DIGITAL COMPETENCY: IS IT ESSENTIAL FOR NURSES?

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The labor market is in transformation. Regardless of the industry analyzed, the speed of changes triggered by technology is remarkable. The same is true in the health care industry: technology, along with its inherent advantages and challenges, has already been incorporated into health care professionals' many work processes. Examples include electronic medical records, decision support systems, the disappearance of film in diagnostic imaging, the advancement of telemedicine, robotic surgery, and automated medication dispensing systems. In critical care units such as in intensive therapies and in the operating room, where there is intensive use of technology, these transformations are more evident.

This transformation, however, is not only limited to new equipment, instruments and materials. With the advancement of Internet-enabled information and communication technologies (ICTs), we are moving towards new practice models and even deeper changes in the way health care services are organized. Thus, nurses are required to be competent in new areas in order to adjust their professional performance and manage assistance processes that are adapted to contexts concerning network connection and interaction.

Digital competency, which is considered a cross-curricular competency,

> is the set of knowledge, skills, attitudes (thus including abilities, strategies, values and awareness) that are required when using ICT and digital media to perform tasks; solve problems; communicate; manage information; collaborate; create and share content; and build knowledge effectively, efficiently, appropriately, critically, creatively, autonomously, flexibly, ethically, reflectively for work, leisure, participation, learning, socializing, consuming, and empowerment[1].

Digital competency has been recognized by the European Parliament and the European Council, since 2006, as one of eight key competencies for lifelong learning and insertion in the society of knowledge. It is necessary to acquire other competencies, which are: communication in one's mother tongue, communication in foreign languages, mathematical competency and basic competency in science and technology, learning how to learn, social and civic competency, initiative and entrepreneurial spirit, and cultural sensitivity and expression. It is proposed to be developed in five areas and evaluated considering three levels of proficiency — basic, intermediate and advanced[2-4]:

1. Information as well as data and information literacy: to identify, locate, retrieve, store, organize and analyze digital information, assessing its relevance and purpose;
2. Communication and collaboration: to communicate in digital environments, share resources through online tools, connect with others, collaborate using digital tools, interact and participate in communities and networks, have intercultural awareness;
3. Digital content creation: to create and edit new content (texts, images, videos etc.), integrate and rework prior content and knowledge, produce creative expressions, multimedia and programming content, handle and enforce intellectual property rights and user licenses;
4. Security: personal protection, data protection, digital identity protection, security measures, safe and sustainable use;
5. Problem solving: to identify digital needs and resources, make informed decisions about the most appropriate digital tools according to purposes/needs, solve conceptual problems through digital media, solve technical problems, use technologies creatively, update one's own and others' digital competency.

From this perspective, it is important to recognize initiatives such as the Center for Technologies and Distance Education of the Federal University of Ceará Medical School (NUTEDS) and the Telemedicine University Network (RUTE), which are aimed at promoting the development of digital competency as well as digital and informational literacy among health care professionals and students, from the undergraduate level onward[5].

In addition, nursing proposals that emerged from the IV National Graduate Studies in the Health Sciences Meeting, in 2010, which are:

> 1º) encouraging the creation of technological and innovative environments to develop nursing and health care models, with sustainability and entrepreneurship strategies;
> 2º) investing in the creation of economic and social impact indicators as well as technology and innovation in nursing and health;
> 3º) promoting the creation of networks for innovation and technology development in nursing and health, to ensure excellent and safe nursing care;
> 4º) proposing, to the development agencies, thematic projects of the Technology and Innovation in Nursing Care, Management and Education and Health, in accordance with the policies of the Unified Health System;
> 5º) proposing the inclusion of nursing care technologies in the Priority Research Agenda; and
> 6º) Increasing the policy of expansion and articulation of Nursing Postgraduate programs, as a strategy for qualifying service professionals with the implementation of evidence-based care technologies[6].

As changes are already underway, the challenges in the field of nursing are not insignificant., and it is not enough to just follow along with the transformation. It is necessary to invest in research efforts in order to understand how ICTs will affect the care, organization and coordination of nursing services, in addition to propose and test educational and management models that enable nurses to act in these new situations.

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ASSESSMENT AND CONTROL OF INSTRUMENTS UTILIZED IN OPERATING ROOM DURING THORACIC SURGERIES

Avaliação e controle de instrumentais utilizados em sala operatória durante cirurgias torácicas

Evaluación y control de instrumentales utilizados en quirófano durante cirugías torácicas

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ABSTRACT: Objective: To assess the number of unused surgical instruments during thoracic surgeries performed at a university hospital. **Methods:** An exploratory, descriptive, cross-sectional study with a quantitative approach, conducted by gathering data on the use or lack of use of surgical instruments present in the surgical box. **Results:** A total of thirty thoracic surgeries were observed, with a mean of 84.53% of instruments utilized for surgery and a mean of 15.48% of instruments left unused. **Conclusion:** A reconfiguration of the surgical boxes for this specialty is needed in order to optimize the utilization and the process of these instruments.

Keywords: Surgical instruments. Cost control. Surgical procedures. Operative procedures. Thoracic surgery. Perioperative nursing.

RESUMO: Objetivo: Avaliar o número de instrumentais cirúrgicos não utilizados durante as cirurgias torácicas realizadas em um hospital universitário. **Métodos:** Trata-se de um estudo exploratório, descritivo, transversal com abordagem quantitativa, realizado a partir do levantamento de dados sobre a utilização ou não de instrumentais cirúrgicos presentes nas caixas cirúrgicas. **Resultados:** Foram observadas 30 cirurgias torácicas, sendo a média de instrumentais utilizados por cirurgia de 84,53% e a média de instrumentais não utilizados de 15,48%. **Conclusão:** São necessárias reformulações na composição das caixas cirúrgicas dessa especialidade a fim de otimizar a utilização e o processamento dos instrumentais.

Palavras-chave: Instrumentos cirúrgicos. Controle de custos. Procedimentos cirúrgicos operatórios. Cirurgia torácica. Enfermagem perioperatória.

RESUMEN: Objetivo: Evaluar el número de instrumentales quirúrgicos no utilizados durante las cirugías torácicas realizadas en un hospital universitario. **Métodos:** Se trata de un estudio exploratorio, descriptivo, transversal con abordaje cuantitativo, realizado a partir del levantamiento de datos sobre a utilización o no de instrumentales quirúrgicos presentes en las cajas quirúrgicas. **Resultados:** Fueron observadas 30 cirugías torácicas, siendo el promedio de instrumentales utilizados por cirugía del 84,53% y el promedio de instrumentales no utilizados del 15,48%. **Conclusión:** Son necesarias reformulaciones en la composición de las cajas quirúrgicas de esa especialidad a fin de optimizar la utilización y el procesamiento de los instrumentales.

Palabras clave: Instrumentos quirúrgicos. Control de costos. Procedimientos quirúrgicos operativos. Cirugía torácica. Enfermería perioperatoria.

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INTRODUCTION

The Surgical Center (SC) is one of the hospital units where high, medium and low complexity surgeries are performed and, therefore, it requires well-trained and highly-qualified staff. It is recommended that the SC be connected to the Intensive Therapy Unit, the Post-Anesthesia Care Unit and the Emergency Care Unit in order to facilitate emergency care. It is also recommended that it be near the Sterile Supply Department (SSD), in order to facilitate the flow of sterilized materials.

An SSD is defined as an area for receiving supplies, waste management, and the preparation, sterilization, storage and distribution of sterile supplies to other hospital units. Access should be restricted to working personnel and should have temperature and humidity control to keep the sterility of processed materials, avoiding bacterial growth and damage to sterile material[1,2].

As soon as it is utilized in surgery, the material is considered contaminated and is sent to the SSD, where it will undergo the process that will make it sterile again. It is worth remembering that, following the Board of Directors Collegiate Resolution (RDC) nº 30, from February 15, 2006, from the Brazilian Health Regulatory Agency (ANVISA), the resterilization of supplies is prohibited; therefore, even the materials that were merely opened yet left unused should be reprocessed, that is, go through the entire process again, from the initial cleaning to storage[3,4].

There is a vast collection of surgical instruments that have been developed to meet the needs of new surgical techniques, with the purpose of aiding, facilitating and promoting precision for surgeons. These instruments are distributed in groups — special, basic or common — according to their use and purposes during each stage of the surgery. The special instruments are utilized only during select stages of certain surgeries; in other words, they are specific instruments. The common instruments are the basic instruments present in every surgery box, and can be used in any type of intervention with the following purposes: incision, such as the scalpel blade and scissors; hemostasis, such as the Kelly forceps; grasping, such as the Allis forceps and field or Backhaus forceps; retaining, such as retractors; and suture or ligation, such as needle holders[3,5-7].

Finally, there are examples of instruments utilized specifically for certain surgical specialties, like the Abadie clamp, used in digestive tract surgeries, or the Sluder-Ballenger tonsillotome, used for tonsil surgery[7].

The surgical instruments utilized in the hospital setting are seen as material resources and are of extreme importance within an institution, be it for profit or otherwise, since they represent 75% of the capital of health care establishments. Therefore, the way they are administrated reflects directly on the hospital's costs. Hence, an excess of instruments being processed and then left unused can result in an increase of costs, in addition to a depreciation, deterioration and waste of resources. To avoid this, instruments should not be found in excess in surgical boxes and operating tables, and only the indispensable instruments, which have been proven useful for the proposed surgical intervention, should be present[6,8].

In assessing the costs, it is extremely important to point out that the final product — in this case, the sterile hospital material — refers to three inter-related factors: utilized materials, manpower and the technology employed in the process. These factors, if well administrated, do not incur losses and guide the expectations for the reduction of costs, all the while maintaining the quality of care. To achieve this, the institution must have quality management that is aware of these factors[9].

To reach the total cost for sterilization, expenses with raw materials, manpower and work hours utilized in the process are calculated, from the washing of each instrument to the stocking of materials at the SSD, and assessing the technology employed for these steps — including here the maintenance of the sterilizer and the energy spent in this process[9,10].

In a study conducted in 2015, researchers found a cost of R$ 0.29 per processed instrument, identifying a total cost of R$ 1,584.17 for 17 medium surgeries performed during one month with the sterilization of instruments that were left unused in the surgeries, but which made up the surgical box[3].

Thoracic surgeries are an important specialty, as they offer interventions in the lungs, pleura, mediastinum and thoracic wall, accompanied by specialized medical staff made up of infectious disease specialists, oncologists and pulmonologists. Under this context, nurses practice complex perioperative nursing in surgeries like thoracotomy, bronchoscopy and lobectomy, among others[5].

A thoracic procedure includes the combination of delicate and heavy instruments utilized in incisions, dissections and retractions, as well as cutting and securing of tissue and vessels in the thorax, in addition to facilitating the inspection and the intervention of thoracic structures. Nurses are responsible for anticipating the need for these instruments and for providing them prior to surgery while avoiding waste; guaranteeing their appropriate and precise use during the

entire procedure, which generally involves long surgeries, guaranteeing that all of the instruments are meticulously checked and counted[5].

Thus, managing the materials in an operating room (OR) is the responsibility of the nurse who works in the SC and is a fundamental part of the perioperative nursing assistance, which involves the safety and care of patients during the preoperative, intraoperative, and postoperative stages[1-3].

For a well-designed and successful surgery, there should not be excess instruments in the operating tables. Only the instruments that are indispensable and which have been proven useful to the procedure should be present. Hence, the main question in this study is: Are all of the instruments that make up the surgical boxes for the thoracic surgeries utilized in the OR?

The results of this study will contribute to the improvement of the perioperative nursing practices regarding the assessment and control of instruments in the OR, in addition to providing assistance in controlling costs in the processing of instruments in the SSD.

OBJECTIVE

To assess the number of used and unused surgical instruments that make up the surgical boxes in thoracic surgeries.

METHODS

A descriptive, observational, cross-sectional study with a quantitative approach, conducted at a university hospital in Campinas (SP). It is a tertiary and quaternary care hospital, fully financed by the Unified Health System (SUS), and contains 403 beds, where all care is conducted and paid for exclusively by SUS. The SC performs an average of 200 surgeries per month, distributed among the 12 ORs for elective surgeries and 4 ORs for emergency procedures. The study was approved by the Research Ethics Committee of Universidade Estadual de Campinas, under protocol number 1.384.178, in January 6, 2016.

Data collection was conducted from February to April 2015, with the authorization of the SC Nursing Board and the nurses responsible for the sector, after the objectives of the study were presented and the Free and Informed Consent was read and signed. Thus, the ethical and legal precepts involved in studies with human beings, contained in Resolution 466/2012 from the National Health Council, were guaranteed[11].

The sample size was calculated considering the objective of estimating the proportion of surgical instruments left unused during thoracic surgeries from February to April 2015. For this calculation, a proportion of p equal to 0.50 was considered, which represents the maximum variability of a binomial distribution, thus generating an estimate with the largest sample size possible.

The population (N) considered when calculating the sample size was made up of 3,195 surgeries of any specialty, performed from February to April 2015, of which 336 were thoracic surgeries. In addition, a sampling error of 5% and a significance level of 5% were assumed. With this, the total calculated sample size was 343 surgeries. This sample was divided proportionally according to the number of surgeries performed and their specialties. For thoracic surgeries, the calculated sample was 30 surgeries.

The following was specified in the data collection instrument: name of the surgery, surgical boxes involved, date and number of surgery, identification of the most common instruments used in surgery by name — divided into incision, hemostasis, suture and ligation, others —; two columns indicating the quantity of each items in the box and the number of items that remained on the table after the end of the surgery; and finally, the sum of the values of both columns and a space for surgical observations.

The majority of surgeries need more than one box, so that each box coming from the SSD is accompanied by a list with the instruments present in each box. To collect the data, the researcher entered the OR during the surgery and, with the help of the lists, completed the first part of the data collection instrument, informing which instruments were available, as well as their quantity. At the end of the surgery, the researcher once again entered the OR and completed the second part of the instrument, registering the number of surgical instruments that remained intact in the boxes coming from the SSD; in other words, those that never touched the operating table.

In the data collection instrument for each surgery, surgical instruments were divided according to the surgical stages: incision, hemostasis, assistance, suture and litigation and others (including, mainly, instruments involved in exeresis). This process was implemented in 30 thoracic surgeries. Only the surgeries performed in the specialty "thoracic surgery" were considered for this study. At this institution this is the specialty that performs the tracheotomies.

RESULTS

From the 30 thoracic surgeries analyzed, a total of 3,333 instruments were observed, of which 516 (15.48%) were left unused. The mean of used instruments per surgery was 111.1, and the mean of unused instruments was 17.87 (Table 1).

The percentage of unused instruments in the thoracic surgeries corresponds to 15.48% (17.87), in 94 boxes observed within 30 procedures.

Minor, medium and major surgeries were performed: 8 tracheostomies (26.6%), 4 tracheoplasties (13.33%), 6 pleuroscopies (20%), 4 mediastinoscopies (13.3%), 3 lobectomies (10.0%) and 5 cystectomies (16.66%), utilizing 1 to 12 surgical boxes. Table 2 presents the distribution of the utilization of boxes and instruments for these specialties according to size and type of surgery.

The percentage of utilized instruments according to the surgical stage in these thoracic surgeries were: incision, 13,17%; hemostasis, 16,14%; assistance, 13,49%; suture and ligation, 11,41%; and other instruments, 19,39% (Table 3).

Hemostasis and other instruments stand out with the highest mean values for unused instruments, with 33.30 and

Table 1. Distribution of surgical instruments and boxes for thoracic surgeries. Campinas, 2016. (n=30).

Variable	Mean	Standard Deviation	Minimum	Maximum
Used Instruments	111.1	93.03	19.0	424.0
Unused Instruments	17.87	22.66	0.0	92.0
Number of Boxes Used	3.13	2.83	1.0	12.0

Table 2. Distribution of the total number of surgical instruments and boxes per surgery. Campinas, 2016.

Surgery	Surgical Instruments			
	Total Boxes	Initial Total	Unused	Used
Major				
Cystectomy	7	244	55	189
Cystectomy	6	214	53	161
Cystectomy	2	106	4	102
Cystectomy	7	424	30	394
Cystectomy	4	112	0	112
Lobectomy	10	220	48	172
Lobectomy	12	246	43	203
Lobectomy	6	206	0	206
Medium				
Tracheoplasty	2	108	0	108
Tracheoplasty	4	111	16	95
Tracheoplasty	4	209	82	127
Tracheoplasty	2	139	23	116
Minor				
Mediastinoscopy	4	123	14	109
Mediastinoscopy	1	37	17	20
Mediastinoscopy	2	65	0	65
Mediastinoscopy	2	122	12	110
Pleuroscopy	1	38	5	33
Pleuroscopy	2	65	10	55
Pleuroscopy	1	38	6	32
Pleuroscopy	2	73	0	73
Pleuroscopy	1	38	5	33
Pleuroscopy	1	22	2	20
Tracheostomy	1	38	5	33
Tracheostomy	1	115	25	90
Tracheostomy	2	32	6	26
Tracheostomy	1	29	0	29
Tracheostomy	2	64	42	22
Tracheostomy	1	19	1	18
Tracheostomy	1	28	3	25
Tracheostomy	2	48	9	39
Total	94	3333	516	2817

Table 3. Distribution of used and unused instruments by stage of surgery in thoracic surgeries. Campinas, 2016 (n=30).

Stages of Surgery	Surgical Instruments	Mean	Standard Deviation	Minimum	Maximum
Incision	Used	9.37	6.63	2.00	26.00
	Unused	1.67	2.64	0.00	10.00
Hemostasis	Used	33.30	21.77	7.00	80.00
	Unused	6.03	7.63	0.00	24.00
Auxiliaries	Used	20.33	14.24	6.00	57.00
	Unused	3.07	4.39	0.00	17.00
Suture or Ligation	Used	8.37	7.38	1.00	25.00
	Unused	1.53	3.76	0.00	20.00
Other	Used	39.73	69.07	0.00	363.00
	Unused	5.57	9.73	0.00	32.00

39.73 respectively, and they are also the instruments found in highest volume in the surgical boxes, as observed in Table 4, with 999 (29.97%) hemostasis instruments and 1,192 (35.7%) other instruments.

The instruments referred to as "other" were the highest number, because they refer to instruments for the "thoracic surgery" specialty, but not for the proposed surgery, such as retractors, clamps, specific forceps, sponge holders, collectors for cytological materials, distractors, tissue-unifying instruments, bone-cutting instruments, among others required to perform thoracic surgeries at this institution.

DISCUSSION

In a similar study — with similar objectives and methodology — conducted at a small hospital in the countryside of the state of São Paulo, a total of 52% of unused instruments were found, as well as a cost of R$ 0.29 per instrument processed by the SSD, when assessing only 17 medium surgeries performed during one month[3].

