINING IN THE PERIOPERATIVE NURSING RESIDENCY PROGRAM

Capacitação em cirurgia robótica no programa de residência em enfermagem perioperatória

Capacitación en cirugía robótica en el programa de residencia en enfermería perioperatoria

Cristina Silva Sousa[1], Daniela Magalhaes Bispo[2], Ana Lucia Mirancos da Cunha[3]

ABSTRACT: Objective: To develop a training program in robotic surgery addressed to resident nurses. **Method:** This is a case report conducted in a major private, philanthropic hospital in the city of São Paulo. For the Nursing Residency Program, resident nurses were trained focusing on the specialization in robotic surgery, including theory and practice, to use the Da Vinci robot system. **Results:** The resident nurses developed cognitive knowledge through virtual training, and technical skills during the simulation of robot handling, as well as the instruments and the equipment. They were referred to practical initiation, supervised by an expert nurse, until they were confident to execute the procedure of assembling the Da Vinci robot. **Conclusion:** The residents considered the training satisfactory to acquire theoretical and practical knowledge. The training of professionals specialized in robotic surgery is a differential in perioperative Nursing residency.
Keywords: Perioperative nursing. Simulation training. Robotic surgical procedures. Education, Nursing. Internship, nonmedical.

RESUMO: Objetivo: Desenvolver um programa de treinamento para enfermeiros residentes em cirurgia robótica. **Método:** Trata-se de um relato de experiência em um hospital filantrópico privado de grande porte no município de São Paulo. Para o programa de residência em Enfermagem foi desenvolvido um treinamento para enfermeiras residentes com foco na especialização em cirurgia robótica com carga teórico-prática para o sistema do robô Da Vinci. **Resultados:** As enfermeiras residentes desenvolveram o conhecimento cognitivo com o treinamento virtual e a habilidade técnica durante a simulação com o manuseio do robô, dos instrumentais e dos equipamentos. Foram liberadas para iniciação prática com supervisão de enfermeiro especialista até que possuam segurança na execução do procedimento de montagem do robô Da Vinci. **Conclusão:** O treinamento foi avaliado pelas residentes como satisfatório para aquisição de conhecimento teórico-prático. A capacitação de profissionais especialistas em cirurgia robótica é um diferencial na residência de Enfermagem perioperatória.
Palavras-chave: Enfermagem perioperatória. Treinamento por simulação. Procedimentos cirúrgicos robóticos. Educação em Enfermagem. Internato não médico.

RESUMEN: Objetivo: Desarrollar un programa de capacitación para enfermeros residentes en cirugía robótica. **Método:** Se trata de un relato de experiencia en un hospital filantrópico privado de grande porte en el municipio de São Paulo. Para el programa de residencia en Enfermería fue desarrollada una capacitación para enfermeras residentes con enfoque en la especialización en cirugía robótica con carga teórico-práctica para el sistema del robot Da Vinci. **Resultados:** Las enfermeras residentes desarrollaron el conocimiento cognitivo con la capacitación virtual y la habilidad técnica durante la simulación con el manejo del robot, de los instrumentos y de los equipos. Fueron liberadas para iniciación práctica con supervisión de enfermero especialista hasta que posean seguridad en la ejecución del procedimiento de montaje del robot Da Vinci. **Conclusión:** La capacitación fue evaluada por las residentes como satisfactorio para adquisición de conocimiento teórico-práctico. La capacitación de profesionales especialistas en cirugía robótica es un diferencial en la residencia de Enfermería perioperatoria.
Palabras clave: Enfermería perioperatoria. Entrenamiento simulado. Procedimientos quirúrgicos robotizados. Educación en Enfermería. Internado no médico.

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INTRODUCTION

Robotic surgery has become popular and has been growing fast since the 2000s. The procedure provides safety and efficiency, and is in between laparoscopy and minimally invasive surgery[1]. Literature describes robotic procedures in the following specialties: urology, gynecology, general surgery, thorax, heart, head and neck, maxillofacial, and pediatrics[14]. Such technological advancement is in accordance with the objective of reducing operative morbidity and mortality rates, as well as of performing less aggressive surgeries, with early recovery of the patient[5].

The XXI century nurse faces the challenge of technological diversity, which requires that this professional catch up with new demands, constant update and search for training to work with different resources[6]. Robotics has provided the perioperative nurse with the opportunity to adjust their practice, to think creatively, and to develop efficient and safe clinical practices to care for their patients[7].

The safety of the patient and the efficiency of the procedure can be compromised if the perioperative nurse is unexperienced regarding the care for patients who undergo robotic procedures. By offering a training program for nurses involved with robotic surgery, hospitals provide skills for the practice of these professionals, reducing risks, and promoting positive results for nursing care[1].

Clinical simulation has become an important tool in nursing education, as a feasible alternative for the practice with patients. Even though simulation cannot replace the real clinical practice, it is a useful tool to create realism before the apprentice can actually care for the patient. Simulation encourages the active learning process, stimulating the students[8].

This article allows coordinators and teachers in the surgery department to get to know a training program intended to develop nurses to become specialists in robotic surgery. This model can be used in other centers, improving the expertise of these professionals. The objective of this study was to develop a training program on robotic surgery for resident nurses.

METHOD

This is a case report conducted in a major private, philanthropic hospital in the city of São Paulo. This hospital has 19 operating rooms and an average of 1,200 surgeries/month. In 2015, this hospital began a nursing residency program in surgery center and in central sterile services department, with ten openings.

As part of the pedagogical agenda of the residency program, the robotic surgery training was planned to provide theoretical and practical information. Therefore, the course was conducted with the company in charge of the Da Vinci system: Intuitive (Figure 1).

Theoretical training was available in Da Vinci's official website[9], and consists of video lessons with interactive exercises about the basic principles of electrosurgery, the Da Vinci's functioning system, the robot assembly, the attachment of Da Vinci to the patient, and problem solving. An evaluation of the learning process is applied at the end of the course – minimum grade for approval is 7.0. After being approved, the participant receives a certificate issued by the company's website, which has to be sent to the tutors of the residency program, as well as to the representative of the company that sells the system.

The online training could be concluded in 60 days. In case of non-approval at this stage, it would not be possible to continue with the practical training.

The tutor of the residency program who accompanies the practical training was in charge of: organizing the operating room and displaying the system with clinical engineering; of the disposable items; of the devices withdrawal and return to the central sterile services department; of supervising the hand antisepsis technique; of proper wearing of surgical attire; and of the evaluation of the practical training.

Practical training was scheduled 60 days ahead, with a representative of Intuitive, to be conducted on a Sunday in the robotics operating room at the referred hospital. The period to conduct this phase lasts six hours, and consists of revising the theoretical concepts learned in the first phase, in the demonstration of specific instruments for robotic surgery, and in the presentation of the console, the video system, and the Da Vinci robot by the company's representative. The tutor accompanying the group reviews the techniques of surgical antisepsis and proper wearing of surgical attire.

During the process, the resident nurses discuss the concepts learned in the group and initiate the practical activities by handling robotic instruments. Afterwards, they are encouraged to individually initiate the robot assembly and execute handling techniques, as well as to evaluate the system functioning and possible flaws. For the robot assembly,

surgical antisepsis and proper wearing of surgical attire are required to keep the procedure sterile.

At the end of practical training, the tutor fills out the evaluation form on competences acquisition that is expected for a nurse who is specialized in robotic surgery. Therefore, an instrument of evaluation was used with the concepts "needs improvements" and "satisfactory" (Chart 1).

RESULTS

Nine resident nurses were trained from September to December 2015. The online training that was launched in September was concluded until November. The practical training was conducted in December 2015.

For the theoretical training, the resident nurses accessed the website and registered their personal data. After this registration, they received a login and a password to access the training area.

The theoretical training included the knowledge of basic principles until the final stage with the Da Vinci robot dock; in each phase, there are exercises to reinforce the learning process and, at the end, there is an evaluation on the specific field of knowledge. It is possible to rewind the content many times, and there is no determination of time to execute each phase.

The training evaluation by the residents was satisfactory, and even though the content is in English, it did not compromise the learning process. The resident nurses were able to conclude the online training in the proposed time.

The practical training was essential to visualize the placement and the operation of the equipment in the operating room, as well as to understand the position of the team members and the organization of materials and instruments,

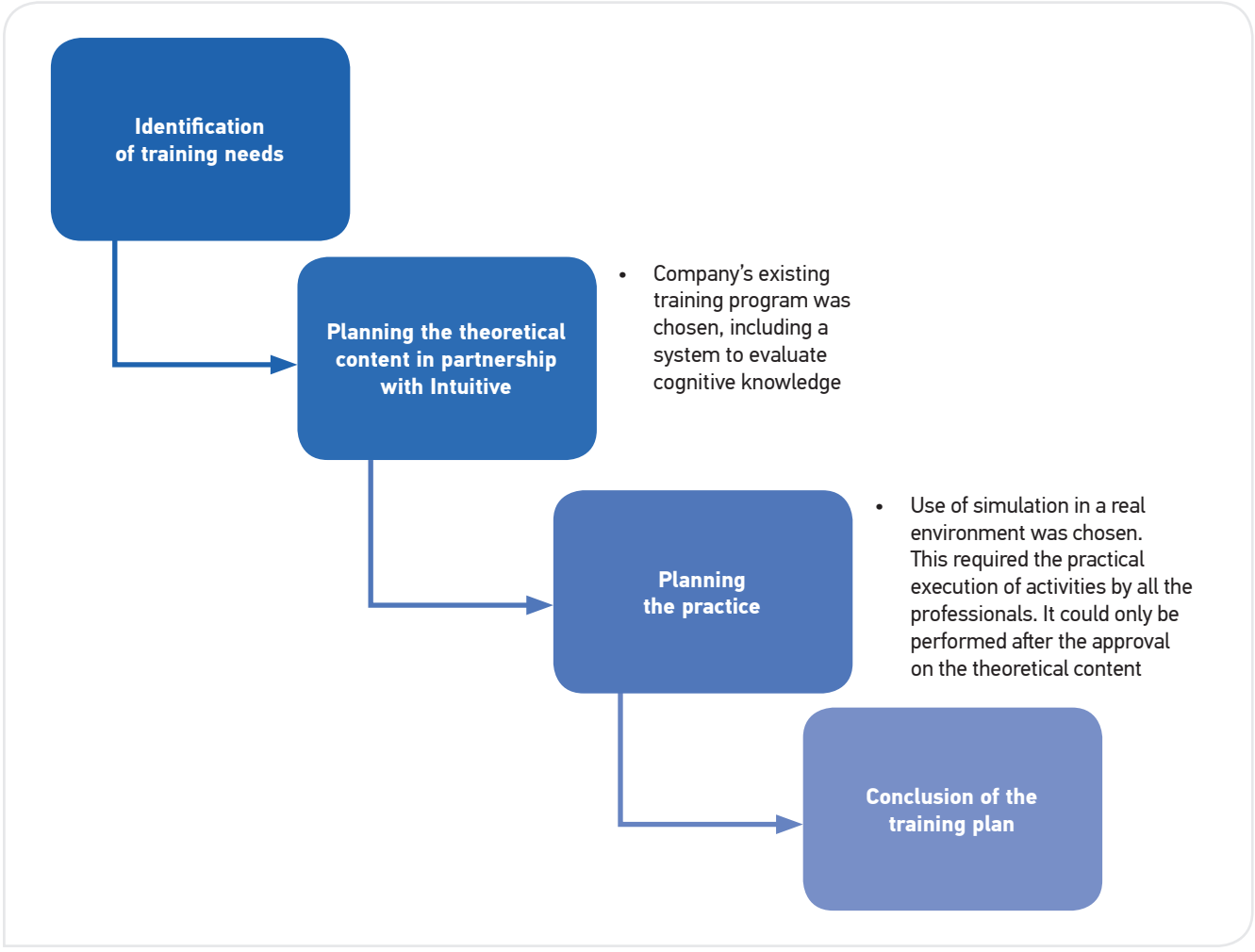

Figure 1. Training program for nurse specialist in robotic surgery.

to practice the content learned, and to provide the unique opportunity to handle the console, the robot, and the video system. The tutor revisited the hand antisepsis technique and the definitions on proper wearing of surgical attire with the residents and observed the execution of the robot assembly and attachment processes, which were executed individually by each of the participant nurses.