When discussing the costs involved in the processing of surgical instruments, there is a series of extremely costly variables, such as a multidisciplinary team made

Table 4. Distribution of used surgical instruments by surgical stage for each surgery. Campinas, 2016.

Surgery	Incision		Hemostasis		Auxiliaries		Suture or ligation		Other	
	Initial Total	Unused	Initial Total	Unused	Initial Total	Unused	Initial Total	Unused	Initial Total	Unused
Major										
Cystectomy	26	10	71	11	57	8	25	2	65	24
Cystectomy	23	4	71	18	55	17	24	4	41	10
Cystectomy	7	0	29	0	16	1	12	0	42	3
Cystectomy	11	0	15	0	26	0	9	0	363	30
Cystectomy	7	0	29	0	17	0	15	0	44	0
Lobectomy	22	4	46	16	29	7	17	1	106	20
Lobectomy	22	5	53	7	38	5	19	4	114	32
Lobectomy	19	0	49	0	31	0	14	0	93	0
Medium										
Tracheoplasty	8	0	45	0	27	0	8	0	20	0
Tracheoplasty	8	1	31	8	17	3	11	4	44	0
Tracheoplasty	14	9	80	24	34	15	23	20	58	24
Tracheoplasty	10	2	55	10	40	2	11	3	23	6
Minor										
Mediastinoscopy	7	1	37	9	21	4	8	0	50	0
Mediastinoscopy	5	3	20	11	10	3	2	0	0	0
Mediastinoscopy	4	0	20	0	10	0	3	0	28	0
Mediastinoscopy	8	0	52	2	38	4	12	3	12	3
Pleuroscopy	4	0	20	3	10	2	2	0	2	0
Pleuroscopy	12	3	25	3	15	0	3	0	10	4
Pleuroscopy	4	0	20	6	7	0	3	0	4	0
Pleuroscopy	4	0	17	0	10	0	3	0	39	0
Pleuroscopy	4	0	20	0	10	4	2	0	2	1
Pleuroscopy	6	0	9	2	6	0	1	0	0	0
Tracheostomy	4	0	20	0	10	3	2	0	2	2
Tracheostomy	9	0	80	23	15	0	5	0	6	2
Tracheostomy	8	2	10	1	6	1	4	2	4	0
Tracheostomy	3	0	14	0	9	0	1	0	2	0
Tracheostomy	7	4	26	22	18	10	5	2	8	4
Tracheostomy	2	0	7	0	6	0	1	0	3	1
Tracheostomy	3	0	14	2	7	1	2	0	2	0
Tracheostomy	10	2	14	3	15	2	4	1	5	1
Total	281	50	999	181	610	92	251	46	1192	167

up of professionals that process the materials, infectious disease specialists and surgeons, professionals who coordinate the control of infection, specific and environmentally controlled areas from the reception desk to the storage of supplies, meeting the manufacturer's specifications for the instrument, from its acquisition to strictly following the prior cleaning, transport, decontamination, inspection, functionality testing, packaging, decontamination and/or sterilization instructions, considering, furthermore, the quality of the water and the equipment used for individual protection by all of these professionals[5,12].

In a study with the objective of reducing the quantity of instruments in the surgical kits for adenotonsillectomies, which were frequently utilized by various surgeons, a prospective quality improvement method by Lean Six Sigma was employed, by mapping the flow of instruments regarding their use and processing. After the intervention, the number of adenotonsillectomy instruments were reduced from 52 to 24, with a reduction in the assembly time of these kits from 8.4 to 4.7 minutes ($p<0001$) and a decrease of 44% in the assembly cost, representing an estimate reduction of US$ 1,468.99 per kit[13].

It is important to consider that, in this same study, 700 adenotonsillectomy procedures were assessed during one year and 850 instrument kits were processed in the same year, being that the targets of intervention for the reduction of costs by the Lean method were: time wasted between the steps for the processing of instruments, transporting unnecessary components, superfluous and unused instruments, unnecessary activities related to the processing of components and unnecessary processing of unused instruments[13].

Thus, verifying unused instruments in certain procedures constitutes a valuable administrative tool that provides important information, with the aim of reducing costs in the processing of surgical instruments, as with the standardization of surgical kits for certain procedures, which is strongly recommended as long as there is a minimum amount and type of surgical instrument in each kit[5].

The instruments utilized from the category "others" of the stages of surgery (corresponding to the surgery itself) present a higher rate of unused instruments in relation to the instruments from remaining stages of surgery, as they are the instruments found in highest volume in the surgical boxes. This can be attributed to the standardization of surgical instruments that are specific to certain procedures, which does not consider a minimum composition recommended by the literature[5,13].

Higher rates of unused instruments were found for the hemostasis surgical boxes, which can be attributed to the use of new technologies, such as the electric scalpel, which presents not only the function of cutting tissue, thereby substituting the manual scalpel, but also the function of hemostasis, substituting hemostasis instruments as it is, above all, safer to handle[14].

This did not occur with suture or ligation instruments, which are found in these boxes at a lower volume and at a necessary ratio.

The operating rooms are hospital units that demand high costs and resources. In a study conducted with the objective of improving the multidisciplinary surgical process, a flow chart was constructed showing the entire surgical process, consisting of the rationalization of the preoperative process; a reduction of non-operative time; the elimination of redundant information; and encouraging the involvement of all employees. The improvements in the process were consecutively implemented by the surgical specialties. The main performance measures were collected before and after the implementation, resulting in improved efficiency and in improved financial performance. One of the actions conducted in this process was the meticulous description of surgical procedures, which allowed for careful anticipation and supply of materials utilized in the OR, considerably reducing the patient's and surgical staff's time in the OR[15].

The authors also observed that the mapping of these processes by a multi-professional team made up of anesthesiologists, surgeons, nurse anesthetists, nurse practitioners, allied health personnel, hospital administrators and systems analysts allowed for the process of information, leadership support, employee participation and the implementation of efficient performance measures, all key elements for improving the efficiency of an operating room, and guaranteeing substantial, sustainable and financially positive performance gains[15,16].

In one study that aimed to identify the types, quantities and costs of materials wasted in surgery in the intraoperative stage of a SC of a university hospital in São Paulo, 105 types of materials from 275 observed surgeries were assessed over a period of four months. Researchers identified that the most wasted items were surgical thread and gauze pads, at a total

cost of R$ 709.84. The study concluded that efficient management of material resources reduces the cost of these processes and reduces waste[17].

A study conducted in the SC in a public teaching hospital in Belém (PA), from July to August 2014, identified that the raw materials wasted during the surgeries were turbans (15%), gauze pads (13%), medication (12%), and gloves (11%). It can be concluded that this waste has a structural and administrative origin, and fighting it requires profound behavioral change from professionals, in addition to rigorous restructuring of the distribution system for materials to the SC. The study suggests the implementation of specific surgical kits for the procedures performed in the SC[18].

This study was limited to the thoracic surgery specialty and did not present variables like the costs generated by unused materials, neither did it investigate if the use or lack of use of these materials was related to the surgical team from that specialty. However, the study provided important information that can be used in future studies and extended to other specialties that work in the researched SC.

CONCLUSION

This study allowed for the quantitative identification of instruments left unused in thoracic surgeries and revealed a need to reformulate the surplus of instruments in the surgical boxes, with the purpose of reducing costs in the processing of instruments that make up these boxes and are left unused during the procedures.

The institutions will be able to reduce the costs of processing instruments by reviewing their work processes, which involves the participation of multi-professional teams working in the SC regarding the use of surgical instruments.

Based on these results, the restructuring of the surgical boxes for this specialty is being implemented as well as the gathering of costs for the processing of materials in the SSD and in the SC of this institution, with the purpose of organizing the work processes involving the administration of surgical instruments.

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ASSESSMENT OF DAMAGES IN FLEXIBLE NASO-FIBROSCOPE DISINFECTED WITH PERACETIC ACID

Avaliação de danos em nasofibroscópio flexível desinfetado com ácido peracético

Evaluación de daños en nasofibroscopio flexible desinfectado con ácido peracético

Mirtes Loeschner Leichsenring[1], Sônia Maria Cavinatto[2], Eliane Molina Psaltikidis[3]

ABSTRACT: Objective: To evaluate possible damages in naso-fiberscopes caused by disinfection with peracetic acid. **Method:** Applied research. Three new naso-fiberscopes subjected to disinfection with peracetic acid were monitored and photographed under stereoscopic microscope, for 18 months, to evaluate the behavior of the polymer and fiber naso-fiberscopes, related to the use of this disinfectant. Nurses and medical team were trained with emphasis on the correct handling and safe processing of the fibers. **Results:** Fibers were regularly analyzed and photographed during the study period, totaling 3,979 uses. In all fibers, cracking of the excess adhesive material around the fiber sealing area was observed, without functional impairment. After more than 2,000 uses, a flexible naso-fiberscope (FNF) developed surface cracks at the distal tip of the fiber cover, without however compromising the sealing test. **Conclusion:** The peracetic acid did not cause functional damage or oxidation in the FNFs, in the formulation used and during the study period, although the manufacturer recommends aldehydes solution to disinfect.
Keywords: Disinfection. Fiber optic technology. Endoscopes. Damage assessment.

RESUMO: Objetivo: Avaliar a ocorrência de possíveis danos em nasofibroscópios causados pela desinfecção em ácido peracético. **Método:** Pesquisa aplicada. Três nasofibroscópios novos, submetidos à desinfecção com ácido peracético, foram acompanhados e fotografados em microscópio esteroscópio, ao longo de 18 meses, para avaliar o comportamento do polímero e da fibra do nasofibroscópio, relacionado ao uso desse desinfetante. Houve capacitação das equipes de enfermagem e médica com ênfase no manuseio correto e no processamento seguro das fibras. **Resultados:** As fibras foram analisadas e fotografadas regularmente, durante o período do estudo, totalizando 3.979 usos. Foi observado, em todas as fibras, craquelamento do excedente de material adesivo em torno da área de vedação das fibras, sem comprometimento funcional. Um nasofibroscópio flexível (NFF), após mais de 2.000 usos, apresentou fissuras superficiais na cobertura da ponta distal da fibra, sem, contudo, comprometer o teste de vedação. **Conclusão:** O ácido peracético, na formulação utilizada e no período estudado, não causou danos funcionais ou oxidação nos NFFs, apesar de o fabricante recomendar a desinfecção por solução de aldeídos.
Palavras-chave: Desinfecção. Tecnologia de fibra óptica. Endoscópios. Avaliação de danos.

RESUMEN: Objetivo: Evaluar la ocurrencia de posibles daños en nasofibroscopios causados por la desinfección en ácido peracético. **Método:** Estudio aplicado. Tres nasofibroscopios nuevos, sometidos a la desinfección con ácido peracético, fueron acompañados y fotografiados en microscopio esteroscopio, a lo largo de 18 meses, para evaluar el comportamiento del polímero y de la fibra del nasofibroscopio, relacionado al uso de ese desinfectante. Hubo capacitación de los equipos de enfermería y médica con énfasis en el manejo correcto y en el procesamiento seguro de las fibras. **Resultados:** Las fibras fueron analizadas y fotografiadas regularmente, durante el período del estudio, totalizando 3.979 usos. Fue observado, en todas las fibras, craquelado del excedente de material adhesivo alrededor del área de sellado de las fibras, sin comprometimiento funcional. Un nasofibroscopio flexible (NFF), tras más de 2.000 usos, presentó fisuras superficiales en la cobertura de la punta distal de la fibra, sin, con todo, comprometer el test de sellado. **Conclusión:** El ácido peracético, en la formulación utilizada y en el período estudiado, no causó daños funcionales u oxidación en los NFFs, a pesar del fabricante recomendar la desinfección por solución de aldehídos.
Palabras clave: Desinfección. Tecnología de fibra óptica. Endoscopios. Evaluación de daños.

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INTRODUCTION

The flexible naso-fiberscope (FNF) is an optical thermosensitive fiber, polymer coated medical device, without internal channel, which has a handle to the distal end direction. FNF provides larger image and aims at examining pathological and normal conditions of the nose, larynx, and pharynx. During its use, FNFs may be contaminated with blood, body fluids, organic waste, and potentially pathogenic microorganisms[1]. Therefore, an appropriate processing of such equipment is crucial to prevent cross contamination between uses. It is considered a semicritical instrument and requires, at least, high-level disinfection for contacting mucous membranes, according to the recommendations from the Centers for Disease Control and Prevention (CDC), from the United States of America[2], and the *Agência Nacional de Vigilância Sanitária* (ANVISA)[3].

The high-level chemical disinfectants recommended by manufacturers of optical fiber generally contain aldehyde formulations as their active ingredient, once they are highly compatible with polymers, rubbers, and metals. Among the aldehydes, the most often employed one is 2% glutaraldehyde (GL), due to their low cost. However, the disadvantage of this formulation is the toxic potential, which may affect especially the professionals who handle it, causing severe eye, nose, throat, and lungs irritations, accompanied by headache, sleepiness, and dizziness, if not properly handled. Another disadvantage is that it may impregnate organic material on surfaces[2,4]. The second option of disinfectant solution would be 0.55% ortho-phthalaldehyde (OPA); however, it may cause eye irritation and spots on the skin, on mucous membranes, on clothing and on environmental surfaces, as well as cause hypersensitivity in patients with repeated exposure. Cases of anaphylactic reaction in patients undergoing cystoscopy have been registered[2,4].

At the *Hospital de Clínicas da Universidade Estadual de Campinas* (HC-Unicamp), the use of disinfectants based on aldehydes was questioned by occupational health associations and by the Unicamp servers' union, due to their potential occupational hazard. The risks to the patient were also weighted, in particular the possibility of anaphylactic post-cystoscopy reaction by OPA. As a result, the hospital abolished the use of aldehydes, replacing them with disinfectant based on peracetic acid (PA), which is similarly suitable for high-level disinfection of endoscopes.

The PA has fast action for all vegetative microorganisms. The mechanism of action is poorly understood, but it is believed to act by denaturing proteins and committing cellular metabolism by oxidation of their structures such as other oxidizing agents. Its main disadvantage is the possibility of rusting metals, noting that this feature depends on the formula[2,4]. In Brazil, PA formulations differ as to the presentation form (liquid or powder) of both the solution and the activating agent. They also vary as to the presence and effectiveness of antioxidants in the formulation components.

In our health service, the solution adopted for disinfection of all endoscopic equipment is the PA solution (Anioxide 1000®) whose presentation is liquid, with neutral pH, and liquid activator. This product is applicable to all types of endoscopes and fibers available in the hospital[5,6].

In August 2013, the HC acquired two naso-fiberscopes for adult patients (Pentax®) and a pediatric one (Olympus®) to be used by Otorhinolaryngology professionals, especially in the outpatient unit, with average daily use of 15 naso-fiberscopic procedures.

The FNFs manufacturers recommend only using GL or OPA for disinfection[7,8]. They warn that there might be a risk of oxidation and loss of useful life of the fibers by using PA, which would result in the cancellation of equipment warranty if this solution is used. Although there is no consistent content in the literature[4] to confirm damages to endoscopes related to the use of PA, there is a concern among professionals on this issue.

Given the institutional policy of non-use of aldehydes, despite the shortcomings and risks referred by the manufacturer, as well as the cancellation of the consequent guarantee, the option was to use PA for disinfecting FNFs. The central question of the study was: what would be the damages in the newly acquired FNFs resulting from disinfection by PA, in HC, over 18 months? Therefore, we planned to implement a methodology to monitor any damage to such equipments.

OBJECTIVE

To evaluate possible damage in naso-fiberscopes caused by PA disinfection.

METHOD

This is an applied research of systematic follow-up of the integrity of 3 new FNFs submitted to PA disinfection, over 18 months, in HC-Unicamp.

Before the use of FNFs, a training was conducted in partnership with the technician of the Biomedical Engineering Center (acronym in Portuguese – CEB) at Unicamp, who is responsible for the maintenance of hospital equipment. The training was directed to both medical and nursing staffs, emphasizing the correct handling and safe processing of FNFs.

A processing protocol was described, step by step, with photographic illustration and included the following procedures:

- Sealing test after each use. It can be accomplished with a manual or electronic system connected to a specific route of FNF. Blowing is carried out between 100 and 200 mmHg and the pressure loss inside the equipment is measured to detect any holes. If the pressure remains stable, the FNF is intact and can be processed and used. If the pressure drops within 30 seconds, there may be a leakage and the FNF should be sent for repairing. The presence of holes can compromise the fiber, once that liquids are infiltrated in the equipment, damaging it, in addition to compromising their cleaning and disinfection;
- Soaking the entire fiber, including the command area, in an enzymatic detergent solution, with contact time and dilution recommended by the manufacturer; then, carry out mechanical cleaning with soft nonwoven fabric throughout the length of the fiber and the command area;
- Rinsing in clean water. Drying with disposable absorbent nonwoven fabric;
- Full immersing in PA for the time recommended by the disinfectant manufacturer (10 minutes);
- Abundant rinsing in potable water for complete removal of disinfectant residues;
- Drying with disposable absorbent nonwoven fabric; and
- Making it available for immediate use or packaging.

The FNFs are kept suspended, in appropriate devices, to packaging during the day. At the end of the work shift, after the last processing, the equipment are dried out and stored in sealed containers, previously disinfected with 70% alcohol, followed by sealing. The breaking of the seal implies new processing.

To ensure traceability, the systematic documentation of processing (date, time, process time, person executing it) and controlled uses is instituted, in which the name and hospital registration number of the patient, as well as the equipment's usage time to perform the exam are recorded.

A procedure for evaluating the fiber structures by stereoscopic microscope (Zeiss®) is also established. This stereoscopic microscope is an optical instrument, associated with an incident and transmitted lighting system, which enables enlarged three-dimensional view of objects. This instrument enables the image to be enlarged by 80 times, without cutting or prior preparation of the object. The equipment can be attached to the camera or the monitor for image registration. The naso-fiberscopes' assessment was performed before their first use and, monthly, during the first six months of use. After this period, assessments were performed quarterly. The medical team was instructed to report any loss of functionality in the analyzed FNFs.

RESULTS

The fibers were observed and photographed regularly, from September 2013 to February 2015.

At first observation, prior to use, white spots, resulted from the manufacturing process, were observed in fiber body 1 (Figure 1), just above the bonding area of the seal test structure. Stains intensified with use and were characterized just as cosmetic changes; no changes were observed in the polymer structure.

After six months of use, a cracking was observed in the surplus of a product around the lens. This was considered by the CEB technician as loss of excess adhesive and did not compromise the fiber (Figure 2). Throughout the

Source: *Hospital de Clínicas da Unicamp* (HC-Unicamp).

Figure 1. Stains in the naso-fiberscope's body displaying before the first use. Date: September 2013.

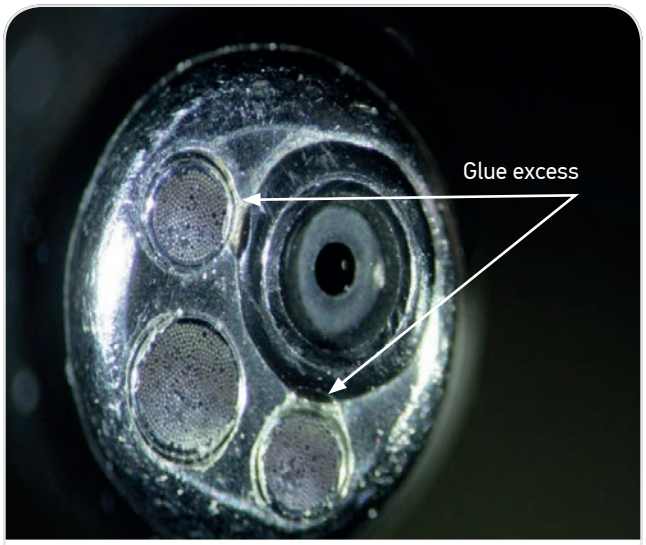
observation period, a reduction in this excess was observed. After 18 months of use (Figure 3), the excess was fully eliminated.

In February 2015, the presence of surface cracks was observed (Figure 4) in the coverage area of the distal tip, which is the fiber movement region. These cracks occurred after more than 2,000 uses of the fiber nº 1 at the time of the FNF assessment in the stereoscopic microscope. However, fiber integrity was preserved and the sealing test was negative. These cracks are expected from wear and tear, resulting from repeated movements during the use of the FNF in the examination, and cannot be attributed to the disinfectant applied. Maintenance work was preventively executed on the fiber to replace the equipment trim.

Air leakage was detected in fiber nº 2 FNF during the sealing test. The protection was ruptured in the top, next to the command area, evidencing a failure in handling, once this damage occurs by traction or improper movement of the fiber caused by the operator. Early detection prevented infiltration and other serious damages to the FNF.

In the analyzed period, from the acquisition of FNFs up to February 2015, the fibers have been intensively used, as shown in Table1. Only slight discoloration and loss of gloss could be observed with the naked eye when the external coating with new fibers was compared with used fibers.

During the study period, the FNFs were processed 3,979 times without any report from the medical team about damages in the fiber's functionality during the exams. Nurses used 56,685 hours for processing, with an average duration of 15 minutes per processing. Examinations took 11,277 hours during the same period, with on average 3 minutes per procedure.

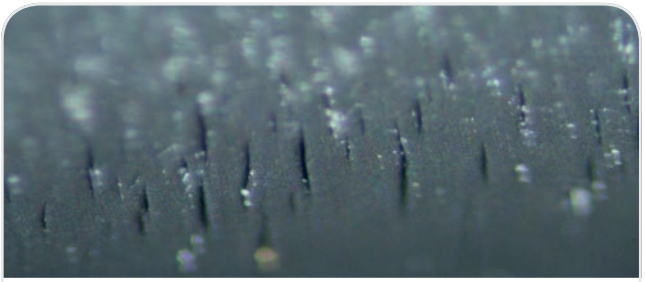


Source: *Hospital de Clínicas da Unicamp* (HC-Unicamp).

Figure 2. Excess of adhesive material loosening around the seal area after six months of use. Date: January 2014.

Source: *Hospital de Clínicas da Unicamp* (HC-Unicamp).

Figure 3. Visualization of the same fiber after 18 months of use without excess of adhesive. Date: January 2015.



Source: *Hospital de Clínicas da Unicamp* (HC-Unicamp).

Figure 4. Surface cracks in the distal tip of the coverage area. Date: February 2015.

Table 1. Number of uses of naso-fiberscopes, from September 2013 to February 2015, at the ENT Clinic of the *Hospital de Clínicas da Universidade Estadual de Campinas.*

Fiber	Uses number
FNF 1 for adult	2,011
FNF 2 for adult	1,897
Pediatric FNF	71
Total	3,979

FNF: flexible naso-fiberscope.

DISCUSSION

Literature is scarce concerning the evaluation of the best method for processing FNFs. Most publications are related to the processing of endoscopes for use in digestive and pulmonary systems. FNFs are classified as semicritical devices according to the Spaulding's classification of health products, and therefore should be minimally subject to high-level disinfection.

The review article published by Collins[9], in 2009, refers to the lack of a policy adopted by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) on FNF processing in the United States. Despite the various opinions on the subject, the authors elaborated basic premises for the handling and processing of such equipment and recommend the use of high-level disinfectant solution.

In Brazil, the *Associação Brasileira de Otorrinolaringologia e Cirurgia Cérvico-Facial* (ABORL-CCF)[10] published a protocol on FNF processing which has been questioned because it recommends disinfection by rubbing with 70% ethanol, after previous cleaning. The validation of this protocol is the theme of a doctoral thesis which has not been published yet, but may contribute to the safety enhancement in their application[11].

Liming et al.[12] conducted a study showing the efficacy of disinfection by means of various methods of decontamination, including 70% alcohol; however, only the distal portion of FNF was evaluated. Alvarado et al.[13] conducted a study which used the sterile sheath in FNFs for the procedures, with a processing protocol using enzyme solution and also disinfection with 70% alcohol. They concluded that the use of sheaths could replace high-level disinfection in the adopted conditions. Another author, Muscarella[1], recommends using only solutions with proven microbicidal activity of high-level disinfection and contraindicates the use of 70% ethanol and quaternary ammonium, and other agents, for the disinfection of FNF.

In HC-Unicamp, the recommendation of the Hospital Infection Control Committee is the use of high-level disinfectant by immersion of the whole fiber. This recommendation is supported by a work published in 2013, in which the authors Bhatt et al.[14] demonstrated that there may be contaminants in the eye area and the light cables surfaces which are commonly ignored in cleaning protocols. Bhattacharyya and Kepnes[15] also endorsed the flexible laryngoscopes complete immersion in disinfectant solution.

With regard to possible damages resulting from the processing, only a study conducted by Statham and Willging[16] was identified. The authors evaluated 60 FNFs processing cycles with OPA in automated washers and their respective repair needed. The observation time was 4 years, during which 4,336 tests were performed and there were 77 repairs. In the 2.2 mm FNFs, the average usage was 61.9 examinations before a repair; on the other hand, for the 3.6 mm FNFs, the average was 154.5 uses.

In our context, the processing is manual and no damages were found related to the use of PA in the period under review, although the greatest use has been with FNFs for adults. During this period, 3,908 tests were performed with FNF for adults, with an average of 1,954 scans/fiber.

This study also reinforces the importance of applying the sealing test in each use as key to the preservation of the fibers. The test is a preventive measure against infiltration of liquids inside the device in the event of a malfunction. Another key aspect for maintaining the integrity of the fiber, evidenced by our experience, is the need for proper handling and use in the FNFs processing. Collins[9] recommends that all professionals who handle FNF should receive adequate training, including being familiar with the equipment, processing techniques, the products involved, and storage.

Patient safety must always be considered with the use of FNFs. FNFs or other semicritical optics can only be warranted if the entire process is carefully executed[17]. Since these are short procedures with a restrained demand, people tend to desire to simplify practices and ignore important processing steps. However, when the team is aware of the importance of applying the protocol, this pressure is well managed.

Although the use of PA is not recommended by the manufacturer for the FNFs purchased at HC-Unicamp, this study revealed that its use did not compromise or caused damage in the evaluated period. It is noteworthy that manufacturers recommend preventive maintenance every 200 uses; in the case of FNFs, the number of uses was reached very soon. In our context, 200 uses were reached after 3 months. Until February 2015, the FNFs for adults were used 1,954 times on average and no significant change of the polymer or structures that could be linked to use of PA were observed or detected.

A further advantage observed in the chosen PA formulation for use in the HC is related to the immersion time

required for disinfection, which is 10 minutes. This time allows a greater number of tests per fiber/day, one of the criteria for selecting this PA formulation in the institution.

It should be highlighted that the processing of FNFs were carried out without the supervision of the Central Sterile Supply Department (CSSD); however, in order to comply with the recommendations established by the Collegiate Board Resolution (CBR) nº 15 of 2012[3], FNFs started to be processed by the CSSD team.

One limitation of this study is that the results cannot be generalized to other endoscopes or PA germicidal, since only one of the AP formulations available in the domestic market was used. Another limitation refers to the period of study, which is shorter than the life cycle of the FNF.

CONCLUSION

With the protocol implementation for processing and monitoring damage in the use of FNFs, it can be concluded that the PA formulation used did not cause rust or damage during the study period. The training of all staff was essential to ensure proper processing and to maintain the integrity of the fibers. The methodology adopted to evaluate the integrity of FNFs by means of the stereoscopic microscope and systematically carrying out sealing tests was effective for the monitoring of damage in this type of equipment. The magnified visual inspection also allowed early detection of changes that could not be identified with the naked eye, such as cracks occurred in the distal cover in a FNF with over 2,000 uses, due to the wear and tear of the equipment.

Although health professionals are concerned about adopting the PA for disinfection of optical materials, this study did not show (with total of 3,979 applications), damages related to that active ingredient with the formulation tested over 18 months in 3 FNFs. Future research is needed, especially to analyze different endoscopes equipment and PA formulations compared with the use of aldehydes, with longer follow-up.

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USE OF SCENARIOS FOR EDUCATION ABOUT PATIENT SAFETY IN A SURGERY CENTER

Utilização de cenários para a educação sobre segurança do paciente em centro cirúrgico

Utilización de escenarios para la educación sobre seguridad del paciente en quirófano

Elena Bohomol[1], Juliana de Abreu Tatarli[2]

ABSTRACT: Objective: To present scenarios in the nursing care and management practice related to the perioperative procedures as an educational strategy. **Method:** The population was composed of scenarios from a previous investigation. There was a secondary analysis of the information available. **Results:** Seven scenarios were identified representing the nurses work routine in relation to perioperative procedures. Of these scenarios, four describe situations that present adverse events that affected the patient, two near misses, and one contextualizing a risk situation. Three scenarios contextualized situations with elderly patients, and one with a pediatric patient. **Conclusion:** The scenarios may present care-related situations, providing reflections to minimize opportunities for error, improving the assertiveness of communication, providing clarification about concepts of quality and promoting the use of patient safety protocols.

Keywords: Patient safety. Operating room nursing. Health education.

RESUMO: Objetivo: Apresentar cenários da prática de enfermagem assistencial e gerencial relacionados aos procedimentos perioperatórios como estratégia educacional. **Método:** A população foi composta de cenários redigidos de uma investigação prévia. Foi realizada uma análise secundária das informações disponíveis. **Resultados:** Foram identificados sete cenários que representam o cotidiano de trabalho dos enfermeiros relacionado aos procedimentos perioperatórios. Desses cenários, quatro descrevem situações que apresentam eventos adversos que atingiram o paciente, dois *near misses*, e um contextualiza uma situação de risco. Três cenários contextualizavam situações com pacientes idosos e um com paciente pediátrico. **Conclusão:** Os cenários podem apresentar situações assistencias e propiciar reflexões para minimizar oportunidades de erros, melhorar a assertividade da comunicação, propiciar esclarecimento sobre conceitos de qualidade e promover a utilização de protocolos de segurança do paciente.

Palavras-chave: Segurança do paciente. Enfermagem de Centro Cirúrgico. Educação em saúde.

RESUMEN: Objetivo: Presentar escenarios de la práctica de enfermería asistencial y de gerencia relacionados a los procedimientos perioperatorios como estrategia educacional. **Método:** La población fue compuesta de escenarios redactados de una investigación previa. Fue realizado un análisis secundario de las informaciones disponibles. **Resultados:** Fueron identificados siete escenarios que representan lo cotidiano de trabajo de los enfermeros relacionado a los procedimientos perioperatorios. De esos escenarios, cuatro describen situaciones que presentan eventos adversos que alcanzaron el paciente, dos near misses, y un contextualiza una situación de riesgo. Tres escenarios contextualizaban situaciones con pacientes ancianos y uno con paciente pediátrico. **Conclusión:** Los escenarios pueden presentar situaciones asistencias y propiciar reflexiones para minimizar oportunidades de errores, mejorar la asertividad de la comunicación, propiciar aclaración sobre conceptos de calidad y promover la utilización de protocolos de seguridad del paciente.

Palabras clave: Seguridad del paciente. Enfermería de quirófano. Educación en salud.

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INTRODUCTION

The history of patient safety is long and well known. *Primum non nocere*, the term attributed to Hippocrates (460AC-377AC) means, in Latin, "first do no harm", and is generally used by professionals to refer to the need of preventing unnecessary risks, costs and harm to patients when they require health care[1].

According to the World Health Organization (WHO), one out of ten patients in the world is a victim of errors and adverse events while receiving care and treatment[2]. Therefore, when talking about adverse events, seen as incidents that result in harm to the patient, it mandatorily implies thinking and proposing actions to be implemented to improve the structure, the process, and the result in the health care organizations, aiming at mitigating the harm to the patient. Educational processes both for professionals and patients and family are among those actions[1,2].

In 1999, the report To Err is Human: Building a Safer Health System called the attention of training organizations to the need of reassessing curricula and of incorporating patient safety concepts for the education of students and professionals, exploring opportunities for the development of interdisciplinary practice[1].

Fifteen years later, a new report stands out eight recommendations that should be implemented to speed up the improvements in patient safety in the health care universe. In this report, the importance of incorporating patient safety to education is recognized, highlighting that organizations should embrace and encourage this process, including aspects of this thematic in the school curricula, as well as in several levels of institutional training[3].

In a worldwide movement addressed to patient safety, the Brazilian Ministry of Health launched the National Patient Safety Program (PNSP), which aims at monitoring and preventing the incidents that result in harm to the user in hospitals and other health units. Producing, systematizing, and disseminating knowledge about patient safety are some of its objectives[4].

Therefore, education in patient safety implies developing learning experiences so that people can have the opportunity of using scientific evidence and being able to describe the components of patient-centered care, besides identifying the flaws in its practice to determine which actions should be adopted for their correction, as members of an interdisciplinary team[5,6].

However, there is a mismatch between what should be done and what in fact happens in educational and care practices, leading to a challenge to professionals regarding how to teach patient safety. The subject is treated in a fragmented manner in the health and education system, and each of them tries to improve their work processes in their own way[2,3].

The curriculum guide of patient safety from the World Health Organization is widely updated regarding the different aspects involving the teaching of patient safety, and advising the diversity of strategies for this process, quotes: lectures, reading material, tutorials, on-line activities, training of skills, videos, games, besides discussions based on case studies and scenarios reporting the practice[7]. However, by proposing scenarios, it is recommended that they come from real situations that allow to subsidize the deepening of the concepts presented, to debate a context that is likely to happen in the practice and to establish the best conducts to be adopted.

The scenarios may include unusual situations and may be presented to a specific professional category, but they should be sufficiently critical to lead to fast and short responses from the participants. The same content can also be discussed between different teams, in order to contextualize their work processes, creating different views about a specific fact[7].

By proposing a scenario, besides the situation itself, it is possible to work with guiding questions that stimulate critical reasoning and debate between people. Different scenarios on adverse events and techniques to minimize opportunities of errors can be developed, such as the practice of briefing (lecture) and debriefing (posterior comments and recommendations). They allow the conduction of different questions, clarification of concepts, training of interpersonal communication assertiveness, and reflection about the use of patient safety protocols.

Since there is a global concern about patient safety in general, it is important to think about the surgery patient in particular. Around the world, about 240 million surgeries are conducted per year, and because of the increasing number of heart conditions, traumas and cancer, associated with the increasing life expectancy of the population, an increasing incidence of surgical conditions are expected in the following years. The assumption is that there is about 3 to 16% of surgical complications, resulting in seven million disabling situations, with mortality rates between 0.4 and 0.8%. The conclusion is that this will lead to an increasing

number of adverse events related to surgical procedures[8]. Therefore, the educational process in this field becomes urgent and important.

The objective of this study is to present scenarios of the care and management nursing practice related to perioperative procedures as an educational strategy.

METHOD

This is a descriptive study whose population was composed of scenarios created for a previous investigation called "Adverse events in surgery patients: knowledge of nursing professionals", approved by the National Research Ethics Commission, and the record is the Certificate of Presentation for Ethics Appreciation (CAAE) 0047.0.360.360-09, in the National Ethics Research System. The study, whose information originated this paper, was cross-sectional and descriptive, developed in a surgery center of a private hospital in the city of São Paulo (SP). It involved nursing professionals who answered a questionnaire elaborated by the researchers and validated by three specialist judges in the surgery center (SC) area. Among the three parts of the questionnaire, this study used the revisit to scenarios which present situations of care practice in the surgery environment[9].

In the occasion, it was used the strategy of documentary research for the creation of scenarios, based on the documents of the reports about the main adverse events that took place in the SC unit, and bibliographic review. For the review, the following descriptors were used: patient care, security management, surgical and operative procedures, surgical adverse events. The bases analyzed were Biblioteca Regional de Medicina (BIREME), Medical Literature Analysis and Retrieval System Online (Medline®), and Scientific Electronic Library Online (SciELO). Thirteen articles were selected in English and in Portuguese.

A secondary analysis of the information available was conducted, and the scenarios were discussed based on the publications contemplating the safety of the surgery patient.

RESULTS

Seven scenarios, presented in Chart 1, were developed.

By the description of scenario 1, it is possible to approach three aspects: the schedule of two different procedures, in two different places, and at the same time; the delay in conducting an elective surgery procedure; and the patient exposed to fasting for more than 12 hours, emphasizing that an adverse event has taken place. Scenario 2 presents the occurrence of an

Chart 1. Description of scenarios.