The residents handled the instruments, performed surgical antisepsis, and wore surgical attire as recommended. They also assembled the robot for surgery, put together the desk for the optical system, identified the number of times the tweezers were used, by video, and disassembled the system. During the optical calibration and the alignment of images, the group had some doubts, which were clarified. Therefore, they conducted all stages in the process.

At the end of the training, the residents were approved to execute the assembly of the robot in the intraoperative scenario. At first, the participants should be supervised by the nurse who is specialized in robotics, until they are confident enough to assemble the system. In general, professionals need three supervised assemblies in order to execute it without supervision.

The result of our experience was considered effective to train nurses in robotic surgery. The deadlines were properly established, and the members of the group could acquire the necessary skills.

DISCUSSION

The technological advancement and the growth of robotic surgery require skilled professionals to guarantee the safety of the patient and the assertiveness of the procedure. Such technological advancement and the generation of young nurses lead to significant change in the practice of care. For this new profile of perioperative nurses, a training model associating theory and practice makes the development of these professionals more dynamic, being effective in the learning process.

Learning is an active and dynamic process, with the potential to transform the apprentice. Efficient educational strategies should be cooperative, collaborative, and attractive to capture and catch the attention of new generations of perioperative nurses[10].

The strategy used to develop nurses to become specialists in robotic surgery aimed at training resident nurses in a simulated environment of professional practice, using the operating room, the placement of the equipment, the disposable items, and the instruments which are identical to those used in the intraoperative period.

The use of simulation in professional health training became prominent owing to the campaign for the safety of the patient. Simulation as a teaching method has grown around the world, and is more frequent in graduate and

Chart 1. Evaluation of the practical training for robotic surgery. São Paulo, 2015.

Actions	Concept	
To describe the movements of the three arms of the robot before and after the procedure	NI	S
To demonstrate how to turn on the robotic system adequately		
To demonstrate the connections of the robotic system		
To do the *"homing"*		
To turn off the equipment properly after use		
To adjust the camera and the alignment of the system properly		
To place the cloaks on the robot's arms, ensuring the perfect fitting of the tweezer		
To identify the basic instruments of the robotic surgery		
To demonstrate the adequate position and the withdrawal of the robotic instruments		
To identify the location of the emergency key		
To verbalize an emergency situation (loss of electric energy or an irrecoverable flaw)		
To verbalize correct actions for recoverable flaws		
To identify the number of times the tweezers were used		
To verbalize how to proceed with the records for control		
To remove the cloak and keep the optical cables		

NI: needs improvement; S: satisfactory.

postgraduate programs in Nursing[11]. In this study, the assembly and the attachment of the robotic system, technical skills, such as hand antisepsis and wearing of surgical attire, and handling of robotic materials are reinforced during the simulation phase, enabling the participants to associate the previous knowledge with the development of the practical skills.

Postgraduate programs with residency are known as a practical learning process in health services. Residency enables the resident to experience health practices, helping this usually recently graduated professional to become familiar with work processes and to acquire professional confidence, together with his or her critical and reflexive development[12]. This type of qualification improves the quality of care and prepares professionals for the labor market[13].

This training model is very similar to that demonstrated in an American study which include theory and practice in robotic surgery, and was addressed to nurses. However, in this study, the theoretical part was carried out by the Nursing department and was based on the needs of the staff; the practical part was initiated afterwards. The process took five weeks[1].

Another study used online training, a practical half-day session, and simulation exercises. Participants were divided in two groups: experienced staff and beginners in robotic practice. This study showed significant efficacy results of this training model[14].

A few studies report how nurses are trained for robotic surgery. In many health institutions, the nurse who is not aware of this technology is involved in the process gradually, followed-up by an experienced professional.

In this type of training, previous cognitive knowledge associated with a practice simulation provides more safety to the professional who begins the execution of care in robotic surgery.

CONCLUSION

The proposed training was satisfactory and occurred in accordance with the desired competences. The residents evaluated the training well, owing to theoretical and practical knowledge acquisition. The development of professionals to become specialists in robotic surgery is a differential in the perioperative nurse residency.

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INTERNATIONAL OVERVIEW OF SINGLE-USE MEDICAL DEVICES REPROCESSING

Panorama internacional do reprocessamento de produtos médicos de uso único

Panorama internacional do reprocesamiento de productos médicos de uso único

Eliana Auxiliadora Magalhães Costa[1]

ABSTRACT: Introduction: The reuse of single-use products occurs worldwide and it leads to major issues. **Objective:** To analyze the international regulatory framework for the reprocessing of single-use medical products, including the Brazilian regulations. **Methods:** This is a narrative review of the literature, using databases with specific descriptors. **Results:** Internationally, there are a variety of regulations on the reuse of single-use medical products that aim at preventing damage. The regulatory environment comprises well-structured protocols, such as the American, Australian, and German protocols, to lack of regulations at a national level, as identified in developed countries such as Canada, Japan, and some European countries. **Conclusion:** Current regulatory controls have considerable gaps that hinder their implementation by the health services and manufacturers. An alternative approach may be the formulation of a regulatory framework of single-use products focused on the control of the processes instead of the current control of products.
Keywords: Patient safety. Equipment reuse. Health policy.

RESUMO: Introdução: O reuso de produtos de uso único é uma realidade mundial e implica em grandes problemas. **Objetivo:** Analisar o sistema regulatório de reprocessamento de produtos médicos de uso único a nível internacional, incluindo o brasileiro. **Método:** Revisão narrativa da literatura, utilizando bases de dados com descritores específicos. **Resultado:** Internacionalmente, as políticas de reuso de produtos médicos de uso único tendem a prevenção de danos. As regulamentações variam desde protocolos bem estruturados, como o norte-americano, o australiano e o alemão, à ausência de normatização a nível nacional, como identificado em países desenvolvidos como Canadá, Japão e alguns países da União Europeia. **Conclusão:** Os controles regulatórios existentes apresentam lacunas que dificultam sua implementação tanto para os serviços de saúde quanto para os fabricantes. Uma metodologia alternativa seria a de um sistema regulatório de produtos de uso único centrado no controle dos processos em lugar dos atuais focados no controle do produto.
Palavras-chave: Segurança do paciente. Reutilização de equipamento. Política de saúde.

RESUMEN: Introducción: El reúso de productos de uso único es una realidad mundial e implica en grandes problemas. **Objetivo:** Analizar el sistema regulatorio de reprocesamiento de productos médicos de uso único a nivel internacional, incluyendo el brasileño. **Método:** Revisión narrativa de la literatura, utilizando bases de datos con descriptores específicos. **Resultado:** Internacionalmente, las políticas de reúso de productos médicos de uso único tienden a prevención de daños. Las reglamentaciones varían desde protocolos bien estructurados, como el norteamericano, el australiano y el alemán, a la ausencia de normativa a nivel nacional, como identificado en países desarrollados como Canadá, Japón y algunos países de la Unión Europea. **Conclusión:** Los controles regulatorios existentes presentan lagunas que dificultan su implementación tanto para los servicios de salud como para los fabricantes. Una metodología alternativa sería la de un sistema regulatorio de productos de uso único centrado en el control de los procesos en lugar de los actuales enfocados en el control del producto.
Palabras clave: Seguridad del paciente. Equipo reutilizado. Política de salud.

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INTRODUCTION

Medical devices are defined by the manufacturers either as reusable or as single-use articles. Reusable or multiple-use devices require reprocessing, which consists of converting a contaminated product into a ready-to-use device, including not only cleaning, disinfection, and sterilization of the device, but also checking technical and functional safety by means of integrity and functionality tests. Single-use products are designed to be used only once in a single patient[1-6].

The practice of reuse of single-use devices has initiated in the 1970s. Since then, this practice has been occurring worldwide, and there are reports of reuse of such devices even in developed nations and in those countries where the reprocessing is prohibited[1-6]. This trend has intensified several debates and considerations on patient safety, informed consents, economic, environmental, legal, and ethical aspects, and regulatory requirements for manufacturers and reprocessors, which indicate different interests of the political actors involved: states, manufacturers of the devices, health services, reprocessing companies, academia, health professionals, associations, and users[1-12].

Among the risks associated with the reuse of both single-use and reusable medical devices, several authors mention the following[1,3-7]: infection, biofilms, material contamination with endotoxins, presence of toxic waste of the products used for cleaning, disinfection, or sterilization, bioincompatibility with proteins of the previous users that eventually remained in the material, functional unreliability, lack of physical integrity, and protection barriers, among others.

In Brazil, the reprocessing of single-use products is a reality in the health services. National data show that these practices are common in all regions of the country, regardless of the size and hospital's sponsor organization. These data also reveal that reuse protocols are adopted in few institutions, and in most of them the protocols are inappropriate, representing actual risks for patients who are users of these products[13-16].

Therefore, in this scenario of global growth of medical products used in the care process, regulations on the use and reuse of these technologies are crucial for the implementation of safe practices and for the prevention of adverse events related to these products. In this regard, this article seeks to answer the following central question: to what extent does the sanitary regulation framework for single-use medical products adopt policies aimed at preventing risks to patients? This study aims at reviewing the international regulatory framework for the reprocessing of single-use medical products, including the Brazilian regulations.

METHOD

This study is a narrative review of the literature carried out by searching the electronic databases Web of Science, PubMed, Lilacs, and SciELO, using the following descriptors: "reprocessing device medical," "reprocessing device single use," "reuse device medical," "regulation device materials," and "regulatory devices medicals." There was no restriction on the publication dates and languages.

We included primary and secondary studies, which were selected by their title and abstract. After reading the abstracts, only those papers that addressed regulatory aspects of single-use medical products and regulations on the reuse and reprocessing were read in full. References of selected articles were also incorporated to the search. The articles that were included in more than one database were analyzed only once. Therefore, of the 110 articles found in the electronic databases mentioned earlier, 33 met the inclusion criteria and were analyzed. In this study, we used the term "medical product" as a synonym for health product, apparatus, equipment, material, and medical article, in agreement with the National Health Surveillance Agency (ANVISA) definitions.

RESULTS

International policies on reuse and reprocessing of single-use medical products

The reprocessing of single-use items is regulated and supervised by the Food and Drug Administration (FDA), which, in 1999–2000, restructured its policy on reuse of single-use devices. The FDA applied the principle of regulatory equity, in which manufacturers of original equipments, outsourced reprocessing companies, and hospitals are subject to the same regulatory control level. Non-hospital medical institutions were

excluded from this legislation (clinics, day hospitals, long-term care facilities, home care), opened but not used single-use devices, permanent pacemaker, and hemodialyzers[3,4,6,9,12].

The core aspect of this regulatory policy is a classification scheme through which the products are categorized according to the risk of harm to the patient, based on the product intended purpose. There are three risk classes – I, II, and III – and two types of premarket submission requirements: premarket notification 510 (K) and the premarket approval application (PMA). The type of submission depends on the risk categorization of the product[3,4,6,9,12].