Scenario 1	For one 12-year-old adolescent, with type 1 diabetes, the surgery was three hours late, because he was in an elective x-ray examination. After the examination, he was referred to the surgery center, once the surgery team was waiting for him. He received the pre-anesthetic. When the anesthetic procedure began, the patient was already fasting for more than 12 hours.
Scenario 2	A 25-year-old young woman was submitted to an aesthetic procedure that should last for four hours. Because of the patient's age, no comfort measures were adopted to prevent a pressure injury. When the anesthetic recovery began, it was observed that the patient had developed stage 1 injuries in the heel bone.
Scenario 3	An abdominal videolaparoscopy procedure was converted into an open surgery. The counting of pads was not conducted at the beginning of the procedure, and at its conclusion, the pads were not checked.
Scenario 4	A 68-year-old woman, smoker, was submitted to a major elective surgery. Neither antithrombotic socks nor the lower limb massager was used as a preventive measure for thromboembolism.
Scenario 5	A 60-year-old man entered the surgery center to perform a hemorrhoidectomy in an operating room with a temperature of 21ºC (69.8°F). The procedure was predicted to last for 45 minutes, so no preventive heating strategies were adopted. The patient started anesthetic recovery with a temperature of 34.5ºC (94.1°F).
Scenario 6	On a surgery day, two knee arthroscopies were scheduled. The room was arranged for the first surgery, which would be on the right knee, with the equipment placed on the left side. However, the patient who was called first should undergo an arthroscopy on the left knee. The medical team insisted on conducting the procedure, claiming there was no need to reorganize the room.
Scenario 7	A 78-year-old man was submitted to a colectomy due to rectal cancer. By removing the surgical piece, the circulating nurse asked the surgical technologist about its destination and was informed it should be disposed of. Three days later, the surgeon asked for a report of the pathological anatomy of this piece.

adverse event that affected the patient with the development of stage I pressure injury. Scenario 3 shows an incident that jeopardizes the safety of the surgical procedure. Since there is no information about whether or not a foreign body was forgotten, the situation is considered as a near miss, that is, an incident that has not affected the patient[2]. Scenario 4 exposes the situation of a patient at risk for the development of thromboembolism. Even if no signs of deep vein thrombosis have been verified, the patient requires observation and monitoring from the team to analyze if there was an adverse event or not. Scenario 5 deals with an adverse event that could have been prevented, related to hypothermia in an elderly patient. Scenario 6 exposes a risk situation for surgery on the wrong location; however, the fact did not occur, denoting a near miss. In scenario 7, there is an adverse event involving the patient, because there is no anatomopathological report, therefore generating doubt as to the conduct to be adopted to treat the patient.

The guiding questions for each scenario were:

1. Is this a perioperative adverse event? Possibility of response: yes or no;
2. Who is responsible for this event? Possibility of response: medical team; nursing team at the SC; nursing team at the unit; multidisciplinary team; all parties involved;
3. Should the event be notified? Possibility of response: yes or no.

DISCUSSION

Education about patient safety both in schools and in care institutions is something new, which requires strategies related to the need for transformation in the traditional manner of teaching and learning[5-7]. The use of scenarios facilitates this exercise, once they enable a moment of reflection, the discussion of ethical issues and attitudinal competencies, and the reinforcement as to the implementation of procedures, protocols, and routines, being financially accessible to several institutions. Due to the repertoire of its content, they encourage the themes that can be developed in the simulation strategy[10].

Three scenarios show situations with elderly people submitted to surgical procedures. This context can be well explored in the education about patient safety as population aging is a phenomenon observed in Brazil and around the world. Because of that, this is a population that has used the health services more often, and, consequently, is subject to more risks and adverse events. With age, the patient is more prone to diseases and complications, and is submitted to more procedures, besides presenting a higher risk of death. Elderly people are biologically, socially and psychologically vulnerable, therefore requiring the health professional to address specific care for their need[11].

Children and adolescents also represent a vulnerable segment, and a surgical approach was presented in one of the scenarios. This type of patient, who requires a complex network of demands for care and attention, also requires a constant exchange of experiences and knowledge of a multiprofessional group. Assertive communication is essential in order to promote safe care, which is relevant for the establishment of a good interaction between patients and their parents or people in charge and members of the care team[12].

All situations exhibited in the scenarios are prone to be found in the work routine of an SC. The adverse event that took place in scenario 1 was the delay of the surgery and the patient's long period of fasting, without, however, presenting the consequences to the patient. These situations are likely to have a solution with the proper management of patient flow, ensuring that patients receive the adequate care, in the right place, at the right time, during the entire period[13]. Another measure to be discussed is the efficient change of shifts, using, for example, structured actions like the SBAR for the communication between shifts, services, and units. SBAR is an acronym of the words situation, background, assessment, and recommendation[7]. Also, in this scenario, it is possible to explore the need to implement protocols of fast abbreviation, especially for kids, once delays to begin the surgery and changes in the schedule of the rooms are common. Studies point out that the abbreviation of perioperative fast in patients who are candidates for elective operations is associated with the shorter time of hospitalization, and reduced postoperative complications[14].

Scenario 2 presents the adverse event of the development of stage I pressure injury during surgery. Even though this is the initial stage of the lesion, this situation requires observation and monitoring measurements since conducts of prevention were not adopted. Placing the patient in the right position should be seen as an important procedure, and often, a complex one, involving several risks that should be observed with responsibility and competence; otherwise, it can compromise the patient's physical and mental health.

Studies show that the occurrence of lesions caused by pressure in elective surgery is high, the sacral-gluteal region is usually the most affected, and there is a higher incidence of stage II injuries[15].

The situation in scenario 3 leads to the second challenge of WHO as to the safe surgery protocol establishment, especially regarding the use of a checklist observing three stages: sign-in (before anesthetic induction), time out (before the surgical incision), and sign-out (before the patient leaves the operation room)[8]. The obligatoriness of its implementation in Brazilian institutions is configured in the PNSP guidelines, and the conclusion of the counting of pads and instruments is emphasized in the specific protocol of the program[4]. The consequence of the non-observance of the proper count of pads may put the patient at risk. The description of foreign bodies retained in the abdominal cavity after a surgical procedure is scarce in the literature, and may be related to under-notification, because this situation exposes not only the surgical team, but the institution in general, possibly causing legal consequences for the parties involved. Events related to foreign body retained in the cavity are serious, and it is the role of the surgery and nursing team to prevent such risk[16].

Scenario 4 allows a wide discussion and approach about the risk factors for the development of deep vein thrombosis in patients submitted to several surgical procedures, besides pointing out to the importance of implementing protocols of prophylaxis and the administration of its use. Deep vein thrombosis is a major cause of intra-hospital deaths in the world, and, paradoxically, the most preventable one. Protocols of prophylaxis have existed for more than 15 years and are not usually fulfilled[17].

Scenario 5 shows a usual situation inside surgery rooms: the risk for hypothermia, that is, when the body temperature is below 36°C (96.8°F). This fact is related to the changes in thermoregulation caused not only by the anesthetic effect, responsible for the reduction of 20% in the metabolic heat production but also due to the cold environment of the room itself. Elderly patients have more risks of hypothermia. Therefore, preventive heating measures should be instituted. It begins with the monitoring of the patient's body temperature and the use of active heating systems, such as heating blankets, mattresses and clothes with circulation of hot water[18].

Scenario 6 does not present an adverse event, but it allows to reflect about the roles of the different professionals working in the surgical procedure. In the case of the medical team, it is possible to verify the objectivity for the resolution of a scheduling problem, without assessing the possibility of an error to occur. Concerning the nursing team, it is possible to observe the lack of positioning regarding the rules of safety, putting the patient at risk. These matters can be considered based on the implementation of a safe surgery checklist, to be used in any hospital, regardless of the procedure complexity level, assisting the teams to follow the critical safety steps in a systematic way. Studies mention the difficulties in implementing and using the checklist in Brazilian hospitals, reporting the lack of a leadership committed to this process, the shortage of resources and structure in the organizations and the inexistence of an organizational culture that values safety as some of the aspects found[19].

Scenario 7 allows to consider three aspects: The routine established to dispose of surgical items; The lack of knowledge about the patient both coming from the surgical technologist and from the nursing team; The inefficient communication of the parties involved.

The implementation and use of the third stage of the safe surgery checklist point out to the obligatoriness of identifying any surgical sample obtained. Caring for this step would be a good barrier in order that the destination of the surgical piece is verified in an adequate moment, with the parties involved still inside the operation room. The proper identification of biopsies is essential for the process to be well conducted, without the need for a new procedure or without having to deal with doubts regarding the treatment guidelines. On the other hand, studies report that the lack of communication between the nursing team and the medical team is a strong reason for the occurrence of adverse events, suggesting that good health care depends on the effective communication between professionals. The inefficient communication can be conditioned to hostile behaviors from the surgical team, or feelings of intimidation from the nursing team, thus omitting important alerts that could prevent adverse events[9].

The use of guiding questions is important since it allows professionals to reflect whether or not they know what is, in fact, an adverse event, and if it should be notified. Studies conclude that there are doubts about a specific situation being or not being considered as an adverse event, demonstrating the need to discuss these issues in the professional scope[9]. It is important to clarify the differences between incident, error, adverse event, sentinel event, among other terms used[2].

Discussing the need for the notification of adverse events may bring to light the difficulties of treating the situations that affect the patient as a learning process. Sometimes, there are fears about the retaliation that may come due to the harm caused to the patients[1-3,11,20], or perhaps, on the contrary, there is the underappreciation of the fact because the event did not affect the patient, which is called near miss, inhibiting preventive conducts to improve the care processes[2,4,20].

Patient safety is not a responsibility of a single professional category, therefore the importance of discussing the roles of each one in the contexts of care. It is possible to imagine that the responsibilities for the situations presented may point only to the nursing team (for instance, the placement of prevention measures for thromboembolism, counting of pads or hypothermia) or to the medical team (for example, adaptation of the room, sending pieces for pathological anatomy, delay in starting n the surgery). However, in the safety culture in the institutions, the roles complete one another in favor of the patient[9,18].

The limitation of the study is related to the presentation of a few scenarios inside the perioperative context. New situations and the possibility of multiprofessional interlocutions could be explored, encouraging other studies in the field.

CONCLUSION

Seven scenarios involving the practice of care and management nursing related to perioperative procedures were shown, enabling an educational proposal to be adopted in care and educational health environments.

Four situations involving adverse events were mentioned, being two near misses and one in which the occurrence of harm to the patient is not clear, demonstrating that not all contexts are clear in the routine, with the possibility to state the occurrence of an adverse event or not. There are also three scenarios contextualizing situations with elderly patients and one pediatric patient.

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CHALLENGES IN SUBSEQUENT LOADS IN SATURATED STEAM STERILIZATION: COMPARATIVE STUDY OF PERFORMANCE

Testes desafio em cargas subsequentes na esterilização a vapor saturado: estudo comparativo dos desempenhos

Pruebas desafío en cargas subsecuentes en la esterilización a vapor saturado: estudio comparativo de los desempeños

Ana Paula Neves Quintino[1]

ABSTRACT: Objectives: To evaluate the performance of the challenges with chemical indicators commercialized in the monitoring of saturated steam sterilization in a hospital autoclave in cycles of 134ºC and 121ºC, and to analyze the performance efficiency of the challenges in the monitoring of the sterilization cycles. **Method:** Descriptive research. The data were collected on the evolution of the turn of the chemical indicators type 5 of the challenge package A*, chemical indicators type 6 of challenge package B* and chemical indicators type 6 of the helix device C*. The challenge packages were submitted to temperatures of 134ºC and 121ºC, following the interruption phases and total cycle time. **Results:** The data of the chemical indicators of the challenges were tabulated according to the time of exposure and the interruption of the cycles. A table shows the results of the evolution of the turn of the chemical indicators type 5 of the challenge package A*, type 6 of the challenge package B* and type 6 of the helix device type C*, submitted to the temperatures of 134ºC and 121ºC, according to the phases of interruptions and total cycle time. **Conclusion:** Packages containing A* and B* have chemical indicators of different types and presented similar results, and the difference between them was not conclusive. The helix device C* with type 6 indicator showed more precise performance in the monitoring of cycles at 134ºC and 121ºC.

Keywords: Sterilization. Surgical instruments. Cross infection.

RESUMO: Objetivos: Avaliar o desempenho dos testes desafio com indicadores químicos (IQs) comercializados na monitorização da esterilização a vapor saturado, em autoclave hospitalar, em ciclos de 134ºC e 121ºC e analisar a eficácia do desempenho dos testes desafio no monitoramento dos ciclos de esterilização. **Método:** Pesquisa descritiva. Foram colhidos dados sobre a evolução da viragem dos IQs tipo 5 do pacote desafio A*, IQs tipo 6 do pacote desafio B* e IQs tipo 6 do dispositivo tipo hélix C*. Os pacotes desafio foram submetidos às temperaturas de 134ºC e 121ºC, seguindo as fases de interrupções e tempo total de ciclo. **Resultados:** Foram tabulados os dados dos IQs dos testes desafio conforme o tempo de exposição e a interrupção dos ciclos. Encontram-se em tabela os resultados da evolução da viragem dos IQs tipo 5 do pacote desafio A*, tipo 6 do pacote desafio B* e tipo 6 do dispositivo tipo hélix C* submetidos à temperatura de 134ºC e 121ºC, de acordo com as fases de interrupções e o tempo total de ciclo. **Conclusão:** Pacotes contendo A* e B* possuem IQs de tipos diferentes e apresentaram resultados similares, não sendo conclusiva a diferença entre ambos. O dispositivo hélix C* com indicador tipo 6 apresentou desempenho mais preciso na monitorização de ciclos a 134ºC e 121ºC.

Palavras-chave: Esterilização. Instrumentos cirúrgicos. Infecção hospitalar.

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RESUMEN: Objetivos: Evaluar el desempeño de las pruebas desafío con indicadores químicos (IQs) comercializados en la monitorización de la esterilización a vapor saturado, en autoclave hospitalaria, en ciclos de 134ºC y 121ºC y analizar la eficacia del desempeño de las pruebas desafío en el monitoreo de los ciclos de esterilización. **Método:** Estudio descriptivo. Fueron recogidos datos sobre la evolución del viraje de los IQs tipo 5 del paquete desafío A*, IQs tipo 6 del paquete desafío B* e IQs tipo 6 del dispositivo tipo hélix C*. Los paquetes desafío fueron sometidos a las temperaturas de 134ºC y 121ºC, siguiendo las fases de interrupciones y tiempo total de ciclo. **Resultados:** Fueron tabulados los datos de los IQs de las pruebas desafío según el tiempo de exposición y la interrupción de los ciclos. Se encuentran en tabla los resultados de la evolución del viraje de los IQs tipo 5 del paquete desafío A*, tipo 6 del paquete desafío B* y tipo 6 del dispositivo tipo hélix C* sometidos a la temperatura de 134ºC y 121ºC, de acuerdo con las fases de interrupciones y el tiempo total de ciclo. **Conclusión:** Paquetes conteniendo A* y B* poseen IQs de tipos diferentes y presentaron resultados similares, no siendo conclusiva la diferencia entre ambos. El dispositivo hélix C* con indicador tipo 6 presentó desempeño más preciso en la monitorización de ciclos a 134ºC y 121ºC.
Palabras clave: Esterilización. Instrumentos quirúrgicos. Infección hospitalaria.

INTRODUCTION

The Material and Sterilization Center (MSC) consists of a space designated for the processing of dental-medical-hospital articles, that is, the cleaning, preparation, sterilization, packaging and distribution of materials for other hospital areas. The MSC is responsible for providing contamination-free materials to be handled in various hospital procedures. It is an indirect aid provided to the patient through the processing and sterilization of these materials, being as important as direct care (that practiced by the health team with the patient)[1].

The sterilization of dental-medical-hospital materials is a complex and very important process that provides reusable materials free from viable microorganisms, offering security to the professionals who handle them — and especially to the patient, their final user[1].

Sterilization is understood as the physical or chemical process which destroys or inactivates all life forms present in a specific material, especially microorganisms including bacteria, fungi (both in their vegetative and sporulated forms) and viruses[2].

For critical articles, the probability of survival is one surviving micro-organism for every 10^6 units processed. This criterion is expressed as 10^{-6} and is known as the level of sterility, conventionally verified in the laboratory as a sterility test[3].

The level of sterility can be determined as the number of accessible microorganisms that survive unit sterilization of the product under consideration. The definition of the operating parameters of the chosen sterilization method indicates the safety margin of the product or the possible failure of the system[2].

Considering that the absolute sterility of an article (100% of death) theoretically does not exist, it is of the utmost importance that the whole sterilization process be widely monitored[4].

Theoretically, a standard sterilization cycle of moist heat is divided into three phases or steps:

- Step 1: conditioning, in which air is removed from the inner chamber of the sterilizer and there is preheating of the load;
- Step 2: Exposure or sterilization, in which contact of the steam with the material occurs under controlled conditions of pressure and temperature to promote the death or inactivation of viable microorganisms;
- Step 3: drying, responsible for the removal of condensed steam from the interior of the load[5].

By destroying all life forms at temperatures between 121 and 134°C, the sterilization process by saturated steam under pressure is the most widely used method in the hospital environment. The times used in the cycles vary according to the chosen temperature and the instructions of the equipment manufacturers'[6].

In health institutions, the release of sterilized material for physical use is accompanied by the observation of the physical results of sterilization, alongside the verification of chemical and biological indicators[1].

The monitoring of the sterilization process by means of physical indicators is done through the printed recording of data regarding time, temperature and pressure of each cycle[7].

The biological indicator consists of a standardized preparation of bacterial spores designed to produce suspensions containing 10^6 spores per unit of filter paper. The method allows to ensure that the set of all critical sterilization parameters is adequate because, after the application of the

process, microorganisms are directly tested for their growth or the lack of it[7].

The biological indicator is a parameter to ensure that the level of sterility established for the product is achieved, conferring the certainty of sterility against the defined minimum safety margin of only one contaminated unit in 10^{-6} units of the processed product[2].

According to the latest version (11140-1: 2014) of the International Organization for Standardization (ISO), CIs are classified into six categories:

- Type 1: process indicator (external indicator for use in individual items and distinguishing processed from unprocessed materials, *e.g.*: zebra tape);
- Type 2: indicator for use in specific tests (*e.g.*: Bowie Dick test);
- Type 3: single parameter indicator (reacts only to one critical variable of the sterilization process);
- Type 4: multiparametric indicator (indicator for internal use in individual items, reacts to two or more critical variables of the sterilization process);
- Type 5: integrator indicator (indicator for internal use in individual items, responds to all critical variables of the sterilization process);
- Type 6: emulator indicator (indicator for internal use on individual items, responds to all critical variables of the sterilization process).

According to the Resolution of the Collegiate Board of Directors (RDC) No. 15, it is recommended to record the monitoring of physical indicators at each sterilization cycle. The use of the biological indicator should be done daily, in a challenge package available commercially or built by the MSC and positioned at the point of greatest challenge of the autoclave. Loads containing implantable materials must be processed with a biological indicator. It is recommended that the monitoring of the loading process subsequent to the biological test be performed in a challenge test package with CIs (type 5 or 6), according to the routine defined by the MSC[9] itself.

In order to ensure the effectiveness and quality of sterilization, it is incumbent upon the MSC's technical head of the health service to analyze and approve the indicators that best meet the process[9].