The 510 (K) or premarket notification is the simplest and most common method for marketing a medical product. Through this submission, the manufacturer should demonstrate that the new product is "substantially equivalent" to a product that is already legally marketed. The assumption is that the new product is as safe, effective, and performs its functions with the same consistency for the intended use as a product that is already marketed. The FDA then reviews the product by means of an assessment of equivalence with the device that is legally marketed. PMA is the route to be used if the new product is not similar to a legally marketed product. In this case, the manufacturer must carry out clinical studies to demonstrate product's safety and effectiveness, and the FDA conducts an inspection at the manufacturer's premises prior to the approval of the PMA. The time required by the FDA for the approval of the 510 (K) is approximately 75–90 days and 180 days for the PMA[3,4,6,9,12].

Currently, the FDA allows the reprocessing of over a hundred different products for single use. Cardiovascular catheters, guide wire, breathing circuits, biopsy forceps, cautery devices, anesthesia equipment circuits, and tracheal tubes are the most reused in the United States of America. According to the FDA, reprocessed single-use products are 50% less costly than new devices[3,4,6,9,12].

In Canada, there is no federal regulation, and the reprocessing of single-use products has historically been delegated to the ministers of health of the provinces and territories of the country. There are reports that the reuse of these products occurs in 40% of provinces and in 28% of national intensive care hospitals. The most reused products are breathing circuits and saws. Most health services (85%) perform reprocessing internally; however, since 2014, there is a growing trend of reprocessing by outsourced companies, most of which North American licensed by the FDA[17-19].

When reprocessing is outsourced, Canadian hospitals have adopted two commercial reprocessing systems, namely "closed-loop procurement model," in which the hospital receives back only its own medical devices that were sent to the third-party reprocessor, or "open-loop procurement model," in which the hospital does not receive its own products back, but rather buys them from a "pool" of reprocessed single-use products[19].

Large provinces have adopted two positions:

1. to prohibit the reuse of single-use products, which was adopted, for example, in Prince Edward Island, Newfoundland, and Labrador, in addition to all three territories (Northwest, Yukon, and Nunavut), Alberta, Quebec, and New Brunswick; or
2. to allow the reprocessing of single-use products only by contractors who are certified by health authorities such as Health Canada or the FDA in the United States of America. This position has been adopted, for example, in British Columbia, Manitoba, Ontario, Nova Scotia, and Saskatchewan[17-19].

In Europe, the European Union (EU) does not have a common policy on the reprocessing of single-use products, and the Member States adopt different regulatory processes[19]. In Germany, since 2001, current regulatory framework only handles quality standards and reprocessing validation procedures, and denominates as illegal the distinction between single- and multiple-use medical products. Reprocessing conducted by the hospital and outsourced reprocessors is allowed, but both should implement quality management systems in accordance with the German Act on Medical Devices[1,2,11,19].

In other EU countries such as the UK, Spain, and France, the reprocessing of disposable items is prohibited by law since 2005; however, France is the only country that does not reuse single-use devices. In Spain, a survey conducted, in 2005, in 42 hospitals in Madrid revealed that 82.4% of them reprocessed single-use devices, with no federal rules to evaluate this practice in the country. The UK allows the reuse of disposable items only in controlled situations, owing to great concern with prions. In Belgium, Denmark, The Netherlands, Slovakia, Sweden, and Switzerland medical products for single use are reprocessed according to strict quality standards. In Greece, Estonia, Cyprus, Latvia, Malta, and Poland, there is no regulation on these practice[17,19,20,21].

In Asia, the reuse of disposable products is common in most countries, and there are no national regulations guiding these practice[19,20]. In Japan, the reprocessing of single-use products is not systematically regulated. Data showed that 86.2% of hospitals reused disposable products, and that such practices were carried out inconsistently, without established standards and protocols[20,21].

In India, hospitals routinely reuse single-use products, without existing regulations on this practice[17,19,20].

In Australia, reprocessing is similar to the American. In 2003, The Australian Therapeutic Goods Administration (TGA) – national governing body for medical products – introduced regulations for hospitals and reprocessing companies of single-use products, naming the as "manufacturer" as described in the legislation. These companies need to follow the same regulatory standards as the original manufacturer and are required to demonstrate that the reprocessed single-use products are as equally safe and perform exactly as a new product. The regulation on reprocessing single-use products excludes "opened but unused" single-use products and individuals who reprocess disposable devices for their own personal use[19,20,22,23].

In New Zealand, the governing body Regulator Medsafe requires compliance with the US regulatory policy or approval according to the Australian policy to reprocess a single-use product[20].

In the Middle East, data indicate that, despite the absence of a regulatory framework, the reuse of these products is common in Arab countries, particularly of cardiac catheters[19,20].

Israel does not have a specific regulation for the reprocessing of single-use products, but, in general, every medical product must be registered with the Ministry of Health before they can be sold in the country. If the product is approved by the US FDA, it shall be registered in this country without any additional testing. As in many other countries, Israel's hospitals are reusing many single-use products without federal government control[20].

The Kingdom of Saudi Arabia is in the process of implementing a regulatory policy on medical products. The Saudi Food and Drug Authority issued a provisional regulation in 2008 stating that a medical product in Saudi Arabia can be marketed if it "adheres to regulatory requirements applied in one or more jurisdictions of Australia, Canada, Japan, and US." It seems that Saudi Arabia government prohibits the reuse of single-use products[20].

In Africa, South America, and Central America the practice of reprocessing single-use devices is prevalent owing to the lack of medical and financial resources[19,20].

Brazilian regulation on the reuse of single-use medical products

In Brazil, ANVISA is responsible for regulating the reprocessing of medical products, and in 2006, it issued three regulations that are still in force:

1. Collegiate Board Resolution (RDC) No. 156, which provides for the registration, labeling, and reprocessing of medical products;
2. Special Resolution (RE) No. 2,605, which establishes a list of 66 single-use products whose reprocessing is prohibited in the country; and
3. RE No. 2.606, which defines the guidelines for development, validation, and implementation of medical products reprocessing protocols[24-26].

ANVISA is the Brazilian agency responsible, among various activities, for the oversight to ensure compliance with the rules intended to protect population's health, such as the reprocessing of medical products.

DISCUSSION

The United States of America, by means of the FDA, currently has the broader established regulatory control on practices for reuse and reprocessing of medical products in the world. However, this institution's regulations have some issues that weaken the system in crucial aspects of the products reprocessing control, raising questions for the implementation of these regulations, especially to the hospitals. Initially, FDA regulatory framework on medical devices has as its policies guiding principle the marketing of these products, which differs from the traditional risk assessment, according to the potential of infection involved on their use. Articles considered critical such as surgical instruments and needles are classified by the FDA as class II (medium risk), and therefore, only require the 510 (K) for their licensing and reprocessing. On the other hand, 510 (K) allows marketing most of the products even when high-quality studies are missing, and therefore, class I and many class II products are granted marketing clearance without more accurate quality controls.

In addition, current FDA policy on single-use products reprocessing requires a great adaptability for its fulfillment, particularly for hospitals that reprocess medical products. The two premarket and/or reprocessing medical devices submissions — 510 (K) and PMA — are ambiguous in their requirements for authorization of such processes. For example, how should manufacturers and outsourced reprocessors or hospitals prove that the "class I and II reprocessed medical device is equivalent in safety and effectiveness to an original unprocessed product," which is required to comply with the 510 (K)? The 510 (K), considering its control focused on the "substantial equivalence" with a product legally marketed, allows marketing the majority of products in the US without more strict quality studies.

Moreover, what are the control standards that the reprocessors of medical products will use to demonstrate "scientific validity and clinical evidence of safety and effectiveness of reprocessed class III single-use medical devices," required by the PMA? Without a clear methodology, there will certainly exist different experiments and clinical trials for compliance with this legislation. Are all the presented methodologies accepted? Another uncertainty is whether the FDA accepts similar groups of products or if the submission of 510 (K) or PMA is mandatory for each product model. Finally, this regulation exempts other health institutions that also reuse and reprocess single-use medical devices, such as clinics, care units for chronic patients (as psychiatry), day hospitals, and home care units, which remain unregulated. We considered these pending issues as gaps and limitations of this regulatory framework.

In Brazil, current regulatory framework that regulates the reprocessing of single-use medical products represents advancements in the standardization of medical products reprocessing in our country. However, there are several inaccuracies and abstract content in these laws, which facilitate various interpretations and hinder their implementation by the health services, outsourced reprocessors, and manufacturers or importers of these products.

Resolution No. 156/2006 categorizes medical products as "subject to reprocessing" and "reprocessing not allowed" and establishes that this categorization need to be performed during the product registration, when the manufacturer or importer shall submit to ANVISA the documentation substantiating this categorization. However, this norm does not specify the required documentation and evaluation parameters for manufacturers or importers, in the registration process of multiple- and single-use products. The main question is: what are the criteria that this agency uses to accept or reject the product classification informed by manufacturers at registration? What are the tests required by ANVISA to the manufacturers to prove that the product is reusable or single-use on registration?

RE No. 2,605/2006 listed 66 products classified as single use whose reprocessing is prohibited, but did not explain the criteria used for selecting the medical products that compose this negative list. This resolution does not favor the understanding of the technical and scientific bases for the regulation of a practice that involves relevant aspects of health in the country. There are many questions to be answered: why are some possibly reusable products, such as dental suckers and rubber dams, gloves, and pads included in the negative list while others that proved to be of high risk, such as endoscopic biopsy forceps, papillotomes, vitrectomy kits, and many others of high risk used in the care process were not included? How to handle the inclusion of an increasing technological arsenal in a finite list of products? Why do they choose to work with a list subject to become obsolete, as it is already, focusing on the product and not on processes involved in the reprocessing steps?

RE No. 2,606/2006 states that the contractors and health services that reprocess critical and semi-critical items must elaborate, validate, and implement protocols for each selected product brand and type, containing detailed description of all reprocessing steps, in addition to the quality assurance of all stages, including the assessment of functionality, sterility, traceability, and storage and disposal conditions of each reprocessed product.

This resolution also defines that each critical and semi-critical product to be reprocessed, without specifying whether it is single- or multiple-use, should have a chart with information related to the devices, such as size, structure, composition, registration at ANVISA, manufacturer and supplier, name of the reprocessing responsible, and place and date of each reprocessing. Although this legislation requires development, validation, and implementation of medical products reprocessing protocols, it does not indicate what is the acceptable methodology for the processes validation to be carried out by hospitals, which not only hinders their implementation, but also facilitates the elaboration of dubious validation protocols, leading to safety issues in the products reprocessing.

Moreover, this regulation is vague on the quality assurance requirement in all stages of the process, including assessment of functionality, sterility, pyrogenicity, non-toxicity, and integrity. We ask again what is the acceptable methodology for these quality controls. Is it necessary to perform these tests to all critical and semi-critical products? How, who, and when should one evaluate functionality and integrity of all reprocessed products, given the large number of existing medical products in a health institution? What should be the minimum frequency of these tests? How should a medical record be created for each critical and semi-critical product containing the data required by this legislation, considering the structural, functional, and organizational contexts of most of the Central Sterile Supply Departments (CSSD) of hospitals in Brazil, and the large number of products that compose their arsenal? Pending questions of this regulatory framework negatively impact the operation of health services.

In addition to the questions elaborated earlier, how can ANVISA monitor, supervise, and control these rules in many health facilities in the country? Do health surveillance professionals have the expertise necessary to carry out the sanitary control of medical products reuse? These are other pending issues of this theme in Brazil.