The test challenge package is a device used to evaluate the performance effectiveness of a sterilization process and should provide a challenge to the process equal to or greater than that of the most difficult item routinely processed[6].

Cycle monitoring can be done by the use of a ready test challenge package or performed by manual construction using cotton fields, a practice currently not recommended due to the difficulty of reproducibility of packages[6].

One type of commercially offered test consists of a porous, ready-to-use package that presents a challenge to the sterilization process. It has a type 5 or 6 CI with immediate reading after the process[9].

For the safety of the sterilization process, it is important that the steam is able to reach all surfaces of the instruments and penetrate into empty instruments. The European Committee for Standardization, CEN TC102, developed the propeller test to demonstrate steam penetration into empty devices. This method uses a long narrow tube[10].

A challenge test available in the market is the helix type (TST Load check BROWNE®, Leicester, UK). It is a reusable device with lumen, made of Teflon with 1.5 m in length and 2.0 mm in internal diameter, and a blind bottom screw with niche to pack a CI that allows to evaluate the effective extraction of the air and the penetration of the sterilizing agent.

Monitoring of steam sterilization cycles is a topic of concern for nurses at MSC and the Hospital Infection Control Commission (CCIH), due to the responsibility these professionals assume in ensuring the safety and quality of sterilization processes[11].

OBJECTIVES

- To evaluate the performance of the challenge tests with CIs marketed in the monitoring of saturated steam sterilization in hospital autoclave with prevacuum system, in cycles of 134 and 121°C;
- To analyze the performance effectiveness of the challenge tests in monitoring sterilization cycles.

METHOD

The present study used as a research design the descriptive experimental study. The tests were developed on December 15th and 16th, 2016, at the Sterilized Materials Center of Hospital Estadual Bauru, managed by the Foundation for Medical and Hospital Development (FAMESP). The MSC covers an important sector of

support to the health institution, relating directly to the quality of services provided.

The equipment used in the study was the saturated steam hospital sterilizer, with an operational capacity of approximately 500 L, by Baumer®, model HI-VAC II. The qualification of operation and performance of the equipment in question was executed on November 28*th*, 2016 by JSLab Qualifications and Tests.

The tests were performed with the support of JSLab Qualifications and Tests, which used the Yokogawa DX 2030 Graphic Recorder, previously calibrated against accredited standards — Brazilian Calibration Network (BCN) with 2x24 AWG teflon/teflon "T" sensors with encapsulation fused at the tip. The objective of this support was to certify that all the items recommended in the Standard ABNT ISO 17665.1 and 17665.2 were fulfilled during the accomplishment of the tests.

Three types of products were used as challenge tests with chemical indicators: a porous package with chemical integrator in the research called Challenge package A*, by 3M® (Comply Sterigage - lot 1628800643, exp.: Oct. 2018); a porous package with a chemical emulator called Challenge package B*, by Browne® (Ref. 3870, lot 027398, exp.: 04-01-2017); and a reusable helix device with a chemical emulator called Challenge package C*, of the brand Browne®(Ref. 3779, lot 028074, exp.: 09-2018).

The temperatures chosen by the study were sterilization cycles of 134 and 121°C, parameters used in the routine of MSC sterilization. For each temperature, interruptions during the cycles in certain phases were observed, described in Table 1.

The assays were performed with the autoclave loaded and, for simulation of the load, 12 packages of surgical lay were used (Figure 1). Each package consisted of 6 units of single cotton fields, measuring 1.60 m x 1.60 m, packed in double sheets of SMS (non-woven) and zebra tape. In addition to each package, sensors were positioned for analysis during the tests of the behavior of the temperature in the inner chamber.

As an initial test of the equipment, a Bowie and Dick cycle was carried out in the empty autoclave, with a ready-to-use disposable package, with a sheet printed in sterilization sensitive ink and positioned on the drain.

After the accepted result of the Bowie and Dick cycle, the challenge tests were placed on all cycles, being positioned next to the load, on the bottom shelf, next to the loading door. At each interruption, the challenge tests were taken out and the reading was performed. New tests were placed, starting the next cycle, following the pre-established interruption times.

The cycles were monitored with 12 thermocouples positioned near the load, aiming to determine the temperature distribution in the inner chamber and to follow the evolution of the results of chemical indicators in the challenge tests, according to the time of exposure and the interruption of the cycles observed in Table 1.

RESULTS

Table 2 shows the evolution of the CIs type A of the challenge package A*, the CIs type 6 of the challenge package B* and the CIs type 6 of the helix device C*.

Table 1. Sterilization cycles of 134ºC and 121ºC and the phases of interruption.

Temperature	Cycle interruption	Cycle interruption phase
134ºC (7 minutes)	A	1st pulse
	B	2nd pulse
	C	3rd pulse
	D	Beginning of the heating ramp
	E	Beginning of sterilization
	F	1 min of sterilization
	G	2 min of sterilization
	H	3 min of sterilization
121ºC (20 minutes)	J	1 min of sterilization
	L	4 min of sterilization
	M	8 min of sterilization
	N	12 min of sterilization
	O	16 min of sterilization
	P	20 min of sterilization

Figure 1. Autoclave loaded with tissue surgical packages.

All challenge packages were subjected to a temperature of 134°C, according to the interruption phases and the total cycle time.

Table 3 shows the evolution of the turn of the chemical indicators type 5 of the challenge package A*, of the CIs type 6 of the challenge package B* and of the CIs type 6 of the helix device C*. The challenge packages were subjected to a temperature of 121°C, according to the interruption phases and the total cycle time.

DISCUSSION

The obtained results showed some deviations regarding the performances proposed by the products.

Every CI has a declared endpoint, value at which a color change occurs. However, type 5 indicators must have 3 declared values: at 121°C, 135°C and at a temperature between these values (where the biological indicator death is reached). Type 6 indicators have only a

Table 2. Evolution of the turning of the chemical indicators submitted to the temperature of 134ºC.

134ºC			
Chemical indicators type 5 of the challenge package A*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package A***
A	1st pulse	12 min	Rejected - no migration
B	2nd pulse	18 min	Rejected - no migration
C	3rd pulse	25 min	Rejected - 11% of migration
D	Beginning of the heating ramp	29 min	Rejected - 33% of migration
E	Beginning of sterilization	32 min	Accepted – 74% of migration
F	1 min sterilization	33 min	Accepted – 81% of migration
G	2 min sterilization	33 min	Accepted – 100% of migration
H	3 min sterilization	34 min	Accepted – 100% of migration
Chemical indicators type 6 of the challenge package B*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package B***
A	1st pulse	12 min	Yellow – Rejected
B	2nd pulse	18 min	Yellow – Rejected
C	3rd pulse	25 min	Yellow – Rejected
D	Beginning of the heating ramp	29 min	Yellow – Rejected
E	Beginning of sterilization	32 min	Blue – Accepted
F	1 min sterilization	33 min	Blue – Accepted
G	2 min sterilization	33 min	Blue – Accepted
H	3 min sterilization	34 min	Blue – Accepted
Chemical indicators type 6 of the helix device C*			
Cycles	**Interruptions**	**Total cycle time**	**Helix device C***
A	1st pulse	12 min	Yellow – Rejected
B	2nd pulse	18 min	Yellow – Rejected
C	3rd pulse	25 min	Yellow – Rejected
D	Beginning of the heating ramp	29 min	Yellow – Rejected
E	Beginning of sterilization	32 min	Yellow – Rejected
F	1 min sterilization	33 min	Yellow – Rejected
G	2 min sterilization	33 min	Yellow Failed - Rejected
H	3 min sterilization	34 min	Blue – Accepted

stated value for specific cycle sterilization, depending on plateau time[12].

According to the technical justification of the chemical integrator 3M Comply, revised in 2016, the CIs type 5 integrate the lethality of the biological indicator, reacting to all critical parameters of the steam sterilization process (time, temperature and steam).

It is important to consider de 2006 American National Standard of ANSI/AAMI/ISO 11140-1, which lists the expected time/temperature end point values of the CIs with the values determined for inactivation of *Geobacillus stearothermophillus* spores, in ISO 11138. This shows that, for CIs type 5, approval (final result or end point) should occur in the estimated time from 56 seconds to 1 min and 30 seconds of the exposure phase of the cycle at 134°C. In the cycles of 121°C, approval is given between 10 min and 30 seconds and 16 min and 30 seconds[13]. In the study, the approval of CI type 5 in the cycle at 134°C was obtained at the beginning of the sterilization. In the cycle at 121°C, approval occurred after 8 minutes of the exposure phase. This is due to the fact that the performance tests were performed in a conventional hospital autoclave, considering pulse times, equipment heating and steam exhaustion. However, it is possible to make a performance evaluation between the products, since they were exposed to the same conditions of time, temperature and pressure.

It was possible to verify that the performance of the challenge package B* with CI type 6 presented performance similar to the challenge package A*.

Table 3. Evolution of the turning of the chemical indicators submitted to the temperature of 121ºC.

121°C			
Chemical indicators type 5 of the challenge package A*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package A***
J	1 min of sterilization	37 min	Rejected – 25% of migration
L	4 min of sterilization	38 min	Rejected – 33% of migration
M	8 min of sterilization	41 min	Accepted – 63% of migration
N	12 min of sterilization	48 min	Accepted – 55% of migration
O	16 min of sterilization	50 min	Accepted – 59% of migration
P	20 min of sterilization	54 min	Accepted – 100% of migration
Chemical indicators type 6 of the challenge package B*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package B***
J	1 min of sterilization	37 min	Yellow – Rejected
L	4 min of sterilization	38 min	Yellow – Rejected
M	8 min of sterilization	41 min	Blue – Accepted
N	12 min of sterilization	48 min	Blue – Accepted
O	16 min of sterilization	50 min	Blue – Accepted
P	20 min of sterilization	54 min	Blue – Accepted
Chemical indicators type 6 of the helix device C*			
Cycles	**Interruptions**	**Total cycle time**	**Helix device C***
J	1 min of sterilization	37 min	Yellow – Rejected
L	4 min of sterilization	38 min	Yellow – Rejected
M	8 min of sterilization	41 min	Yellow – Rejected
N	12 min of sterilization	48 min	Yellow Failed – Rejected
O	16 min of sterilization	50 min	Blue Failed – Rejected
P	20 min of sterilization	54 min	Blue – Accepted

By analyzing the data obtained, the CIs type 5 of the challenge package A* and the type 6 of the challenge package B* presented linear performance according to the time of exposure to the temperature, being by migration of the color in the window of the indicator or change in coloration from yellow to blue.

The helix device type C* was approved for CI type 6 after 3 minutes of the exposure phase at 134ºC, corresponding to 43% of the exposure phase. In the cycle at 121ºC, the indicator approval occurred after 20 minutes of the exposure phase, that is, 100% of the exposure phase.

CONCLUSION

The results of the tests led to the following conclusions: although the porous packages A* and B* have CIs of different types (type 5 - A* - and type 6 - B*), both presented similar results, and the difference between both products are not conclusive. The results obtained by the porous challenge tests were fully satisfactory or approved at the same time when the cycles were discontinued.

It was conclusive that the challenge packages A* and B* presented cycle approval before the sterilization phase at 134ºC, and this result is an uncertainty for decision making for the nurse responsible for the MSC.

The helix device C* with indicator type 6 showed a more efficient performance in the monitoring of cycles at 134ºC and 121ºC, resulting in acceptance of the cycle in the sterilization phase, as proposed. The monitoring of the cycle until the end of the exposure phase is decisive for guaranteeing the penetration of the steam in all the material processed and the minimum lethality expected, ensuring the sterility of the materials.

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EFFECTIVENESS OF THE PROTOCOL FOR THE PREVENTION OF SKIN LESIONS IN ROBOTIC UROLOGICAL SURGERIES

Efetividade do protocolo prevenção de lesões de pele em cirurgias urológicas robóticas

Efectividad del protocolo prevención de lesions de piel en cirugías urológicas robóticas

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ABSTRACT: Objectives: To verify the effectiveness of the Skin Lesion Prevention Protocol by analyzing the occurrence of lesions caused by surgical positioning in cancer patients undergoing robotic urological surgeries; to demonstrate the importance of simulations as educational strategies for training nursing teams. **Method:** This study includes a descriptive, retrospective, quantitative approach, and refers to the year of 2015. The study was performed at the surgery center of a cancer hospital that performs on average 1,000 surgeries per month. **Results**: In 2015, 359 robotic urological procedures were performed, of which 298 cases were prostatectomies. There were no skin lesions caused by positioning in the observed period. **Conclusion:** In this study, the occurrence of skin lesions associated with the surgical positioning of cancer patients undergoing robotic urological surgeries was zero. This result proves the effectiveness of the institutional protocol and demonstrates the importance of simulation as an educational improvement strategy to guarantee the success of robotic surgical positioning.

Keywords: Perioperative nursing. Pressure ulcer. Robotics. Patient positioning.

RESUMO: Objetivos: Verificar a efetividade do Protocolo Prevenção de Lesão de Pele, por meio do levantamento de ocorrências causadas pelo posicionamento cirúrgico em pacientes oncológicos submetidos às cirurgias urológicas robóticas e demonstrar a importância da simulação como estratégia educativa no treinamento da equipe de enfermagem. **Método:** Trata-se de uma pesquisa descritiva, retrospectiva, abordagem quantitativa, referente ao ano de 2015. O estudo foi feito no centro cirúrgico de um hospital oncológico que realiza em média 1.000 cirurgias/mês. **Resultados:** Em 2015, foram realizados 359 procedimentos urológicos robóticos, sendo 298 casos de prostatectomia. Não houve nenhuma lesão de pele por posicionamento no período observado. **Conclusão:** A ocorrência de lesões de pele em pacientes oncológicos submetidos a cirurgias urológicas robóticas, associada ao posicionamento cirúrgico, neste estudo, foi zero. Esse resultado comprova a efetividade do protocolo institucional demonstrando a importância da simulação como estratégia educativa de melhoria para garantir o sucesso do posicionamento cirúrgico robótico.

Palavras-chave: Enfermagem perioperatória. Úlcera por pressão. Robótica. Posicionamento do paciente.

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RESUMEN: Objetivos: Verificar la efectividad del Protocolo Prevención de Lesión de Piel, por medio del levantamiento de ocurrencias causadas por el posicionamiento quirúrgico en pacientes oncológicos sometidos a las cirugías urológicas robóticas e demostrar la importancia de la simulación como estrategia educativa en la capacitación del equipo de enfermería. **Método:** Se trata de un estudio descriptivo, retrospectivo, abordaje cuantitativo, referente al año 2015. El estudio fue hecho en el centro quirúrgico de un hospital oncológico que realiza en promedio 1.000 cirugías/mes. **Resultados:** En 2015, fueron realizados 359 procedimientos urológicos robóticos, siendo 298 casos de prostatectomía. No hubo ninguna lesión de piel por posicionamiento en el período observado. **Conclusión:** La ocurrencia de lesiones de piel en pacientes oncológicos sometidos a cirugías urológicas robóticas, asociada al posicionamiento quirúrgico, en este estudio, fue cero. Ese resultado comprueba la efectividad del protocolo institucional demostrando la importancia de la simulación como estrategia educativa de mejoría para garantizar el éxito del posicionamiento quirúrgico robótico.

Palabras clave: Enfermería perioperatoria. Úlcera por presión. Robótica. Posicionamiento del paciente.

INTRODUCTION

Recent national research estimates that for the years 2016 and 2017 there will be approximately 600,000 new cases of cancer (CA). In men, the most frequent type will be prostate cancer (28.6%)[1].

Currently, there are several surgery techniques that can be used for the treatment of prostate cancer, and the most modern and innovative one utilizes a minimally invasive and videolaparoscopic approach with the use of robots. Videosurgery emerged in the late 1980s and began to be used after the invention of the first endoscope, developed by Philipp Bozzini, a German physician, and even more so after the improvement of the laparoscope by other physicians[2,3].

Robot-assisted surgery is defined as "a computer-controlled manipulator with artificial sensors, which can be reprogrammed to move and position surgical instruments in order to perform surgical tasks," according to the Robot Institute of America[4].

In addition, the robotic system improves the visualization, exposure and dissection of important structures in a reduced space, thus decreasing the risk of complications, surgical trauma, pain and the duration of hospital stay[5,6].

When undergoing a surgical procedure, the patient is exposed to several situations that may compromise his or her physical and psycho-emotional integrity during the perioperative period. Among them, robotic urological surgical positioning stands out, since the surgical position should guarantee the patient's comfort and safety with respect to their anatomical and physiological limits. It is necessary that nurses be technically and scientifically able to perform these procedures, and that they be part of a multi-professional team to position the patient, which minimizes the risks of developing skin lesions (SL) resulting from surgical positioning[7-9]. Appropriate surgical positioning ensures efficiency and safety during the procedure, as it is one of the main quality indicators in perioperative care. Appropriate surgical positioning maintains the body aligned, making the operation site evident. This reduces tension and pressure on the tissues, preserves circulatory and respiratory functions, and prevents possible harmful effects due to the surgical position maintained for prolonged periods[10,11].

Intraoperative surgical patients are prone to numerous risks and to the development of various complications due to chemical agents, electrical burns and lesions caused by pressure, which are most commonly found. Pressure lesions can be defined as a SL and/or in the underlying tissue or structure, and are most evident in bone prominences, caused by pressure alone or in combination with friction and / or shearing while transferring the patients to the bed, and may be associated with significant patient comorbidities[8].

Recent studies have emphasized several risk factors associated with SL in surgical patients, and these factors are divided into two groups: intrinsic, such as age, body weight, nutritional status and chronic diseases, like diabetes mellitus, vasculopathies, neuropathies, hypertension and anemia; and extrinsic, for example, type and time of surgery, anesthesia, surgical positions and positioning. The intensity of these factors and the duration of the anesthetic-surgical procedure demonstrate the major or minor risk of developing SL, which can be observed after the end of the procedure and can increase rapidly. The most common sites for SL development from surgical positioning are: the sacral region, the calcaneus, the mandibular region, and the trochanters[8,11].

Thus, the basis for ensuring patient safety during intraoperative robotic surgeries is the early assessment of surgical risks, so as to implement improvement strategies and to minimize adverse events, such as SL from surgical positioning, through support and prevention mechanisms[8,12]. Improvement

strategies can be developed using educational actions in professional improvement training, such as simulations.

According to the guidelines from the Association of Perioperative Registered Nurses (AORN, 2017), the surgical positioning of the patient allows for the assessment of the quality of care provided[13]. With quality indicators, it is possible to monitor the occurrence of adverse events during the intraoperative period, since these events may be associated with the learning level of the nursing professionals. Such learning, in turn, meets the educational actions implemented to ensure the safety of the patient and the reduction of SL risks due to surgical positioning.