Studies show that without proper supervision, the regulation on medical products reprocessing, published since 2006, has been delayed or boycotted in its implementation in Brazilian hospitals[13-16]. In addition to the issues it raises, such delay challenges the regulation legitimacy, which reinforces the problems surrounding the reuse of single- or multiple-use medical products.

CONCLUSION

The literature review showed that there are a variety of international regulations on the reuse of single-use medical products, which generally tend to have a preventive character, with recommendations aimed at the safety of public health.

Although these regulations have substantial differences, the risk management principle should be their guiding principle and the degree of regulatory scrutiny imposed for any medical product, regardless whether single- or multiple-use, should be proportional to the intended purpose of the device, to their risk level, and degree of invasiveness of the product in the human body.

The regulatory environment comprises well-structured protocols, such as the North American, Australian, and German protocols, to the lack of regulations at a national level, which was also identified in developed countries such as Canada, Japan, some European countries, Asia, and the Middle East, indicating a lack of political priority to the issues surrounding the reuse of medical products.

Even current regulatory controls in countries such as the United States of America, Australia, and Brazil have considerable gaps, as those mentioned in this study, which hinder their implementation by the health services and manufacturers.

In Brazil, the monitoring of the implementation of these regulations by ANVISA is another pending issue which relates to the actual technical and operational capability of this body to perform sanitary control of the medical products reuse in country.

An alternative approach is to develop a regulatory framework for reuse and reprocessing of single-use products focused on the control of the processes instead of the current control of products, which is currently implemented internationally.

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WATER QUALITY: FACTS AND MYTHS!

Qualidade da água: fatos e mitos!

Calidad del agua: ¡hechos y mitos!

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ABSTRACT: Objective: To discuss the importance of water in Central Sterile Services Department (CSSD) and the main evidence of risks, standards, related legislation, and guidelines to develop a water treatment system to rinse products. **Method:** A narrative review to investigate both facts and myths and to describe the aspects related to the need to control the quality of the water used to process medical devices. **Results:** Reports of local toxic effects and pyrogenic reactions in patients require the standardization and quality control of water to rinse products and steam generation in autoclaves. **Conclusion:** Water treatment and quality monitoring should be incorporated by health services.

Keywords: Surgical instruments. Sterilization. Water quality.

RESUMO: Objetivo: Discorrer sobre a importância da água no Centro de Material e Esterilização, sobre as principais evidências de risco, normas, legislação relacionada e orientações para a definição de um sistema de tratamento de água para enxágue de produtos. **Método:** Revisão narrativa buscando fatos, mitos e descrevendo aspectos relacionados à necessidade de controle da qualidade de água utilizada no processamento de produtos para a saúde. **Resultados:** Relatos de efeitos tóxicos locais e reações pirogênicas em pacientes demandam a padronização e o controle de qualidade da água para enxágue de produtos e geração de vapor nas autoclaves. **Conclusão:** O tratamento e o monitoramento da qualidade da água devem ser incorporados pelos serviços de saúde.

Palavras-chave: Instrumentos cirúrgicos. Esterilização. Qualidade da água.

RESUMEN: Objetivo: Analizar la importancia del agua en el Centro de Material y Esterilización, sobre las principales evidencias de riesgo, normas, legislación relacionada y orientaciones para la definición de un sistema de tratamiento de agua para enjuague de productos. **Método:** Revisión narrativa buscando hechos, mitos y describiendo aspectos relacionados a la necesidad de control de la calidad del agua utilizada en el procesamiento de productos para la salud. **Resultados:** Relatos de efectos tóxicos locales y reacciones pirógenas en pacientes demandan la estandarización y el control de la calidad del agua para enjuague de productos y generación de vapor en las autoclaves. **Conclusión:** El tratamiento y el monitoreo de la calidad del agua deben ser incorporados por los servicios de salud.

Palabras clave: Instrumentos quirúrgicos. Esterilización. Calidad del agua.

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INTRODUCTION

In 2012, the ANVISA Board Resolution (RDC) No. 15, from the Brazilian Health Surveillance Agency (ANVISA)[1], established that the rinsing of health products should be carried out with water that meets the potability standards specified in regulations, namely Directive No. 2,914, dated December 12, 2011[2], which legislates in relation to procedures for the control and surveillance of water quality for human consumption and to its potability standards. In addition, it determined that the final rinsing of critical products for orthopedic and ophthalmic implants as well as cardiac and neurological surgeries should be performed with purified water, with water-quality monitoring and recording at set protocol intervals. Monitoring should include the measurement of water hardness, pH, chloride, copper, iron, manganese ions, and microbial load at the rinsing points in the cleaning area; however, microbiological and physicochemical acceptability standards are not determined.

These measures are not myths, noting that the literature contains several toxicity reports related to water quality in the processing of health products. Holland et al.[3] hypothesize about the association of diffuse lamellar keratitis in patients who underwent ocular surgery and the release of endotoxins by the biofilm present in autoclave reservoirs. The investigation of the outbreak involving 52 patients revealed biofilm of *Burkholderia pickettii* in autoclave reservoirs. The adoption of strategies for the control of biofilms in reservoirs, which included cleaning with boiling water, brushing, and application of 70% isopropyl rubbing alcohol, resulted in a significant reduction of cases.

Endotoxins may cause toxic anterior segment syndrome[4,5] besides inducing aseptic loosening in orthopedic implants, leading to serious consequences for patients[6]. Furthermore, there are reports of pyrogenic reactions in patients who had their cardiac catheters reprocessed with water without any microorganism and endotoxin control[7].

In Brazil, although water microbiological and physicochemical quality control is required, there are no set acceptable parameters. Nevertheless, it is suggested that the quality standards for the water used during the final rinsing, for regulatory compliance, are guided by the *Technical Information Report 34* from 2007, published by the Association for the Advancement of Medical Instrumentation (AAMI)[8] (Chart 1). Although not required by the ANVISA Board Resolution (RDC) No. 15[1], the standard should include the control of endotoxins and other contaminants required by manufacturers of the equipment and surgical instruments.

Chart 1. Water physicochemical and microbiological characterization for processing health products, in compliance with the *Technical Information Report 34*, 2007, by the Association for the Advancement of Medical Instrumentation (AAMI)*.

Contaminants	Potable water	Soft water	Deionized water	High-purity water**
Bacteria (cfu/mL)	<200	<200	<200	≤10
Endotoxins (EU/mL)	N/A	N/A	N/A	<10
Total organic carbon (mg/L)	<1.0	<1.0	<1.0	<0.05
pH	6.5 to 8.5	6.5 to 8.5	N/A	N/A
Hardness ($CaCO_3$ in ppm)	<150	<10.0	<1.0	<1.0
Resistivity (MΩ-cm)	N/A	N/A	>1.0	>1.0
Total dissolved solids ($CaCO_3$ in mg/L)	<500	<500	<0.4	<0.4
Chloride (mg/L)	<250	<250	<1.0	<0.2
Iron (mg/L)	<0.3	<0.3	<0.2	<0.2
Copper (mg/L)	<0.1	<0.1	<0.1	<0.1
Manganese (mg/L)	<0.1	<0.1	<0.1	<0.1
Color and turbidity	Colorless, clear and without residues	Colorless, clear and without residues	Colorless, clear and without residues	Colorless, clear and without residues

*Document updated in 2014; the 2007 edition, however, is in accordance with the parameters required by article 74 of the ANVISA Board Resolution (RDC) No. 15[(1)]. **Recommended for final rinsing; cfu: colony-forming units; EU: endotoxin units; N/A: not applicable.
Source: Translated and adapted from the AAMI, 2007[8].

Aiming at a concrete estimate of the real impact of water quality on the processing safety for health products, one study assessed the cytotoxicity of hydrodissection cannulae submitted to a contamination challenge, a cleaning process based on a validated standard operating procedure (SOP) and the final rinsing in different types of water: tap, deionized, distilled, treated by reverse osmosis, and ultra-purified water[9]. Samples were internally and externally contaminated by a solution containing 20% of defibrinated sheep blood and 80% of 0.9% sodium chloride. Later, the lumen was filled with a viscoelastic solution, letting it remain in contact with the contaminant for 50 minutes and was then processed, in accordance with a validated SOP[10]. Results showed that the quality of the water used for the last rinsing, as an isolated variable, does not affect the cytotoxicity of the cannulae; however, this statement is valid only if cleaning quality is assured[9]. In the study, the authors did not recommend the use of water without the control of physicochemical and microbiological standards, by seasonal and geographic variation of water[11], and the possibility of corrosion of instruments. They also establish that these results do not ensure the process is free from the control of vapor contaminants, in accordance with the second part of the standards of the American National Standards Institute (ANSI), the AAMI, and the International Organization Standardization (ISO) 17665-1[2].

Based on the data presented, we conclude that controlling the water quality in the processing of health products is of paramount importance, and its monitoring should be incorporated by health services.

Several technologies for water treatment are available in the market; thus, it is recommended that health services adopt a quality standard for the water used in the last rinsing and estimate treatment technologies according to Central Supply needs, considering the required volume of water and treatment system efficiency. Since water monitoring must be performed in conformity with protocol, analyses should be performed at shorter intervals after the installation of the system to assess its effectiveness. In line with the constancy in the results, monitoring may be performed with less frequency, considering that, with the history of the values obtained, it is possible to determine whether the exchange of consumables and the preventive maintenance of the treatment system are necessary, aiming at maintaining the quality standard for the treated water.

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CHALLENGE LOAD VALIDATION AND ASSEMBLY: FROM THEORY TO PRACTICE

Validação e montagem de carga desafio: da teoria à prática

Validación y montaje de carga desafío: de la teoría a la práctica

Emerson Aparecido Miguel[1], Paulo Roberto Laranjeira[2]

ABSTRACT: Objectives: The need to comply with the Collegiate Board Resolution (*Resolução da Diretoria Colegiada* – RDC) ANVISA No. 15/2012 presented many challenges to the Material and Sterilization Center (*Centro de Material e Esterilização* – CME), among which, was determining the greatest challenge load to be used during the sterilization validation process through moist heat in the performance qualification stage **Methods:** This article presents technical regulations which support this activity, as well as the result of a thorough analysis regarding a common result when there is lack of determination of the greatest challenge load: the problems with wet loads. **Results:** The many materials used as health products affect the performance of sterilizers and may compromise the sterilization process. **Conclusion:** Considering this scenario, the use of national and international technical regulations references, the use of devices to challenge the process, and validation of the sterilization are essential in order to ensure the quality of this activity and avoid risks to patients.
Keywords: Sterilization. Condensation. Credentialing. Patients.

RESUMO: Objetivos: A necessidade de cumprimento da Resolução da Diretoria Colegiada (RDC) ANVISA n° 15/2012 trouxe para o Centro de Material e Esterilização (CME) diversos desafios. Entre eles, determinar a carga de maior desafio para utilização durante a validação do processo de esterilização por calor úmido na etapa de qualificação de desempenho. **Métodos:** O presente artigo apresenta normas técnicas que respaldam essa atividade, assim como o resultado de uma análise profunda a respeito de um resultado comum quando há falha da determinação da carga de maior desafio: os problemas com carga molhada. **Resultados**: Os diversos materiais utilizados como produtos para saúde afetam o desempenho dos esterilizadores e podem comprometer o processo de esterilização. **Conclusão:** Diante desse cenário, o uso de referências normativas técnicas nacionais e internacionais, de dispositivos de desafio de processo e de validação do processo de esterilização é indispensável para garantir a qualidade dessa atividade, evitando riscos aos pacientes.
Palavras-chave: Esterilização. Condensação. Credenciamento. Pacientes.