In this situation, the nursing professional can develop skills and abilities focused on the surgical patients and their needs. As such, robotic simulations provide opportunities for better interaction within the interdisciplinary team, ensuring the success of surgical positioning[14].

OBJECTIVES

To verify the effectiveness of the SL Prevention Protocol through the review of the occurrences of lesions caused by the surgical positioning in cancer patients undergoing robotic urological surgeries; to demonstrate the importance of simulations as educational strategies for training nursing teams.

METHOD

The study has a documental and retrospective design, and contains quantitative data analysis.

The study was developed at a national cancer hospital with 361 beds. The Surgery Center (SC) has 14 operating rooms, and the surgical volume is around 1,000 procedures per month (outpatient, inpatient, urgency and emergency). Of these 1,000 procedures, about 40 surgeries are performed with robotic technology, and 85% of those are urological surgeries.

The protocol analyzes the variables: age, gender, presence or absence of SL from surgical positioning, SL site, type of surgical positioning, duration of surgery, time during which the patient was positioned, time during which the patient remained under anesthesia, type of surgical procedure, time during which the surgeon remained in the console and laterality.

The inclusion criteria were: adult patients (both genders) undergoing elective robotic urological surgeries, in which the SL Prevention Protocol was applied.

Exclusion criteria: patients undergoing emergency surgeries, and who had SL from other causes and those undergoing other types of robotic surgery.

Data was collected from all patients undergoing robotic urological surgeries in the year of 2015, which accounted for 359 surgeries. This study was approved by the Ethics Committee of the institution hosting the study, according to report n. 2.278 / 16.

The data was collected through the creation of an instrument called the Systematization of Robotic Perioperative Nursing Assistance (SAEP Robotics), stored in the MV2000 database. The instrument highlights the variables as provided in the protocol. Based on its analysis, it is possible to create a graphic representation.

In the "intercurrent" field, nurses reported the presence or absence of SL from surgical positioning according to the SL Prevention Protocol, which refers to all types of surgical positions, including robotic surgeries.

Based on this data, figures were constructed to represent the profile of cancer patients undergoing robotic urological surgeries and their association with SL.

Training of the Surgery Center Nursing Team

The training of the nursing team is carried out using the realistic simulation model. Simulation scenarios bring the nursing professional closer to reality. They take advantage of the opportunity to predict errors, which can then be prevented in similar situations in the future, increasing the safety of the nursing professional and the cancer patient, thus avoiding damage to the patient on the date of surgery.

In this type of training, it is possible to practice technical skills and develop critical reasoning to evaluate the best actions to be taken, according to the particularities and specificities of the surgical procedures and of each patient.

The simulation of surgical positioning is performed prior to the procedure, and nurses, nursing technicians, surgeons and anesthesiologists are invited to participate in the training. In the simulation, one of the medical professionals is selected to be a living model, and then the SL Prevention Protocol is applied with the involvement of the interdisciplinary and multi-professional team, according to the surgical proposal and the clinical case of the surgical patient.

Thus, the absence of SL from surgical positioning reflects the integrated performance of the interdisciplinary and multi-professional team, which enhances their skills and competences through evidence-based practice, ensuring patient safety during the intraoperative period.

SL Prevention Protocol: Surgery Center

Upon arriving at the SC, the patient is admitted by the nurse using the document called "peri-admission." This is one of the steps in the Systematization of Perioperative Nursing Care (SAEP). In this document, there is a specific field for describing the intraoperative surgical risks, which highlights the risk of perioperative positioning lesions.

After going over the risk factors, the nurse confirms the intraoperative care to be provided based on the flowchart from Figure 1.

In this flowchart, the SL Prevention Protocol is applied according to the institutional scale of the surgery risk, which evaluates the time during which the patient underwent the surgical procedure. The institutional risk scale is composed of four classifications: low risk, moderate risk, high risk and special high risk.

In the low risk classification, the following are available for surgical positioning: positioners (head, back, arms, whole body and calcaneus), viscoelastic mattress, pyramidal mattress and pillows. In the classifications of moderate risk, high risk and special high risk, the following are available for surgical positioning: positioners (head, back, arms, whole body and calcaneus), viscoelastic mattress, pyramidal mattress, pillows and 15 × 20 cm protective films and specific special objects, in accordance with the nurse's assessment in the "peri-admission".

As such, risk assessment will guide what types of materials and aids will be required for surgical positioning, minimizing potential lesion risks. Therefore, according to the type of risk exposure in the proposed surgical procedure, positioners, pyramidal mattresses and specific 15 × 20 cm protective films are available.

The protective films are impermeable, that is, humidity and bacteria proof. It is possible to replace them several times without altering their ability to adhere to the patient's skin.

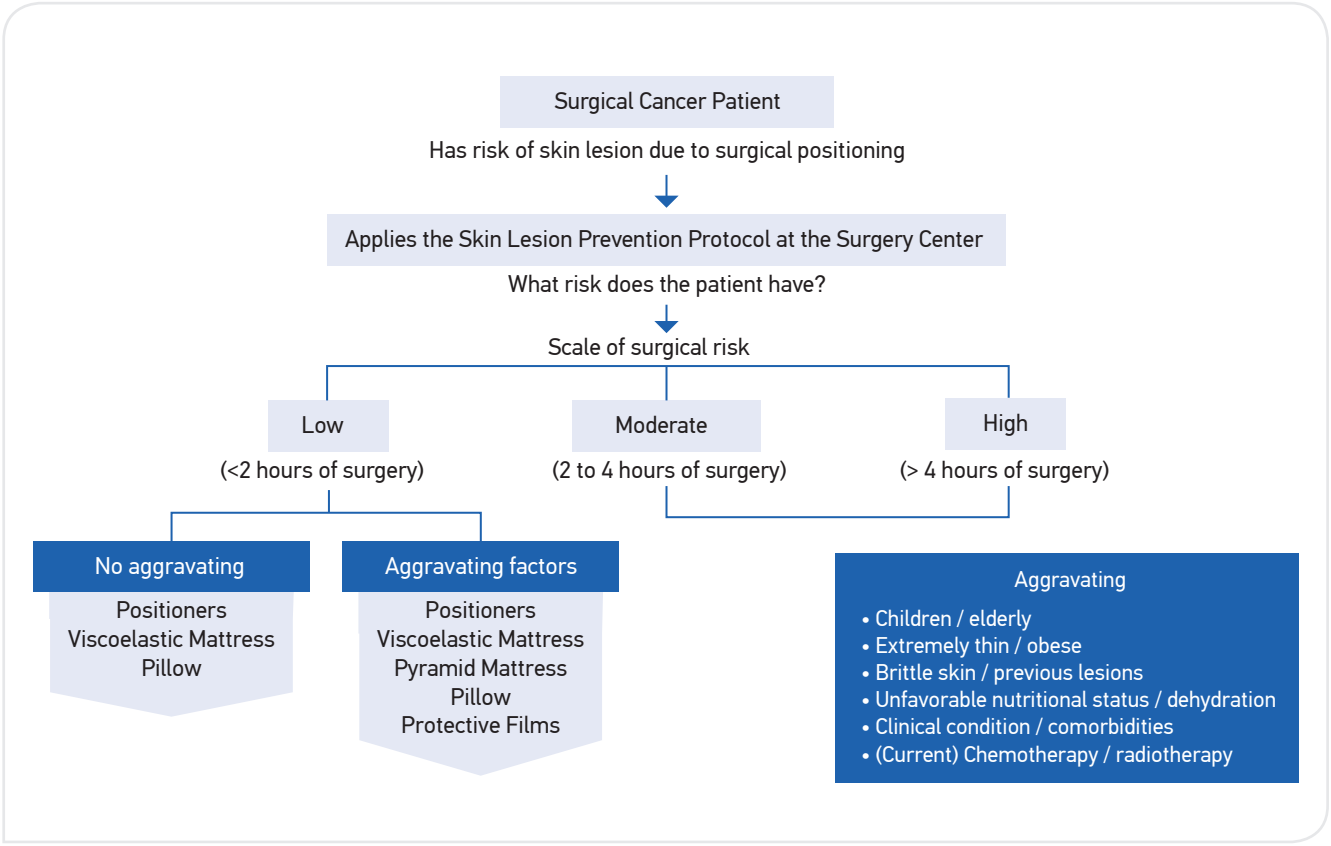

Figure 1. Skin Lesion Prevention in the Surgical Center Flowchart prepared by the A.C. Camargo Cancer Center.

In addition, in the absence of 15 × 20 cm protective film size, 15 × 15 cm sized film may be applied, according to the evaluation of the nurse at the "peri-admission". As such, the sites where the films are to be placed are highlighted in the nursing staff's pocket manual (Figure 2).

In the next section, the sites for placement of these protective films, according to the type of surgical positioning, can be observed by means of a pocket manual made available to all SC staff.

Surgical Positions

- Dorsal decubitus or supine position: natural position of the body in which the patient's back and spine are resting on the operating table mattress. The following stand out as potential areas of pressure: occipital, scapular, sacrococcygeal regions, elbows and calcaneum. Mainly observed in: head and neck surgeries, thoracic surgeries, pelvic-abdominal surgeries, breast surgeries, reparative surgeries, interventional radiology surgeries, endoscopic surgeries, urological surgeries, orthopedic surgeries, cardiovascular and vascular surgeries, surgeries for pain control, cutaneous oncology surgeries, dental surgeries, liver transplants and neurosurgery;
- Ventricular decubitus or prone: in this position, the patient's stomach or abdomen comes in contact with the operating table mattress. The following stands out as potential areas of pressure: periauricular, parietal, mandibular, thoracic and patellar regions, genitalia and dorsum of the feet. Mainly observed in: neurosurgeries, orthopedic surgeries and pelvic surgeries;
- Lateral decubitus: in this position, the patient is anesthetized in the supine position and, later, moved to the lateral thoracic position, or lateral renal position. The following stand out as potential areas of pressure: trochanteric, calcaneal, parietal, malleolar, thoracolateral, periauricular and condylopatellar regions. Observed mainly in: thoracic surgeries, orthopedic surgeries and urological surgeries.
- Lithotomic or gynecological position: position in which the patient is anesthetized in the supine position and moved to the lower fold of the operative table, so that the gluteal region is aligned with the "table break", for posterior placement of the leg rests. The following stand out as potential areas of pressure: occipital, scapular and sacrococcygeal regions, calves, calcaneus and soles of the feet. Mainly observed in: gynecological surgeries, pelvic surgeries and colorectal surgeries;
- Modified Fowler's position: commonly known as the "beach chair" position. It allows the patient to remain seated at angles 30 to 90 ° above the horizontal plane.

Objectives: to protect from friction and shearing, and control the microclimate					
Positions					
Table	Dorsal or supine decubitus / Reverse Inclined Trendelenburg		Lateral or Sims / Lying on side	Lithotomy	Knife (Kraske)/ ventral or prone decubitus
Areas at risk	Occipital Arms and elbows Sacrum and coccyx	Scapula Column Calcaneus	Shoulder Hip Ankle Side of face and ear Overlapping areas (skin on skin) Armpit Knee Feet	Occipital Shoulder Blade Calcaneus Sacrum and coccyx Lateral side of the legs Shoulders Hips	Forehead, eyes and ears Lower shoulders Iliac crests Knees and legs Toes Chin Chest Male genitalia Back of feet

Figure 2. Handbook made by the A.C. Camargo Cancer Center.

The following stand out as potential areas of pressure: scapular, gluteal, sacrococcygeal and popliteal regions, calcaneus and soles. Mainly observed in: orthopedic surgeries and neurosurgeries;

- Trendelenburg position: this position is a variation of the dorsal decubitus, in which the upper back is lowered and the feet are raised. The following stand out as potential areas of pressure: occipital, scapular, sacrococcygeal, elbow and calcaneal regions. Mainly observed in: vascular surgeries and lower abdominal surgeries;
- Reverse or inclined Trendelenburg position: in this position, the patient is placed in the back position so that the head is at a higher level in relation to the feet. The following stand out as potential areas of pressure: occipital, scapular, sacrococcygeal and calcaneal regions. Mainly observed in: upper abdominal surgeries and head and neck surgeries;
- Knife or Kraske position: modified position of the ventral decubitus. The following stand out as potential areas of pressure: parietal, periauricular, thoracic, genitalia, patellar and lower ankle regions. Mainly observed in: orthopedic surgeries and pelvic / colorectal surgeries;
- Robotic position: in this decubitus, the patient remains positioned in accentuated Trendelenburg in conjunction with the lithotomic position. The following stand out as potential areas of pressure: occipital, scapular, sacrococcygeal, calf, calcaneum and plantar regions. Observed mainly in: robotic urological surgeries. In this position, a profiled mattress will be made into an x on the thorax so that it is not directly in contact with the patient's skin. That is, it is in direct contact with the protective films adhered to the anterior thoracic region, and the mattress is fixed with adhesive tape. And, also, a profiled footrest is placed in the patient's hands, to guarantee their protection and safety.

RESULTS

The data collected were represented by three figures, which show the following items: age, number of patients undergoing urological procedures, presence or absence of SL from surgical positioning, SL location, duration of surgery and type of surgical procedure.

Figure 3 shows the total number of patients undergoing robotic urological surgical procedures (359 cases) in 2015, and demonstrates the percentage of each type of surgery performed. The 1% (four cases) of the category called "Others" refers to types of surgeries that had only one case in 2015. These include: adrenalectomy, kidney biopsy, ureteral implant and the resection of periprosthetic sarcoma.

Figure 4 shows the age group of patients undergoing urological surgeries according to the type of surgical procedure performed. The most prevalent age group is between 50 and 79 years old, both for prostatectomy surgeries (283 patients) and nephrectomy (30 patients).

Figure 5 shows the total surgery time for each type of surgical procedure. The surgery category with the highest percentage in the shortest period — that is, between 1 and 2 hours in duration — was prostatectomy (89.11%).

In the 359 robotic urological surgeries that strictly followed the SL Prevention Protocol, there was no occurrence of SL. No SL was detected in the more frequent surgery (prostatectomy: 89.11%) or in longer surgeries (cystectomy: 3%), which lasted more than 6 hours.

DISCUSSION

Nursing interventions are necessary to prevent risks and guarantee the integrity of the surgical patient with safety and the

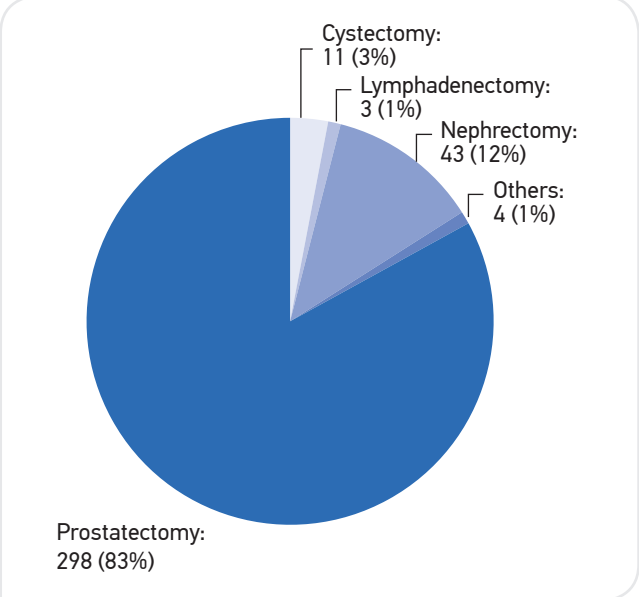

Figure 3. Number of patients per robotic urological procedure.

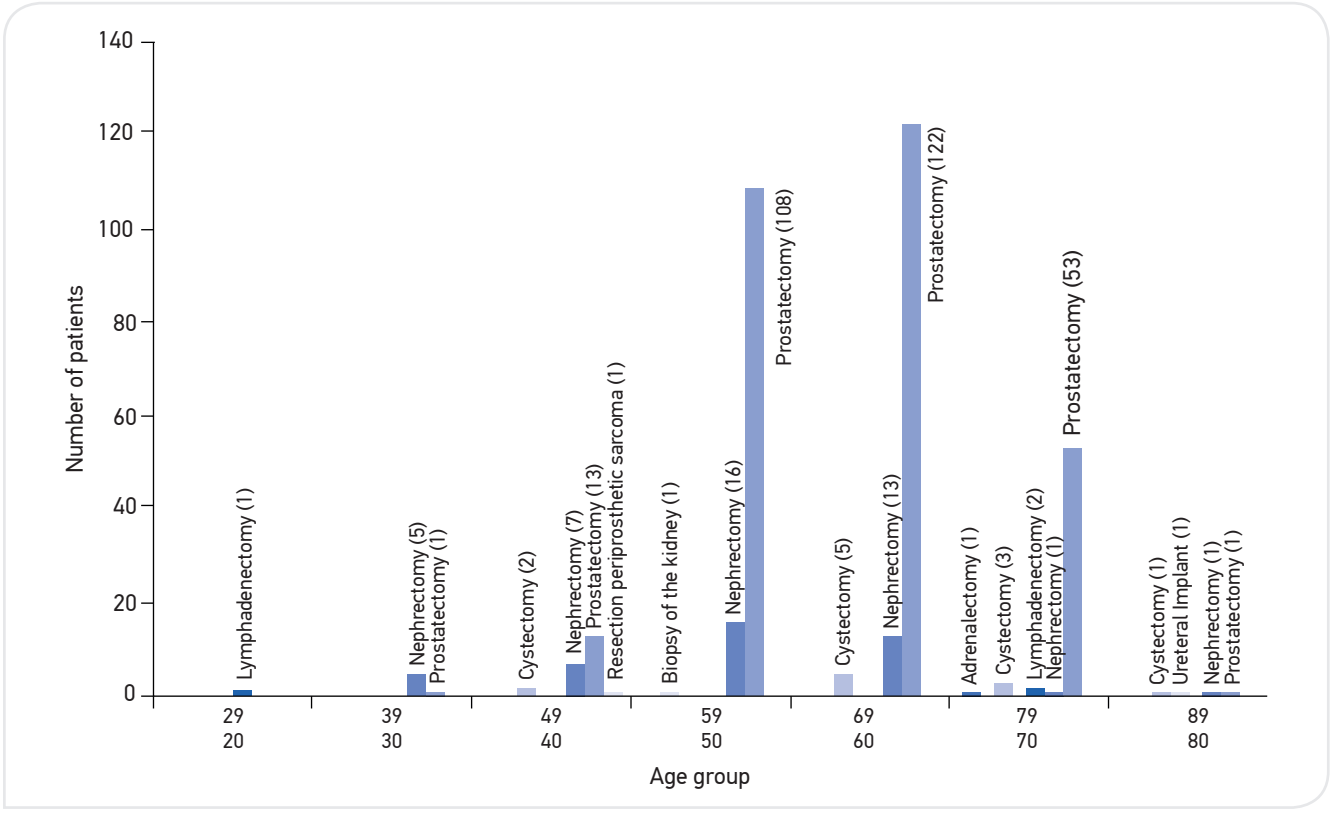

Figure 4. Number of surgical procedures × age range of patients.

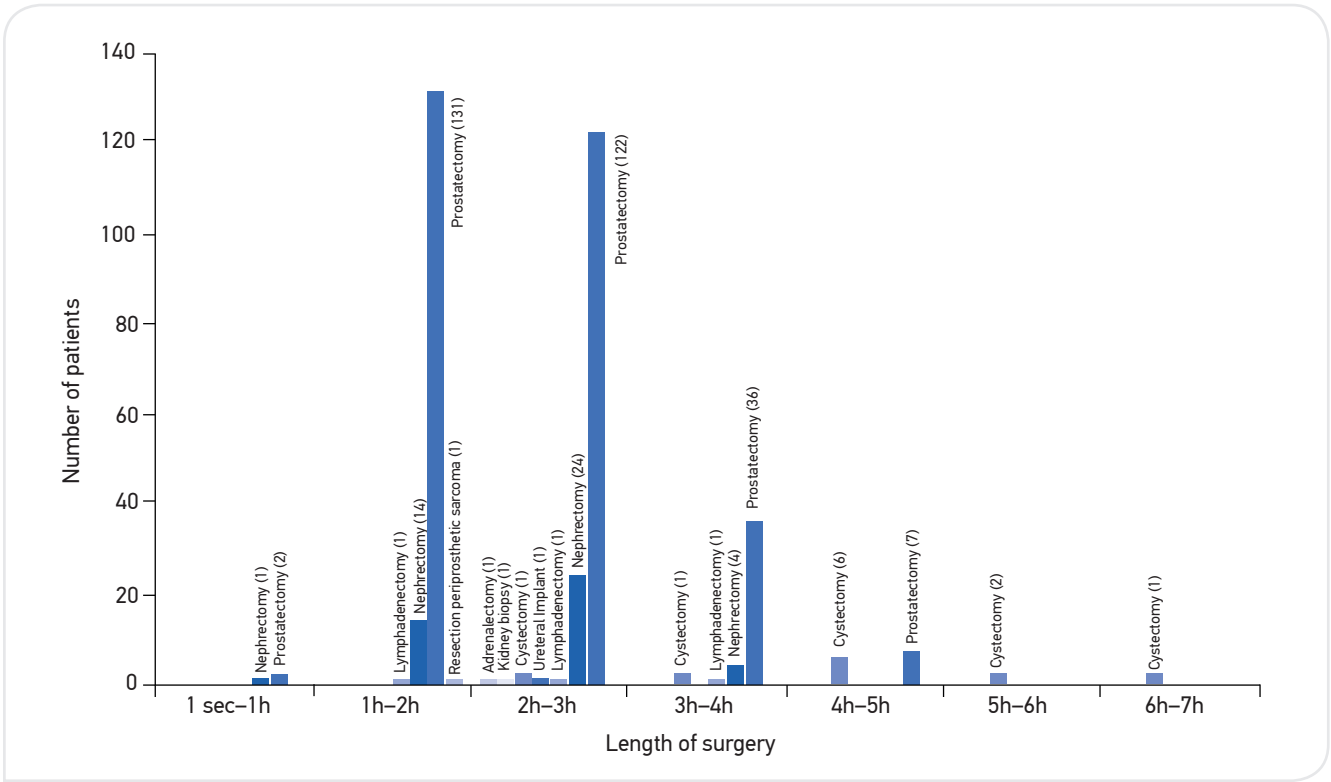

Figure 5. Range of surgery time × type of procedure.

effective management of their actions[10]. Therefore, the application and effectiveness of the SL Prevention Protocol in the SC guide the perioperative care behaviors defined by the nurse according to the needs of the cancer patient.

The occurrence of SL may be associated with the duration of the surgery, the time during which the patient is anesthetized, the period of time the surgeon stays on the console (the equipment used by the surgeon to manipulate the robot), and the type of the patient's surgical positioning[8,15]. In this regard, our data did not demonstrate any SL cases from positioning in robotic urologic surgical procedures. This result reflects the implementation of the best care practices as preventive barriers, such as, simulation, strengthening ethical attitudes and a responsible multi-professional team involved[14].

In robotic urological surgeries, the following surgical positions can be observed: accentuated Trendelenburg (15 to 20°), associated with the lithotomic position; and right or left lateral decubitus. In the accentuated Trendelenburg position associated with the lithotomic position, the following stands out as potential areas of pressure: occipital, bilateral scapular and sacrococcygeal regions, calves, calcaneus and soles of the feet. In the right or left lateral decubitus, the following are potential areas of pressure: trochanteric, calcaneal, parietal, malleolar, lateral thoracic, periauricular and condylopatellar regions[16,17]. This type of positioning implies hemodynamic changes, which may result in increased blood pressure, increased intraocular pressure, increased intracranial pressure, ventilatory difficulty and SL[17,18].

Thus, the quality and safety of the robotic devices used to position the patient need to be considered, since the success of this surgical modality is owed to SL prevention protocols[16-18].

Therefore, the present article allowed us to verify the effectiveness of the SL Prevention Protocol, in light of studies reported in the literature, since the occurrence of SL in cancer patients undergoing robotic urological surgeries associated with the surgical positioning was zero in this study.

CONCLUSION

In this study, the occurrence of LP associated with the surgical positioning in cancer patients undergoing robotic urological surgeries was zero.

This research proves the great effectiveness of the SL Prevention Protocol of the SC, as it shows the integrated actions of various medical professionals in implementing prevention strategies and protocols for robotic urological oncology surgeries. This demonstrates that simulation training for the interdisciplinary and multi-professional team is essential to ensure the effectiveness of robotic surgical positioning.

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EXCEPTIONAL USE OF INFERIOR EPIGASTRIC VEINS IN INFANT ANESTHESIA WITH IMPRACTICAL VENOUS ACCESS

Uso excepcional da veia epigástrica inferior na anestesia de lactente com acesso venoso impraticável

Uso excepcional de la vena epigástrica inferior en la anestesia de lactante con acceso venoso impracticable

Manoel Carlos Prieto Velhote[1], Jeferson Brito do Prado[2], Patrícia de Salles Tito Albuquerque[3], Andre Bohomol Velhote[4]

ABSTRACT: Objective: To report an exceptional venous access situation for anesthesia by cannulation (at the surgical site) of the inferior epigastric vein. **Method:** This article reports on the experience obtained in a maternal and children hospital in the city of Guarulhos, São Paulo. **Result:** We report the case of an eight-month patient who underwent left inguinal hernia repair after incarceration episodes of difficult reduction. After routine monitoring and inhalational anesthetic induction, we obtained no venous access due to excessive adipose panicle, even with numerous attempts by several professionals. Venous access was obtained at the surgical site by dissection and catheterization of the inferior epigastric vein with a Jelco® catheter. C**onclusion:** In special cases, the inferior epigastric vein is a possible catheterization vessel for venous infusions. It is an exception procedure that requires evaluation of the child's condition, preparation for the procedure and constant monitoring by all professionals involved in the care during the perioperative period.
Keywords: Catheters. Surgical procedures, operative. Patient care team.

RESUMO: Objetivo: Relatar uma condição excepcional de aceso venoso para anestesia por meio da canulação, no campo cirúrgico, da veia epigástrica inferior. **Método:** Relato de experiência ocorrida em hospital materno-infantil do município de Guarulhos, em São Paulo. **Resultado:** Relata-se o caso de um paciente de oito meses, submetido ao procedimento de correção de hérnia inguinal esquerda após episódios de encarceramento de difícil redução. Após monitoração de rotina e indução anestésica inalatória, não se conseguiu acesso venoso, mesmo com inúmeras tentativas realizadas por vários profissionais presentes decorrente do excesso de panículo adiposo. Realizado acesso venoso no campo cirúrgico por dissecção e cateterismo com Jelco® da veia epigástrica inferior. **Conclusão:** Em casos especiais, a veia epigástrica inferior é um vaso passível de cateterização para infusões venosas. É um procedimento de exceção que requer avaliação das condições da criança, preparo para o procedimento e monitorização constante, por todos os profissionais envolvidos na assistência, no período perioperatório.
Palavras-chave: Cateteres. Procedimentos cirúrgicos operatórios. Equipe de assistência ao paciente.

RESUMEN: Objetivo: Relatar una condición excepcional de acceso venoso para anestesia por medio de la canulación, en el campo quirúrgico, de la vena epigástrica inferior. **Método:** Relato de experiencia ocurrida en hospital materno-infantil del municipio de Guarulhos, en São Paulo. **Resultado:** Se relata el caso de un paciente de ocho meses, sometido al procedimiento de corrección de hernia inguinal izquierda tras episodios de encarcelamiento de difícil reducción. Tras monitoreo de rutina e inducción anestésica inhalatoria, no se consiguió acceso venoso, mismo con innumerables tentativas realizadas por varios profesionales presentes decurrente del exceso de panículo adiposo. Realizado acceso venoso en el campo quirúrgico por disección y cateterismo con Jelco® de la vena epigástrica inferior. **Conclusión:** En casos especiales, la vena epigástrica inferior es un vaso pasible de cateterización para infusiones venosas. Es un procedimiento de excepción que requiere evaluación de las condiciones del niño, preparo para el procedimiento y monitorización constante, por todos los profesionales involucrados en la asistencia, en el período perioperatorio.
Palabras clave: Catéteres. Procedimientos quirúrgicos operativos. Grupo de atención al paciente.

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INTRODUCTION

In anesthetic procedures in general, and especially in pediatric anesthesia, reliable venous access is required so that the anesthetic act unfolds safely, which is usually obtained by implanting the access device in the peripheral venous system by puncture. Venipuncture can be particularly laborious and difficult in infants, due to their natural agitation, lack of collaboration and poorly visible veins, which can be masked by excessive adipose tissue.

It is common in pediatric surgery to induce anesthesia with *halogenated* inhalational *anesthetics*. The venous access is then reached with the child in an anesthetic state.

Several superficial veins are available for peripheral access in the upper and lower limbs and neck. Strategies for better visualization include the use of tourniquets and application of heat, avoiding surgery rooms with inadequate temperature. Although the use devices that facilitate venipuncture is also advisable, they are rarely available in Brazilian hospitals. Some examples are: Vein Locator-Universal (which transilluminates the hand, highlighting the venous vasculature), AV-300 (which uses infrared radiation), Vein Viewer (which uses near-infrared radiation to detect the presence of hemoglobin), as well as ultrasound devices designed to guide vascular access procedures by puncture.

Research shows that the number of failures in venous access increases when the first puncture is not successful, to the point of suggesting that, after the third attempt, the professional or the access method should be changed.[1]

It is not infrequent that the first attempt of venous access in a eutrophic infant after anesthetic induction is not successful. This procedure often lasts for more than half an hour with several professionals taking turns on the attempt to access the vein.

In Brazil, peripheral venous puncture is routinely performed by both nursing assistants or certified nurses.[2] However, the medical team must also have technical training to perform venous or arterial vascular accesses, but with a greater responsibility, since surgical procedures may be required.[3]

This article aimed to report an exceptional situation in which, after anesthetic induction, the vascular access to anesthesia was maintained after cannulation of the inferior epigastric vein at the surgical site.

METHOD

We report the experience obtained in a maternal and children hospital in the city of Guarulhos, state of São Paulo, Brazil, in September 2016. ABC, an 8-month-old patient was scheduled to undergo left inguinal herniorrhaphy after hernia incarceration episodes of difficult reduction. His general condition, preoperative examinations and preanesthetic evaluation were normal.

After routine monitoring and anesthetic induction with sevoflurane, vascular access was not achieved, even after numerous attempts by several professionals — including the surgeon and nurses of the Surgical Center — due to excessive adipose panicle. Intraosseous access was considered, but there was no adequate material to perform the procedure.

Considering the real need to perform the surgical procedure due to the incarcerations that had already occurred, the anesthesiologist suggested the passage of a central venous catheter inserted by puncture to perform anesthesia. Because the surgery is performed with an incision in the inferior inguinal fold, we discussed the possibility of rapidly dissecting and cannulating the inferior epigastric vein — a constant vessel whose caliber normally accepts a thin caliber catheter — in the herniorrhaphy surgical site.

Once this approach was agreed, the patient was placed in an inguinal herniorrhaphy position supported by a gluteal cushion for the usual transverse incision in the inferior abdominal fold. We carefully dissected the inferior epigastric vein in the surgical site, which normally perpendicularly crosses the operative field. This procedure was performed without difficulty.

Despite the small caliber of the vein, its catheterization with Jelco® 22 was not a challenge. Then, a sterile infusion set was installed and administered a glucose solution to maintain venous access (Figure 1). The anesthesiologist was then able to inject anesthetics, to intubate the patient and to maintain the anesthetic level without difficulty.

The surgery was performed without abnormalities, allowing the correction of the massive indirect inguinal hernia. After the surgical procedure, we removed the Jelco® catheter, attached the epigastric vein and closed the skin after local ropivacaine injection (Figure 2).

Anesthesia recovery occurred uneventfully, allowing the child to be discharged three hours after the end of the procedure.

DISCUSSION

In pediatrics, peripheral venous access failure is reported in up to 5% of cases worldwide.[1] In Brazil, a study carried out

in a pediatric unit reports that failures can reach up to 11% of procedures.[4] The literature provides us with indexes to predict peripheral venous access difficulty. Therefore, for these presumably more difficult patients, it is justifiable to select a more experienced professional to perform the puncture, since it has been proved that individual expertise is a success factor in the attempts.[5]

In pediatric anesthesia, especially among well-nourished infants, peripheral venous access is not always easy, with puncture access failure reported in 10% of cases.[6] In addition, in Brazil, it is mandatory that anesthesia be performed with a vascular access installed for safety reasons, with reports of deaths and criminal proceedings resulting from the lack of venoclysis during the surgical procedure.[7]

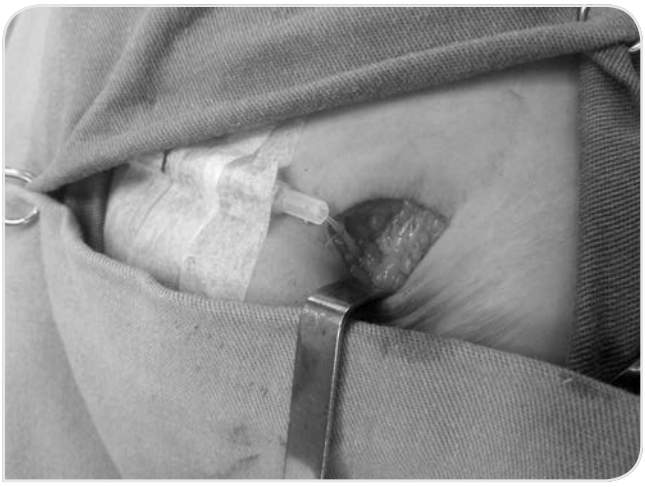

Figure 1. Jelco® catheter fixed in the inferior epigastric vein accessed through the herniorraphy incision.

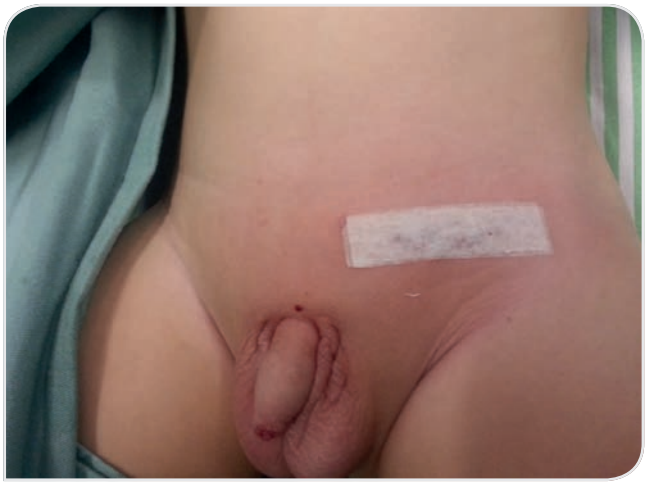

Figure 2. Surgical site at the end of the procedure.

Under these circumstances, an intraosseous vascular access would be acceptable,[3,6] which was not attempted in our case because of the lack of adequate material, a common fact in Brazilian hospitals due to the lack of familiarity with this type of vascular access.

Although the passage of a central catheter would be an option, it is a more invasive procedure with a risk of complications from 1-3%[8] with 35% of access failures.

The inferior epigastric vessels are constant in human anatomy, draining blood into the saphenous vein system and communicating cranially with the superior epigastric veins, making accessory communication between the superior and inferior vena cava systems.

There are no reported cases, exceptionally, of the use of the inferior epigastric vein for venous infusion. Since inferior epigastric vessels can be used as vascular pedicles for microsurgery grafts, there are reports of cannulation of the inferior epigastric vein in these grafts in cases of venous thrombosis until venous drainage recovery.[10] Catheterization of the inferior epigastric vein is not a challenge for a surgeon familiar with the cannulation of the facial vein in newborns.

Performing peripheral venous catheterization with knowledge and ability is part of the scope of practice for nurses, since this procedure represents approximately 80% of their activities.[11] However, when vascular access has to be performed by other routes and by a medical staff, it is the team's responsibility to promote safe conditions for the success of the procedure, which includes provision of appropriate devices, preparing the patient for surgery, prevention of complications and child-specific care for anesthesia recovery.[12]

In the present case, the use of the inferior epigastric vein made it possible to perform safe anesthesia, with reliable venous access without involving a procedure that is more risky or harmful to the patient.

CONCLUSION

In special cases, the inferior epigastric vein is a possible catheterization vessel for venous infusions and, like others, requires assessment of the child's condition, preparation for the procedure and constant monitoring by all professionals involved in the care during the perioperative period.