RESUMEN: Objetivos: La necesidad de cumplimiento de la Resolución de la Dirección Colegiada (RDC) ANVISA n° 15/2012 trajo para el Centro de Material y Esterilización (CME) diversos desafíos. Entre ellos, determinar la carga de mayor desafío para utilización durante la validación del proceso de esterilización por calor húmedo en la etapa de calificación de desempeño. **Métodos:** El presente artículo presenta normas técnicas que respaldan esa actividad, así como el resultado de un análisis profundo al respecto de un resultado común cuando hay falla de la determinación de la carga de mayor desafío: los problemas con carga mojada. **Resultados**: Los diversos materiales utilizados como productos para la salud afectan el desempeño de los esterilizadores y pueden comprometer el proceso de esterilización. **Conclusión:** Ante este escenario, el uso de referencias normativas técnicas nacionales e internacionales, de dispositivos de desafío de proceso y de validación del proceso de esterilización es indispensable para garantizar la calidad de esa actividad, evitando riesgos a los pacientes.
Palabras clave: Esterilización. Condensación. Habilitación Profesional. Pacientes.

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CHALLENGE LOAD VALIDATION AND ASSEMBLY: FROM THEORY TO PRACTICE

With the publication of the Collegiate Board Resolution (*Resolução da Diretoria Colegiada* – RDC) ANVISA No. 15, from March 15th 2012[1], the standardization of several processes which occur inside a Material and Sterilization Center (*Centro de Material e Esterilização* – CME) is now mandatory. The centers are classified as CME class I and CME class II, in order to establish good practices for processing health products. In this context, load standardization, which undergoes the sterilization process, was also included. The concept defined in article 4°, item II, was used in order to meet article 37 of RDC ANVISA No. 15, whose objective is to represent the greatest challenge load, by considering the worst case scenario in the routine of a CME's service, and to verify which routines are used for sterilizers in the performance qualification stage during the validation process[1].

The institutions and their professionals have long realized the need to use a challenge load that tests the equipment limits during the validation process, in order to prepare for the worst case scenario in the institution's routine. However, the selection or definition of the parameters to be challenged are often misleading or lacking scientific or regulatory support[2].

A misleading selection results in harmful mistakes, which may compromise both the safety of the process and the sterilization's effectiveness, consequently presenting risks to the patient.

Most mistakes on the sterilization's effectiveness are observed and corrected in order to follow the best options. Currently, a very relevant issue (and which concerns professionals working in this activity) regards the quality level of drying during the sterilization process[2].

In theory, the standard sterilization cycle for moist heat is divided into three stages or steps:

- Step 1: preparation, in which air is removed from the internal sterilization chamber and the load is preheated.
- Step 2: exposure or sterilization, in which steam makes contact with the material under controlled pressure and temperature conditions to promote the death or inactivation of viable microorganisms.
- Step 3: drying, responsible for steam removal and steam condensate inside the load[3].

This last step is gaining more recognition in current discussions on the sterilization process; despite being a historical problem in institutions, it is worsening due to its increasing complexity and the rise of new materials used in the making of Health Products (HP).

More and more frequently, the loads that are to be sterilized are heterogeneous, with a great mixture of components within them, for example: plastic, fabrics, steel alloys and other metals, such as aluminum, titanium, etc. This diversity of materials comprising a box of HP has a direct negative impact on the sterilization cycle, which presents extreme difficulty in achieving efficiency, regardless of the sterilizer brand or model used.

The drying problems became the main cause for the compliance of RDC ANVISA 15[1] and, in order to solve them, the parameter definitions in the sterilization process need to improve in addition to improving the definition of the greatest challenge load.

An example of an assembly mistake with the greatest challenge loads is overloading a basket with HP with the intention of creating the worst possible conditions for the process, resulting in excessive condensate formation, and commonly not representing actual reality (Figure 1).

The definition of challenge loads must consider technical references, which support their selection and lead the process to an evaluation by a proven, safe scientific methodology.

The best reference to fulfill the requirements of RDC ANVISA No. 15[1] is the new technical regulation by ABNT NBR/ISO 17.665-1[3], which defines the greatest challenge load as the reference load created in order to represent difficult combinations of the items to be sterilized. This regulation also suggests the use of ISO/TS 17.665-3[4] in order to define the HP family to be processed.

ISO/TS 17.665-3 proposes the creation of HP families divided according to their conception, following a classification

Source: Photography collection of OrionCE

Figure 1. Excessive condensate formation.

based on the design, the material, the weight and the sterile barrier used in processing[4].

The division of loads into product families helps define which loads are more difficult to process[4] in order to correctly comply with the demands of RDC ANVISA No. 15[1], by looking for more efficient and safer pathways, working more clearly with the problems regarding the drying stage, ensuring sterilization effectiveness and increasing process quality (Figure 2).

Figure 3 shows an assembly with different types of HP: temperature sensors were placed to make contact with each type of material and the heating profile of these materials was observed during the sterilization cycle, which should represent the greatest challenge load of the institution. There were stainless steel, rubber, aluminum and plastic boxes within the loads.

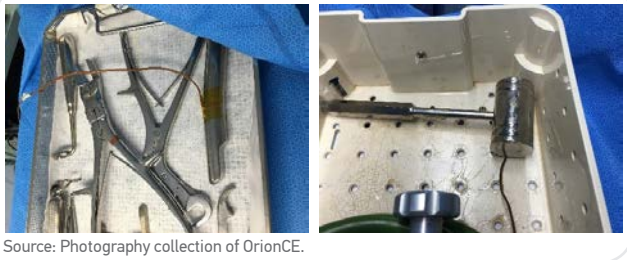
In the thermal study with the greatest challenge load indicated in Figure 3, 12 temperature sensors were selected and used according to ABNT NBR 16.328:2014[5] and placed to make contract with the material to be processed.

During the cycle's development, the temperature was monitored in each item. Figure 4 is the graphic with the results from monitoring a sterilization cycle by moist heat. Four materials of different compositions were selected. In addition to the sterilizer's control sensor located near the drain, the T-03 sensor was placed in contact with a plastic item; sensor T-04 with an aluminum item; sensor T-08 with a stainless steel item; sensor T-11 with a rubber item; and sensor T-12 was placed with the equipment's control sensor near the drain.

It is possible to observe in the Figure 4 graphic that the temperature differences in materials made of plastic, rubber, and aluminum are large when compared to steel materials (no temperature rise during most of the

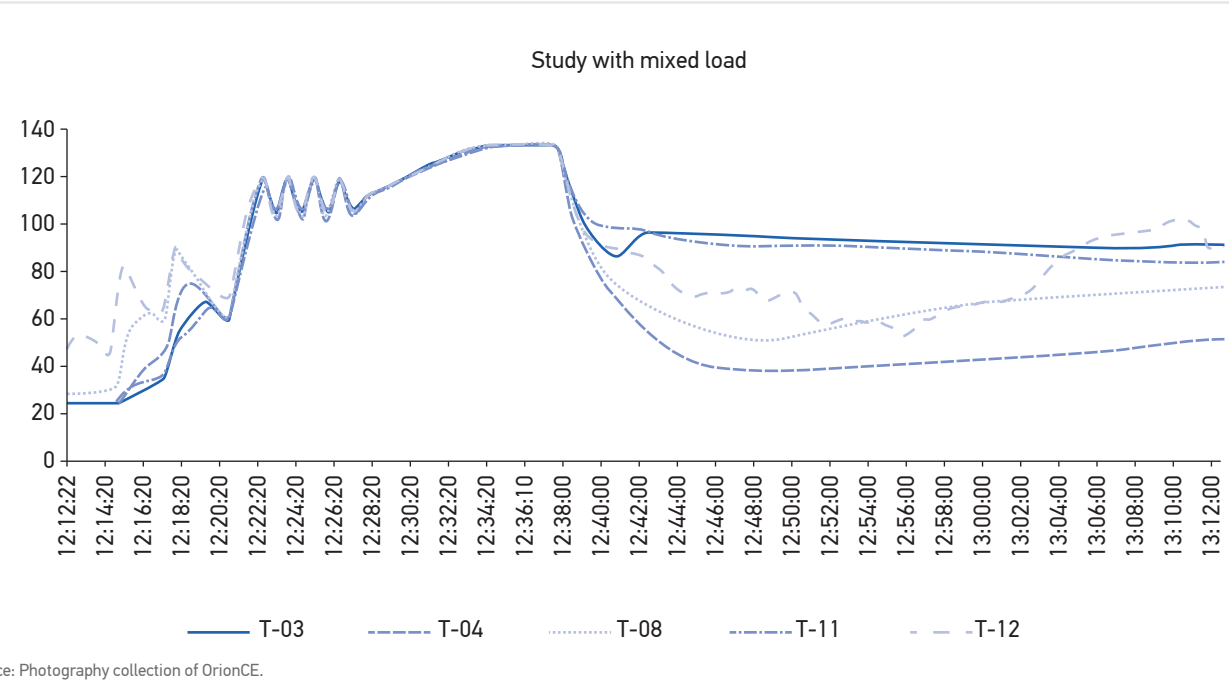
Source: Photography collection of OrionCE.

Figure 2. Greatest challenge load (fabrics, containers and cannulas).



Source: Photography collection of OrionCE.

Figure 3. Example of greatest challenge load.



Source: Photography collection of OrionCE.

Figure 4. Graphic with load temperature values.

packaging stage). Thermal differences are also observed during the drying stage. The thermal difference was irrelevant only in the heating and exposure stages (sterilization step) of the cycle.

The conclusion drawn from this study is that, due to the differences in the heating of materials, there was a high rate of moist condensate inside the boxes during packaging. Additionally, the condensate excess was not removed during the drying stage, resulting in wet packages at the end of the cycle and failing the cycle during the validation process.

The reasonable use of the principles and system established by ISO/TS 17.665-3[4] avoids the excessive formation of condensate and allows the loads to be dry at the end of the cycle, regardless of the brand of equipment.

Special attention should be given to the configuration of the sterilizer's cycle since it significantly influences the validation process results in the case they do not agree with the established criteria in technical variation regulations for values of temperature and pressure, dryness, and non-condensable gases[4].

All the points mentioned above must be tested in order to be checked for their compliance to the current and relevant technical regulation[3], allowing users to use the commercially available Process Challenge Devices (PCD), or to create their own, according to the technical regulation, in order to monitor the cycles according to the requirements of RDC ANVISA 15[1].

ABNT NBR ISO 17665-1[3] characterized these PCD as items designated to constitute a defined resistance to a sterilization process, and are used for the performance evaluation in the process. They challenge the process for air removal, steam penetration and the presence of non-condensate gases; they also verify if the energy present in steam is sufficient to promote the inactivation of microorganisms. Every PCD must meet the construction and technical efficiency regulations in order to ensure that the results definitely indicate whether the sterilization cycle was approved or not.

The institution may use these devices in their routine, according to article 96 of RDC ANVISA No. 15, for monitoring each cycle. However, they should be used within the chemical integrators devices (class 5 or 6), only by adding a biological indicator in implantable health products according to article 98[1].

When using these devices, the institution should also be attentive to the development of the following items, mandatory to the remaining parameters of their processes[3]:

- compliance regarding the definition of the product;
- compliance regarding the definition of the process to which they were developed;
- compliance during Performance Qualification (PQ);
- review and approval of the validation process; and
- monitoring and control of the routine.

It is recommended to create a validation group comprising teams of CME nurses, engineers and maintenance workers, suppliers and service providers (which need certified professional qualifications in order to perform their activities, to develop and carry out the qualification, to control changes and monitor equipment protocols)[3].

We conclude that the shared responsibility of each item of the process, the use of current and relevant technical regulations and the compliance with the recommendations from national and international associations are essential items in order to overcome current challenges in sterilization processes, to comply with legal requirements and to increase patient safety.

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TRENDS AND CHALLENGES OF SURGICAL HAND PREPARATION

Tendências e desafios do preparo cirúrgico das mãos

Tendencias y desafíos em la preparación quirúrgica de las manos

Julia Yaeko Kawagoe[1]

ABSTRACT: Objective: To describe trends and challenges of surgical hand preparation. **Method:** Narrative literature review, consulting the current international and national guidelines and searching the following databases: the Cochrane Systematic Reviews and the VHL portal (Latin American and Caribbean Center on Health Sciences Information), LILACS, IBECS, MEDLINE, Nursing Reference Center, and SciELO, using the keywords: Desinfecção das Mãos, Salas Cirúrgicas; Hand Disinfection, Operating Rooms; Desinfección de las Manos, Quirófanos, and Boolean connectors AND/OR in the period between 2006 and 2016. **Results:** Five guidelines of surgical hand preparation and two regulations on product evaluation for surgical hand preparation were consulted. Twenty-two articles were identified in the database search and seven were selected: four literature reviews – three of them were systematic reviews – and three studies evaluating cost and ecological sustainability. **Conclusion:** In the last decades, there have been major changes in the type of antiseptic product, which favored the use of alcoholic preparation (AP), without using water and brush, considering the cost-effectiveness and ecological sustainability when compared to traditional procedures such as surgical hand scrubbing with Polyvinylpyrrolidone Iodine (PVP-I) or Chlorhexedine Gluconate (CHG). To incorporate best practices based on scientific evidence, a programmatic approach must be adopted, policies, and programs must be implemented in order to manage including products and processes and monitor compliance with the procedures.

Keywords: Hand disinfection. Operating rooms. Hand hygiene.

RESUMO: Objetivo: Descrever tendências e desafios no preparo cirúrgico das mãos. **Método:** Revisão de literatura narrativa, consulta aos manuais internacionais e nacionais atuais, além de consulta à *Cochrane Database of Systematic Reviews,* e ao portal BVS, à base de dados LILACS, IBECS, MEDLINE, *Nursing Reference Center* e SciELO, utilizando os descritores: Desinfecção das Mãos, Salas Cirúrgicas; Hand Disinfection, Operating Rooms; Desinfección de las Manos, Quirófanos e conectores booleanos AND/OR no período entre 2006 e 2016. **Resultados**: Foram consultados cinco manuais sobre preparo cirúrgico das mãos; duas normatizações de avaliação de produtos para preparo cirúrgico das mãos. Dos 22 artigos identificados na busca, foram selecionados sete: quatro revisões de literatura, sendo três revisões sistemáticas; e três estudos avaliando o custo e a sustentabilidade ecológica. **Conclusão:** Nas últimas décadas, houve grandes mudanças quanto ao tipo de produto antisséptico — favorecendo o uso de preparação alcoólica (PA), sem o uso de água e escova, representando custo-efetividade e sustentabilidade ecológica quando comparada aos procedimentos tradicionais como a degermação cirúrgica das mãos com Polivinilpirrolidona Iodo (PVP-I) ou Gluconato de Clorexedina (CHG). Para incorporar melhores práticas baseadas em evidências científicas, deve-se adotar abordagem programática, implementar políticas e programas que regem os processos e produtos utilizados, bem como o controle desse cumprimento.

Palavras-chave: Desinfecção de mãos. Salas cirúrgicas. Higiene das mãos.

RESUMEN: Objetivo: Describir tendencias y desafíos en la preparación quirúrgica de las manos. **Método:** Revisión de literatura narrativa, consulta a los manuales internacionales y nacionales actuales, además de consulta a Cochrane Database of Systematic Reviews, al portal BVS, y a la base de datos LILACS, IBECS, MEDLINE, Nursing Reference Center y SciELO, utilizando los descriptores: Desinfecção das Mãos, Salas Cirúrgicas; Hand Disinfection, Operating Rooms; Desinfección de las Manos, Quirófanos y conectores booleanos AND/OR en el período entre 2006 y 2016. **Resultados:** Se consultaron cinco manuales sobre la preparación quirúrgica de

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las manos y dos normatizaciones de evaluación de productos para la preparación quirúrgica de las manos. Veintidós fueron los artículos identificados en la búsqueda en la base de datos y se seleccionaron 7: cuatro revisiones de literatura — tres de ellas revisiones sistemáticas; y tres estudios evaluando el costo y la sustentabilidad ecológica. **Conclusión:** En las últimas décadas, hubo grandes cambios referente al tipo de producto antiséptico — favoreciendo el uso de preparación alcohólica (PA), sin el uso de agua y cepillo, representando costo-efectividad y sustentabilidad ecológica comparada a los procedimientos tradicionales como la degermación quirúrgica de las manos con polivinil-pirrolidona yodada (PVP-I) o Gluconato de Clorhexidina (CHG). Para incorporar mejores prácticas basadas en evidencias científicas, se debe adoptar un abordaje programático, implementar políticas y programas que rigen los procesos y productos utilizados, así como el control de ese cumplimiento.
Palabras clave: Desinfección de las manos. Quirófanos. Higiene de las manos.

INTRODUCTION

Surgical patients safety is a global concern that affects patients in developed and developing countries. Healthcare-associated infections (HAI), and mainly the surgical site infections are a public health problem, considering their magnitude and impact on morbidity and mortality[1].

As part of the World Alliance for Patient Safety launched in October 2004, the World Health Organization (WHO) published, in June 2008, the WHO Guidelines for safe surgery (First Edition) to ensure a safer care to the patient. One of this guideline objective was based on the assumption that the team will consistently use methods known to minimize the risk for surgical site infection (SSI)[2].

Among the preventive measures of HAI in surgical patients during the perioperative period is hand hygiene (HH). On May 5th, 2016, the WHO launched the following theme on the campaign "Clean care is safer care:" "See your hands: hand hygiene supports safe surgical care," whose poster is available on the Brazilian Health Surveillance Agency (ANVISA) website[3].

Considering the surgical patient safety, this literature review had the following guiding question: what are the trends and challenges of surgical hand preparation in the international and national contexts?

OBJECTIVE

To describe trends and challenges in the surgical hand preparation through a literature review.

METHOD

A narrative literature review was carried out by analyzing current international and national guidelines, as well as searching Cochrane Database of Systematic Reviews, BVS website, LILACS, IBECS, and MEDLINE databases, Nursing Reference Center, and SciELO. The following descriptors (keywords and Medical Subject Headings -MeSH) were used: in Portuguese — *Desinfecção das Mãos*, *Salas Cirúrgicas*; in English – Hand Disinfection, Operating Rooms; in Spanish — *Desinfección de las Manos*, *Quirófanos*; and Boolean connectors AND / OR between 2006 and 2016.

Papers were selected based on the reading of the abstracts. Those papers that addressed significant changes over time in surgical hand preparation with regard to the product, methods, and duration of the procedures, as well as those articles that included cost-effectiveness analysis, were selected.

RESULTS

Five guidelines on surgical hand preparation and two regulations on the assessment of related products were analyzed. Of the 22 articles identified in the search, 7 were included: 4 literature reviews – 3 of them were systematic reviews – and 3 studies evaluating the costs and ecological sustainability.

Recommendations on surgical hand preparation

The following manuals were consulted: Prevention of Surgical Site Infection (Centers for Disease Control and Prevention – CDC)[4], Hand Hygiene in Health-Care Settings (CDC)[5], Hand Hygiene in Health Care (WHO)[6], Guidelines from the Association of periOperative Registered Nurses (AORN)[7], and ANVISA Guidelines on HH[8].

In the perioperative period, there are basically two HH components[4-8]:

1. routine hand hygiene: to rub hands with alcohol-based products – or to wash hands with plain or antimicrobial soap and water if the hands are visibly soiled;
2. pre-surgical hand antisepsis: corresponds to the surgical hand preparation with an antimicrobial product containing Polyvinylpyrrolidone iodine (PVP-I) or Gluconate Chlorhexidine (CHG), or rubbing with alcohol-based preparation (AP).

The Centers for Disease Control and Prevention (CDC), in the Guideline for Prevention of Surgical Site Infection[4], recommends a surgical scrub in hands and forearms up to the elbows for at least two to five minutes. Only in 2002, in the Guideline for Hand Hygiene in Health-Care Settings, the CDC[5] has included the recommendation on the alcohol-based hand antisepsis, with sustained activity, before donning sterile gloves to perform surgical procedure, in addition to the use of antimicrobial soap. In this regard, the CDC recommends to follow the manufacturer's instructions, prewash hands and forearms with a non-antimicrobial soap and dry completely before applying the AP. After application of the AP as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves. CDC also recommends avoiding excessive antisepsis time (10 minutes) and the use of brush, which are unnecessary as it may cause dermatitis of the hands and forearms.

In 2009[6], WHO published HH manual in accordance with the recommendations of the CDC (2002), emphasizing that the surgical hand antisepsis should be performed using antiseptic agents or suitable AP, preferably with a product that ensures sustained activity, before donning sterile gloves. If hands are visibly soiled, one should wash them with plain liquid soap before surgical hand preparation, removing residues from underneath fingernails using a nail cleaner, preferably under running water. If the water quality is not assured in the operating facility, surgical hand antisepsis with AP is recommended before donning sterile gloves when performing surgical procedures.

The technique to perform surgical hand antisepsis using an antiseptic agent containing PVP-I or CHG consists of the following steps[6]:

- scrub hands and forearms surfaces for the length of time recommended by the manufacturer, usually two to five minutes. Long scrub times, for example, ten minutes, are not necessary and the use of brushes is not recommended.
- rinse hands and arms by passing them through the water in one direction only, from fingertips to elbow.
- dry hands and arms using a sterile towel and aseptic technique before donning gown and gloves.

In the surgical hands antisepsis using AP, the following steps are recommended[6]:

- perform surgical hand antisepsis by rubbing AP with sustained activity (residual) according to the manufacturer's instructions for the application times;
- apply the product only in dry hands, using sufficient product to keep hands and forearms wet with the AP throughout the surgical hand preparation procedure;
- do not sequentially combine other antiseptic agents and alcohol-based products;
- after the AP application as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves[6].

According to The Association of periOperative Registered Nurses (AORN)[7], the surgical hand preparation should be performed before donning sterile gloves for surgical or invasive procedures. AORN recommends the use of antimicrobial agent for the surgical hand scrub or AP for rubbing hands with sustained and cumulative documented activity that meets the requirements of the *Food and Drug Administration* (FDA). The product selection for surgical hand antisepsis should consider the effectiveness of the product, the application requirements, and user acceptance[7].

ANVISA guideline "Patient Safety – Hand Hygiene"[8] recommends using disposable soft bristles brushes in surgical hand preparation only in the subungual area. The duration of the procedure should be three to five minutes for the first surgery and two to three minutes for subsequent surgeries. With regard to the technique, one should collect the antiseptic with the hands cupped and spread it over the hands, forearms, and elbows. If the brush is impregnated with antiseptics, one need to press the side of the sponge against the skin and spread all over or scrub the hands, between fingers and forearms, holding hands above the elbows.

Methods to evaluate the antimicrobial efficacy of products for surgical hand preparation

Basically, there are two methods to evaluate the antimicrobial efficacy for approval of antiseptics for surgical hand preparation: EN 12791, from the European Committee for Standardization (CEN)[9]; and E 1115, from the American Society for Testing and Methods (ASTM)[10]. These tests verify the reduction of resident hand flora, and the persistence and/or cumulative effect.

The European Standard EN 12791[9] recommends testing 18 to 22 subjects, using the split-hands model to assess the immediate effect in one hand while the other continues wearing gloves, aiming at evaluating the sustained/residual effect in 3 hours. The crossover study design should be applied. Two experiments are carried out with an interval of one week to compare the bacterial reduction. The reference product is n-propanol 60% (per volume), applied with approximately three milliliters for three minutes to keep the hands wet. The test product must follow manufacturer's

recommendations; however, it should be applied for less than five minutes. Microbial samples are collected after handwashing with soap without antimicrobial agents (baseline), immediately after antisepsis (immediate effect) and after three hours with gloved hands (residual effect), by the method of fingertips friction on plates with culture medium and neutralizers, one for each hand. The product is approved if:

- immediate and three-hours values may not be smaller than the reference product (n-propanol 60%)
- if the product has sustained activity, bacterial release from skin should be lower than the product reference in the 3rd hour.

American ASTM E1115[10] – *in* vivo – evaluates the immediate and sustained effect. The study design employed is the randomized, blinded, with parallel group (parallel arm), whose sample size is defined according to the formula $n \geq 2S^2 (Za/2 + Zb)^2 / D^2$, where S^2 is the estimated variation, $Za/2$ corresponds to the test level (to 5%, test level = 1.96), Zb is the power of the test (to 80%, power = 0.842), and D is a clinically significant difference of the exclusions. The test product is used for five consecutive days: days 1 and 5 — only one antisepsis; days 2, 3, and 4 — three times a day, with a minimum interval of one hour between the procedures; total of 11 procedures at the end of the study. Microbial samples are taken before the beginning of the study (baseline); immediately after antisepsis (immediate effect); three hours and six hours after the antisepsis with gloved hands on day 1 (sustained effect) and on the days 2 and 5 (cumulative effect), using the glove juice method. For the product to be approved, following requirements must be met:

- day 1: within a minute after the procedure, reduce the number of bacteria 1-$\log_{10}$; after six hours, not exceed the baseline (residual effect);
- day 2: within one minute after the last application of the day (3rd use), reduce the number of bacteria 2-$\log_{10}$,
- day 5: within one minute after the procedure, reduce the bacterial counts 3-$\log_{10}$ (cumulative effect).

Effectiveness of alcoholic preparation in surgical hand preparation

Three systematic reviews assessed the AP in the surgical hand preparation: Gonçalves et al.[11], Tanner et al.[12], and Liu et al.[13].

The systematic review of Gonçalves et al.[11] aimed at comparing the antimicrobial effectiveness of AP with traditional products (TP) in surgical hand antisepsis. The authors evaluated 25 studies. In most of them, AP had a microbial reduction greater or equal to TP, and SSI rates were similar in five studies. The authors concluded that there is scientific evidence supporting AP safety for surgical hand antisepsis.

The review of Tanner et al.[12] intended to evaluate the effects of surgical hand antisepsis in the prevention of SSI; the secondary objective was to evaluate the number of colony forming units (CFU) of bacteria in the hands of the surgical team. Fourteen studies were included in the updated review of 2006. Four studies reported the results of SSI rates and showed no difference between AP and other antimicrobial products, and ten studies reported the number of CFU, but not SSI rates. However, the authors concluded that in general the studies were performed with a small sample, and others had no data or analysis that could be interpreted or related to clinical outcomes. These factors reduced the quality of the evidence.

Liu et al.[13] evaluated the effect of surgical hand preparation techniques on the integrity of the skin and in the incidence of SSI. Ten studies were included in this review; eight were randomized clinical studies and two were nonrandomized clinical studies. There was no difference in the SSI rates when comparing AP with antimicrobial products containing CHG/PVP-I (brush/brushless); however, the AP was tolerated better and caused less skin problems. The brushless technique was associated with a better skin condition compared to brushing. The authors concluded that the surgical hand preparation protocol using AP could be as effective as the protocol that uses the traditional preparation on the prevention of SSI.

A review of literature by Widmer et al.[14], which addressed the state of the art in the surgical hand preparation, summarized the evidence and the main objectives of this surgical preparation, as well as the criteria for the selection of products currently in use. Among the findings, the authors do not recommend the use of brushes for surgical hand antisepsis and reinforce the use of AP owing to fast-acting, broad-spectrum antimicrobial activity, the lower incidence of side effects, and the absence of risks of hand contamination by the water. They also recommended washing hands before surgical antisepsis only if they are visibly soiled, and considered that washing hands with nonantimicrobial soap is enough, when the surgical team enters the operating room.

In the technique of hand preparation with AP, hands must remain wet with alcohol during friction throughout the entire procedure, thus requiring approximately 9 to 15 ml, depending on the hand size. The time required

for AP friction depends on the formulation, generally with exposure time of three-minutes. However, this time may be reduced to one and a half minute or less for some formulations[14].

In a one-year prospective study, Jehle et al.[15] quantified the volume of water applied in surgical hand antisepsis to estimate the water savings and investigate the cost involved in the adoption of AP in the surgical hand preparation. Considering the standard three-minutes period for the surgical hand antisepsis procedure, the water usage was estimated at 18.5 L. The water usage for 3.25 procedures per surgery totaled 60.2 L. When multiplied by 15,500 surgical procedures per year, the annual water consumption in surgical antisepsis was equivalent to 931,938 L. The authors considered that AP had more favorable relative costs compared with PVP-I or CHG, according to the AP volume applied (6 mL).

Tavolacci et al.[16] compared the efficacy of surgical antisepsis using AP with surgical antisepsis using other antimicrobial agents and determined the costs of both surgical hand preparation techniques. The literature review was conducted in MEDLINE to compare the efficacy of both techniques. The costs were estimated based on standard hospital costs. Literature showed that AP has a similar immediate antimicrobial efficacy of surgical scrubbing; however, the AP had a longer lasting effect. The use of AP reduced costs by 67%. Therefore, the authors concluded that the AP is a low-cost alternative to the surgical hand preparation.

A national study carried out by Graf et al.[17] evaluated the cost-effectiveness of antisepsis technique with the AP — during one minute — *versus* scrubbing with CHG under a Brazilian hospital perspective. The total cost of the AP was 46% lower than the average cost of scrubbing with CHG. In an ecological context, a reduction of 18.5 L of water per procedure when applying AP generates financial savings and prevent waste disposal (for example, brushes), in addition to saving a natural resource such as water.

CONCLUSION

Guidelines and studies revealed advantages and cost-effectiveness of APs in the surgical hand preparation, such as shorter procedure time, which could facilitate compliance with the procedure, better skin condition, greater antibacterial efficacy, cost-saving, water saving, and reduction of solid waste.

The challenges surrounding the surgical hand preparation are:

1. the need to produce further national scientific content to understand our reality and/or culture with regard to acceptance and implementation of the AP in Brazilian health services;
2. to provide scientific updates to health professionals, particularly to surgical teams;
3. to evaluate adherence to recommended procedures by using structure, processes, and results indicators.

Finally, to promote a change in this practice, it is recommended to engage the sectors and teams (multisector and multidisciplinary approach) to implement best scientific evidence-based practices, and to develop a process improvement project, containing the following phases: assessment of the current situation (baseline measurement), implementation of improvement strategies, and change impact assessment.

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TECHNOLOGY ASSESSMENT IN THE SURGICAL CENTER, POST-ANESTHETIC RECOVERY, AND CENTRAL STERILE SUPPLY DEPARTMENT

Avaliação de tecnologias no centro cirúrgico, recuperação pós-anestésica e centro de material e esterilização

Evaluación de la tecnología en el centro quirúrgico, recuperación pos anestésica y centro de material y esterilización

Eliane Molina Psaltikidis[1]

ABSTRACT: Introduction: Health technologies are essential in the surgical center (SC), in post-anesthetic recovery (PAR), and in the Central Sterile Supply Department (CSSD). Therefore, there is great pressure for the incorporation of technology in them, which demands high investment and high operating costs. **Objectives:** To propose a reflection on the concepts and principles of the health technology assessment (HTA) and to discuss examples of its application in the context of SC, PAR, and CSSD. **Results:** The HTA methodology allows analysis of clinical, social, and economic impacts of the incorporation of technologies, seeking to improve the quality of care and the health of the population. The Brazilian Ministry of Health has sponsored several initiatives to disseminate the principles of HTA that seek to support managers' decision-making process regarding technological resources, both within the public health system and in private hospitals. **Conclusion:** The nursing staff must, during the decision-making process, take ownership of the HTA methodology for critical analysis of the real benefit of the surgical center technologies.
Keywords: Technology assessment, biomedical. Surgicenters. Sterilization. Anesthesia recovery period.

RESUMO: Introdução: As tecnologias em saúde são essenciais no centro cirúrgico (CC), na recuperação pós-anestésica (RPA) e no centro de material e esterilização (CME). Por isso, há grande pressão para sua incorporação tecnológica, o que demanda alto investimento e elevados custos operacionais. **Objetivos:** Refletir sobre os conceitos e princípios da avaliação de tecnologias em saúde (ATS) e discutir exemplos de sua aplicação no contexto do CC, da RPA e do CME. **Resultados:** A metodologia de ATS permite análise dos impactos clínicos, sociais e econômicos da incorporação de tecnologias, buscando melhorar a qualidade de atendimento e a saúde da população. O Ministério da Saúde tem patrocinado diversas iniciativas para difusão dos princípios de ATS que visam subsidiar os gestores para a tomada de decisão em incorporação tecnológica, tanto no âmbito do sistema de saúde quanto nas instituições hospitalares. **Conclusão**: A equipe de enfermagem deve, na tomada de decisões, apropriar-se da metodologia de ATS para análise crítica do real benefício das tecnologias do bloco operatório.
Palavras-chave: Avaliação da tecnologia biomédica. Centros cirúrgicos. Esterilização. Período de recuperação da anestesia.

RESUMEN: Introducción: Las tecnologías de la salud son esenciales en el centro quirúrgico (CQ), en la recuperación post-anestésica (RPA) y en el centro de material y esterilización (CME). Por lo tanto, existe una gran presión para la incorporación de tecnología en ellos, lo que exige una alta inversión y altos costos de operación. **Objetivos**: Proponer una reflexión sobre los conceptos y principios de evaluación de las tecnologías de salud (ETS) y discutir ejemplos de su aplicación en el contexto de SC, PAR y MSC. **Resultados**: La metodología ETS permite analizar los impactos clínicos, sociales y económicos de la incorporación de tecnologías, buscando mejorar la calidad de la atención y la salud de la población. El Ministerio de Salud de Brasil ha patrocinado varias iniciativas para difundir los principios de la ETS que buscan apoyar el proceso de toma de decisiones de los gestores con respecto a los recursos tecnológicos, tanto dentro del sistema público de salud como en los hospitales privados. **Conclusión**: Durante el proceso de toma de decisiones, el personal de enfermería debe apropiarse de la metodología ETS para el análisis crítico del beneficio real de las tecnologías del centro quirúrgico.
Palabras clave: Evaluación de la tecnología biomédica. Centros Quirúrgicos. Esterilización. Período de recuperación de la anestesia.

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INTRODUCTION

Surgical centers (SC) are characterized as hospital units that make intensive use of health technologies and have an outstanding vocation for pioneering in the adoption of new health techniques, equipment, and products[1]. It also consists of one of the hospital areas with higher cost and turnover. For these reasons, it is always under great pressure for incorporating new technologies from manufacturers, health professionals, and even patients who wish to have access to innovative procedures in their care.

It should be noted that, inevitably, the technologies adopted in the SC cause repercussions in the work processes of post-anesthetic recovery (PAR) and in the Central Sterile Supply Department (CSSD). In the latter, the impacts are due to new equipment and instruments, mostly complex structures, which need to be properly processed. Another impact of the application of new technologies is the pressure for the practice of reutilization of high-cost health products, whose manufacturers recommend single use.

However, there is not always solid evidence of the efficacy, effectiveness, and efficiency of these new technologies in health. Therefore, their benefits, risks, and costs should be considered. The health technology assessment (HTA) consists of a methodology that produces technical subsidy to aid the manager's decision-making process, in a rational and transparent way, regarding the incorporation of a given technology[2-4].

This article aims to propose a reflection on the concepts and principles of EHR and discuss examples of its application in the context of SC, PAR, and CSSD.

IMPORTANT CONCEPTS AND PRINCIPLES ON THE HEALTH TECHNOLOGY ASSESSMENT

Health technologies include medicine, technical equipment and procedures, organizational systems, informational, educational, and supportive programs and protocols, through which health attention and care are provided to the population[4].

The rapid innovation of healthcare technologies and their impact on healthcare costs concern both public and private systems managers, for the world health scenario has shown a virtually endless supply of technological options, as opposed to increasingly smaller, limited, and finite features. In addition, there is a wide range of economic interests involved in the expected incorporation of technologies[3,4]. Many of these concerns are legitimate and guided by good and ethical market practices in health. However, several complaints have been made about criminal actions in the incorporation of drugs and procedures with a high cost or that do not benefit patients[5-7].

The nursing team has intensive contact with health technologies, even though in which the definition of patient assistance adopted does not come from the nurse[1]. Due to this proximity to the technology, nurses are able to realize the difficulties in its use, problems in its application that may pose a risk to patients and staff, the patient's reaction to the applied technology, and the needs not met by current technology. In addition to this role, nurses can often act as managers, decision-makers, and influencers on the incorporation of technologies.

All health managers need reliable and detailed information that enable them to make rational, consistent, and transparent decisions when establishing priorities in the incorporation of technologies, aiming to obtain the maximum benefit with the available budget. The HTA is the main methodological tool for this process, as it analyzes the clinical, social, and economic impacts of the incorporation of technologies to improve the quality of care and the health of the population[3,4,8].

HTA allows measurement of the efficacy (evidence of favorable results for the health condition for which it is), effectiveness (confirmation that the favorable results identified in the efficacy research are kept in care practice), and efficiency (analysis of the benefits in the outcomes with respect to cost) of the technologies in all stages of their life cycle. HTA can also generate technological horizon monitoring studies for innovative technologies, cost-effectiveness, and comparative effectiveness studies for propagating technology and obsolescence and disincorporation to those already in disposal phase[2-4,8].

To perform the HTA, some methodological principles are fundamental:

- analysis question explicit and based on the PICO tool, which defines the intended population (P), the intervention (I), i.e., the technology analyzed, the comparator (C), and the relevant outcomes (O) to be adopted;
- wide, systematic, and reproducible literature search in the main electronic databases, HTA agencies and gray literature, preferably without publishing language restriction;
- analysis of studies by at least two independent reviewers and no conflict of interest with the evaluated technology;

- selection of studies by the best available evidence, prioritizing designs with lower risk of bias;
- assessment of the methodological quality of studies with validated instruments;
- analysis of the quality of the body of evidence for each outcome defined in PICO;
- critical analysis of the results compared to the local health reality and its clinical and economic impacts;
- economic evaluation and studies of budget impact using the methodologies of health economics;
- preparation of the HTA report in the language and perspective of the requesting manager[3,9,10].

HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL

Although the principles of HTA are already established in many countries, this is still a new issue in Brazil. The Brazilian Ministry of Health has invested in structuring Center for Health Technology Assessment (CHTA) in teaching hospitals, health departments, research institutions, and major hospitals in the country. These centers assist in the training of professionals, offer guidance to the managers of the institution in decisions about technological development, and meet the demands of the Ministry of Health and the secretariats with HTA studies in analyses for incorporation in the Unified Health System (SUS). The CHTA are linked to the Brazilian HTA Network (REBRATS), also under the Ministry of Health, which provides interaction, training courses, organization of working groups, and elaboration of methodological guidelines that guide and standardize HTA documents produced in the country (http://rebrats.saude.gov.br/).

The main legal framework for the institutionalization of HTA in Brazil was given by 2011 Law No. 12,401 of 2011, which amended Law No. 8,080 of 1990, which governs SUS, specifically in Article 19[11]. The new wording of this article defines the integrated care guaranteed by the SUS, which is now established by national therapeutic guidelines and clinical protocols or by scientific evidence of efficacy, safety, effectiveness, and cost-effectiveness for the different phases of the disease or health condition. That is, any procedure, drug, or health product shall be part of the SUS comprehensive care, provided that the technology assessed justifies its incorporation by their benefits, nationwide. This law also established the National Technology Incorporation Commission on SUS (CONITEC) to advise the Ministry of Health in the development, exclusion, or modification of health technologies in the public system, and to develop and update clinical protocols and national treatment guidelines (http://conitec.gov.br/).

Since its establishment in 2012 until July 2016, CONITEC already assessed 492 claims, 56% of which were sent by the Ministry of Health aimed at updating the therapeutic and diagnostic arsenal in SUS. Of the total claims, most were drugs (65%), followed by procedures (21%) and medical devices (14%). Through these actions, CONITEC enabled the incorporation of 173 new technologies in the SUS list with budgetary impact estimated at R$ 2.5 billion[12].

The work of CONITEC even impacts the private health system. With the incorporation of a given technology in the SUS (through effectiveness evidence), health plan operators find themselves under pressure to also increase their coverage.

Despite this evolution, the principles of HTA are barely practiced by managers of local health services, largely because of the lack of information on this resource for decision-making and the lack of trained professionals to prepare evaluations for their institutional demands. In the face of this reality, the Ministry of Health has been supporting several courses on HTA for managers and encouraging the increase in the number of NATS the country.

REFLECTIONS ON THE IMPLEMENTATION OF HEALTH TECHNOLOGY ASSESSMENT IN SURGICAL CENTER, POST-ANESTHETIC RECOVERY, AND CENTRAL STERILE SUPPLY DEPARTMENT

There are several questions about the excessive use of technology in the surgical field and its impact on healthcare costs without the corresponding benefits to the patient. Época magazine, in May 2015, published a comprehensive report on healthcare costs, and cited that doctors from Hospital Israelita Albert Einstein in São Paulo reassessed the condition of nearly 1,500 clients of Bradesco Saúde insurance who were about to undergo spine surgery. In conclusion, they found that two thirds of them would not need the procedure and that they would benefit more from the indication for conservative treatment[13]. This reality is not unique to Brazil. In August 2016, The New York Times, in an article entitled "Why 'useless' surgery is still popular," questioned the routine performance of orthopedic surgery which studies with high-quality evidence have shown to represent no benefit when compared to conservative

treatment[14-17]. These issues must permeate the entire society, so that professionals and users of the health system become more critical to the healthcare practices.

Some highly valued and recommended surgical techniques, when undergoing examination by systematic HTA, show to be supported by research with low methodological quality, that is, lack of evidence of their actual benefits. One technique in this situation is the artificial urinary sphincter, which, despite being considered the gold standard for treatment of moderate or severe urinary incontinence or after radical prostatectomy, is based on only one randomized controlled trial with a small sample size and low methodological quality, compared only to the macroplastique injection. Other studies on the artificial urinary sphincter are very low-quality observational studies that showed significant results in continence and patient satisfaction, but higher risk of complications (infection, urethral stricture, malfunction, need for device revision over the years and possible replacement or withdrawal)[18,19].

Robotic surgery is another example of high-cost technology with considerable repercussion on scientific and media events, which does not have solid evidence on benefits that justify its inclusion in the healthcare practice. In Brazil, an investigation was carried out, on demand of the Ministry of Health, on robotic-assisted radical prostatectomy (RARP), compared to the open and laparoscopic techniques[20]. The study was conducted in three hospitals that already possessed the surgical robot and conducted about 25 RARPs/month. The results indicated less blood loss in RARP compared to open surgery, but compared to the laparoscopic technique, the difference was not significant. The other outcomes measured, such as length of hospital stay and surgery, were not encouraging; however, the cost of procurement of the equipment and supplies were huge. The first randomized clinical study on RARP is in progress; the partial results were recently published, reflecting the monitoring of patients for 12 weeks[21]. In the study, there was a significant difference between the RARP group compared to open surgery, only in pain in the first 24 hours and in the first week after surgery, in blood loss and in hospital stay. However, there was no significant difference in blood transfusion, and the difference in room time was not relevant. However, the most surprising result is that there is no statistical difference between the groups for functional outcomes such as urinary function, sexual function, positive margin in surgical samples, and the time to return to work. The authors' conclusion is that there is need for more monitoring and that, for radical prostatectomy, the surgeon's experience is more important than the type of surgical approach.

As for the instruments used in surgery, the NATS of Hospital de Clínicas of Universidade Estadual de Campinas (UNICAMP) had the opportunity to evaluate the single-use surgical staplers, on demand of the institution, due to the high cost of products and reimbursement restrictions by SUS, which foresees its use only for some surgeries. In the literature analysis, studies with high-quality evidence showed that, in gastrointestinal tract and lung surgery, there was no evidence of better postoperative clinical outcomes with the use of staplers. As the analysis of their consumption in the institution resulted in a 25% higher cost than that reimbursed, the hospital opted to restrict its use only for procedures in which the staplers are provided by SUS[22].

Another technology that has been widely promoted is the no-touch surface disinfection system with hydrogen peroxide vaporization or ultraviolet radiation. These devices are suitable for terminal cleaning of critical areas, especially where there is risk of contamination with multiresistant bacteria and *Clostridium difficile*. Although studies show the effectiveness of such systems in inactivating a broad spectrum of microorganisms and some result in the reduction of related infections, especially in outbreak situations, the operationalization of this method is the major limiting factor. That is, the effectiveness is weak because there is a need for pre-cleaning of all surfaces in the area, of sealing of air inlets and outlets, the blocking of the area during the time of application and of exhaustion (which may take more than 1 hour), as well as staff training and costs with equipment and supplies. In the case of ultraviolet radiation, there is still a shadowing limitation, because places the light cannot reach will not undergo the microbicidal action. A study conducted by the Canadian Agency for HTA (CADTH) analyzed the system and concluded that there is insufficient evidence to recommend its incorporation.[23].

With regard to the CSSD, there is a great need for HTA studies, despite the wide range of new products for the area. One HTA agency of the Province of Quebec, Canada, made a comparative assessment of pasteurizers and thermodisinfection washers for respiratory care equipment, proving the cost-effectiveness of both, with a slight advantage to washers, for providing cleaning in different cycles[24].

In Hospital de Clínicas of UNICAMP, as a result of the questioning of the replacement of glutaraldehyde for peracetic acid for disinfection of endoscopes, HTA was performed on high-level disinfectants. The analysis summarized the evidence on the issue

regarding the effectiveness, compatibility, and limitations of each germicide and demonstrated the worldwide shortage of studies on damage to equipment related to different disinfectants[25].

FINAL CONSIDERATIONS

The inevitable scarcity of resources in healthcare and the pressure for the incorporation of technology have led to the spread of HTA principles among managers at all levels of the health system. There is plenty to evolve in the HTA adopted in SC, PAR, and CSSD, which open wide space for nursing professionals to qualify in the methodological tools of HTA. Decision making for investment in these areas often involves significant financial support and requires guided analysis of the best evidence available, to ensure that the ratio between cost and effectiveness is favorable.

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