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ELABORATION OF DIDACTIC MATERIAL FOR PROCESSING HEALTH PRODUCTS IN PRIMARY HEALTH CARE UNITS

Elaboração de material didático para processamento de produtos para saúde em unidades de atenção primária à saúde

Elaboración de material didáctico para procesamiento de productos para salud en unidades de atención primaria a la salud

Fabia Maria Souza Paula[1], Natalia Camelo do Nascimento Beserra[2], Rebeca Cristina Souza Lopes[2], Débora Rodrigues Guerra[3]

ABSTRACT: Objective: To report the experience of elaborating a booklet on the processing of health products in a Primary Health Care Unit. **Methods:** Descriptive research, reporting an experience of 2015, in a Primary Health Care Unit located in the city of Fortaleza (Ceará). A guide was elaborated with a method comprised of five stages: choice of technology; content preparation based on the scientific literature; illustration selection; elaboration; edition. **Results:** The guide was structured in chapters considering good practices in Material and Sterilization Center (MSC), as follows: 1) MSC – concepts and infrastructure requirements; 2) Classification of articles and biosafety in MSC; 3) Areas of the MSC and stages for processing health products; and 4) Monitoring the sterilization process. **Conclusion:** The elaboration of the guide met the objective of sharing theoretical contents with the purpose of making professionals aware of the importance of their adherence to the good practices for processing health products.

Keywords: Sterilization. Nursing. Biomedical technology.

RESUMO: Objetivo: Relatar a experiência de elaboração de uma cartilha sobre o processamento de produtos para saúde na Unidade de Atenção Primaria à Saúde. **Métodos:** Pesquisa descritiva, do tipo relato de experiência, realizada em 2015, em uma Unidade de Atenção Primária à Saúde, localizada no município de Fortaleza (Ceará). Trata-se da elaboração de uma cartilha que seguiu cinco etapas: escolha da tecnologia; preparação do conteúdo baseado na literatura científica; seleção de ilustrações; elaboração; e montagem. **Resultados:** A cartilha foi estruturada em capítulos considerando as boas práticas em Centro de Material e Esterilização (CME), conforme disposto: 1) CME – conceitos e requisitos de infraestrutura; 2) Classificação dos artigos e biossegurança em CME; 3) Áreas do CME e etapas do processamento de produtos para saúde e 4) Monitoramento do processo de esterilização. **Conclusão:** A elaboração da cartilha cumpriu o intuito de compartilhar conteúdos teóricos com o propósito de conscientizar os profissionais da importância de sua adesão às boas praticas de processamento de produtos para a saúde.

Palavras-chave: Esterilização. Enfermagem. Tecnologia biomédica.

RESUMEN: Objetivo: Relatar la experiencia de elaboración de una cartilla sobre el procesamiento de productos para salud en la Unidad de Atención Primaria a la Salud. **Métodos:** Estudio descriptivo, del tipo relato de experiencia, realizado en 2015, en una Unidad de Atención Primaria a la Salude, localizada en el municipio de Fortaleza (Ceará). Se trata de la elaboración de una cartilla que siguió cinco etapas: elección de la tecnología; preparación del contenido basado en la literatura científica; selección de ilustraciones; elaboración; y montaje. **Resultados:** La cartilla fue estructurada en capítulos considerando las buenas prácticas en Centro de Material y Esterilización (CME), según dispuesto: 1) CME – conceptos y requisitos de infraestructura; 2) Clasificación de los artículos y bioseguridad en CME; 3) Áreas del CME y etapas del procesamiento de productos para salud y 4) Monitoreo del proceso de esterilización. **Conclusión:** La elaboración de la cartilla cumplió la idea de compartir contenidos teóricos con el propósito de concientizar los profesionales de la importancia de su adhesión a las buenas prácticas de procesamiento de productos para la salud.

Palabras clave: Esterilización. Enfermería. Tecnología biomédica.

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INTRODUCTION

Processing health products is challenging, and when it comes to Primary Health Care Units (PHCU), this becomes evident.

Primary Health Care has been developing more effective care practices, and its demand for minor invasive procedures has increased. This includes the removal of surgical stitches and open wound dressings (such as pressure ulcers), which requires critical health products (HP) processed inside the PHCU[1].

HP processing involves a set of actions related to cleaning, disinfection and sterilization procedures, including quality control at all stages, in order to ensure safety. It is a complex activity that aims to avoid any undesirable event regarding its use[2].

HP processing should follow a plan so that all steps have systematic methods and pre-established criteria. In the event of adverse conditions and in the absence of a standard protocol, users may be at risk. The execution of the recommended practices becomes indispensable, in order to make sure processing is efficient[3].

The Material and Sterilization Center (MSC) is the service responsible for HP processing to be used in the procedures. Problems related to the physical and organizational structure of services destined to processing of products, as well as shortage of permanent education in PHCU, motivated the authors to develop an educational guide, using soft technology.

This technology allows the production of relationships between the professional-user by listening, interest and management. It is a way of guiding processes and building connections, trust and management, used in the search for the quality of care provided to users[4,5].

In this context, education is considered as an instrument of awareness, liberation and transformation. Health education is related to the forms of caring, because through education, the capacity to care gains strength[6].

Thus, the objective of this study was to report the experience of the elaboration of a guide on HP processing in the PHCU.

METHOD

This is a descriptive study, as a case report, involving the elaboration of educational material in the form of a guide, carried out at a PHCU, located in the city of Fortaleza (Ceará), in the first semester of 2015.

The production of the guide involved the following steps: preparation of content based on scientific literature; selection of illustrations on internet search sites; elaboration; and edition[4].

A bibliographic survey was conducted in books and in the databases Scielo, Medline and PubMed, using the descriptors: "sterilization", "nursing" and "biomedical technology". Articles published in Portuguese, from 2008 to 2015, as well as the legislation in force in Brazil were analyzed, in addition to the norms in the Manual of the Brazilian Society of Surgical Center Nurses (SOBECC). The selected articles were analyzed by the reading and listing of the most important aspects, which subsidized the elaboration of the guide addressed to health professionals, especially in Nursing.

Specific contents were used on the basic principles of sterilization, transmission of infectious diseases and infection control.

Because there was no direct contact with human beings, the present study was not submitted to the Research Ethics Committee as regulated by Resolution 466/12. The ethical principles were respected, mentioning the authors of each section of the guide.

RESULTS

The guide was structured in four chapters with topics on HP processing, as follows:

1. MSC: Concepts and infrastructure requirements;
2. Classification of articles and biosafety in MSC;
3. Areas of the MSC and steps in the processing of health products; and
4. Monitoring the sterilization process.

Chapter 1 "MSC: Concepts and infrastructure requirements" presents the aspects of a MSC. According to the "Manual of physical structure of basic health units: family health", MSC is considered to be simple. The physical structure comprises an area for receiving, cleaning and decontaminating, and another one for the sterilization and storage of sterilized material, measuring at least 2.00x2.00m and 3.00x2.50m, respectively. The finishing touches, the infrastructure (floor, walls, doors, counters) and the lighting

and ventilation systems are important, as they directly influence the efficiency of work and the cross infection control (Figure 1)[7,8].

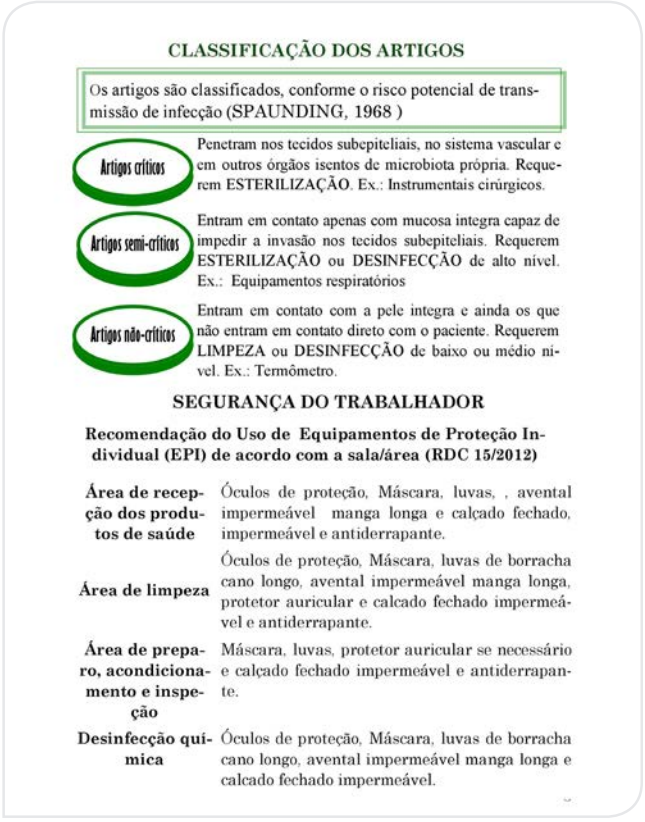
In Chapter 2, "Classification of articles and biosafety in MSC", HPs are categorized as critical, semi-critical and non-critical — according to the potential risk of infection transmission[8]. This classification affects the processing method, be it disinfection or sterilization[3]. At this point, for the worker's health and safety, the use personal protective equipment (PPE) is recommended — (personal clothing, cap, closed shoes, mask, glasses) — observing the area where professionals perform their activities (Figure 2)[8,9].

Chapter 3, "Areas of the MSC and HP Processing Steps", informs that the reception and cleaning areas have a space physically defined for receiving, separating and cleaning the contaminated products, being, therefore, the most critical area. Cleaning consists of the mechanical removal of dirt with water, detergents or enzymatic products, both manually and automatically[3]. It is in this stage that the integrity and the functioning of the products are evaluated (Figure 3A).

In the preparation room, products are inspected, selected and stored in sterile barrier systems such as cotton fabric, surgical grade paper, creped paper, polypropylene mat, rigid container, perforated metallized carton and high density polyethylene (HDPE). They are also identified with a name, lot number, date of sterilization, deadline for use, sterilization method and name of the person responsible for preparation (Figure 3B)[8]. The disinfection that destroys most microorganisms of semi-critical items can be conducted using chemical and physical methods. The MSC that performs the disinfection must have an exclusive room for that end. Sterilization is the process of destruction of all forms of microbial life indicated for critical products, which are those used in invasive procedures[8].

The product storage room has the purpose of centralizing the sterilized material for later distribution. Storage conditions may interfere with the maintenance of product sterility.

Chapter 4, "Monitoring the sterilization process", describes this type of process, which is monitored by checking critical cycle parameters (time, temperature and pressure); chemical control by means of chemical indicators; and biological monitoring, by using biological indicators, which are important to guarantee product sterilization. Records should be kept for five years (Figure 4)[8,10].



CLASSIFICAÇÃO DOS ARTIGOS

Os artigos são classificados, conforme o risco potencial de transmissão de infecção (SPAUNDING, 1968)

Artigos críticos — Penetram nos tecidos subepiteliais, no sistema vascular e em outros órgãos isentos de microbiota própria. Requerem ESTERILIZAÇÃO. Ex.: Instrumentais cirúrgicos.

Artigos semi-críticos — Entram em contato apenas com mucosa integra capaz de impedir a invasão nos tecidos subepiteliais. Requerem ESTERILIZAÇÃO ou DESINFECÇÃO de alto nível. Ex.: Equipamentos respiratórios

Artigos não-críticos — Entram em contato com a pele integra e ainda os que não entram em contato direto com o paciente. Requerem LIMPEZA ou DESINFECÇÃO de baixo ou médio nível. Ex.: Termômetro.

SEGURANÇA DO TRABALHADOR

Recomendação do Uso de Equipamentos de Proteção Individual (EPI) de acordo com a sala/área (RDC 15/2012)

Área de recepção dos produtos de saúde	Óculos de proteção, Máscara, luvas, , avental impermeável manga longa e calçado fechado, impermeável e antiderrapante.
Área de limpeza	Óculos de proteção, Máscara, luvas de borracha cano longo, avental impermeável manga longa, protetor auricular e calcado fechado impermeável e antiderrapante.
Área de preparo, acondicionamento e inspeção	Máscara, luvas, protetor auricular se necessário e calçado fechado impermeável e antiderrapante.
Desinfecção química	Óculos de proteção, Máscara, luvas de borracha cano longo, avental impermeável manga longa e calcado fechado impermeável.

Figure 1. Chapter 1.

ESTRUTURA FÍSICA DA CME DAS UBS

Sala de recepção, limpeza e descontaminação	Sala de esterilização e estocagem de material
Características: Ambiente medindo, no mínimo, 2,00 x 2,00m, comunicando-se com a área de esterilização por meio de guichê (medindo 50 x 50cm) com porta de abrir. **Prever:** - Visores entre esta sala e a de esterilização, bancada com bojo medindo 50(L)x40(C)x40(P), localizado no eixo da bancada. - Instalação de bancada com pia, pia de despejo, ducha para lavagem e lixeira com tampa e pedal.	**Características:** Ambiente medindo, no mínimo, 3,00 x 2,50m, comunicando-se com a sala de lavagem e descontaminação por meio de guichê (medindo 50 x 50cm) com porta de abrir, bancada seca (sem bojo). **Prever:** - Instalação de bancada com pia, dois bancos de altura compatível com a manipulação de materiais sobre a bancada, torneiras com fechamento que dispense o uso das mãos, armários sobre e/ou sob bancada, autoclave (sobre bancada), guichê de distribuição de material, lavatório e exaustor.

Quadro 1 – Demonstrativo de áreas, dimensões mínimas e instalações de Centro de Material e Esterilização Simplificado (MS, 2007)

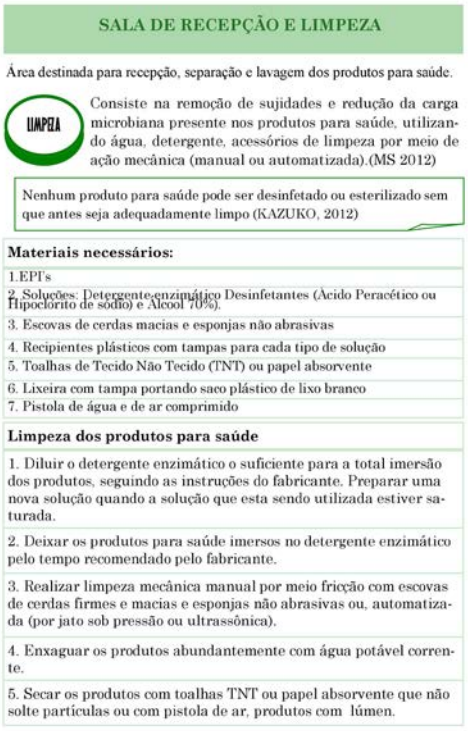
O acabamento influi diretamente no controle de infecções cruzadas e auxilia sobremaneira na estática.

Piso: Cor clara, resistente e de fácil limpeza. Não poroso e bom condutor de eletricidade estática.
Parede: Lisa, lavável e de cor suave.
Porta: Lavável e durável.
Bancadas: Material não poroso, resistente à limpeza úmida e ao uso de produtos saneantes.
Iluminação: Adequada e, se possível, iluminação direta nas mesas e nas bancadas de preparo de artigos.
Exaustão de calor: Área de instalação da autoclave.
Ventilação: Temperatura adequada para o conforto do profissional e acondicionamento dos produtos. **(RDC 50/2002 ;MS, 2007)**

4

Figure 2. Chapter 2.

A



SALA DE RECEPÇÃO E LIMPEZA

Área destinada para recepção, separação e lavagem dos produtos para saúde.

LIMPEZA

Consiste na remoção de sujidades e redução da carga microbiana presente nos produtos para saúde, utilizando água, detergente, acessórios de limpeza por meio de ação mecânica (manual ou automatizada).(MS 2012)

Nenhum produto para saúde pode ser desinfetado ou esterilizado sem que antes seja adequadamente limpo (KAZUKO, 2012)

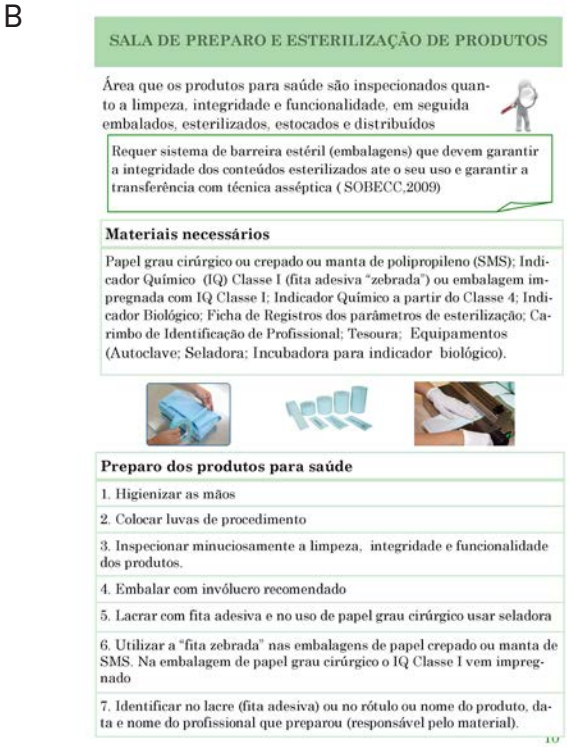
Materiais necessários:

1.EPI's
2. Soluções: Detergente enzimático Desinfetantes (Ácido Peracético ou Hipoclorito de sódio) e Álcool 70%).
3. Escovas de cerdas macias e esponjas não abrasivas
4. Recipientes plásticos com tampas para cada tipo de solução
5. Toalhas de Tecido Não Tecido (TNT) ou papel absorvente
6. Lixeira com tampa portando saco plástico de lixo branco
7. Pistola de água e de ar comprimido

Limpeza dos produtos para saúde

1. Diluir o detergente enzimático o suficiente para a total imersão dos produtos, seguindo as instruções do fabricante. Preparar uma nova solução quando a solução que esta sendo utilizada estiver saturada.
2. Deixar os produtos para saúde imersos no detergente enzimático pelo tempo recomendado pelo fabricante.
3. Realizar limpeza mecânica manual por meio fricção com escovas de cerdas firmes e macias e esponjas não abrasivas ou, automatizada (por jato sob pressão ou ultrassônica).
4. Enxaguar os produtos abundantemente com água potável corrente.
5. Secar os produtos com toalhas TNT ou papel absorvente que não solte partículas ou com pistola de ar, produtos com lúmen.

B



SALA DE PREPARO E ESTERILIZAÇÃO DE PRODUTOS

Área que os produtos para saúde são inspecionados quanto a limpeza, integridade e funcionalidade, em seguida embalados, esterilizados, estocados e distribuídos

Requer sistema de barreira estéril (embalagens) que devem garantir a integridade dos conteúdos esterilizados ate o seu uso e garantir a transferência com técnica asséptica (SOBECC,2009)

Materiais necessários

Papel grau cirúrgico ou crepado ou manta de polipropileno (SMS); Indicador Químico (IQ) Classe I (fita adesiva "zebrada") ou embalagem impregnada com IQ Classe I; Indicador Químico a partir do Classe 4; Indicador Biológico; Ficha de Registros dos parâmetros de esterilização; Carimbo de Identificação de Profissional; Tesoura; Equipamentos (Autoclave; Seladora; Incubadora para indicador biológico).

Preparo dos produtos para saúde

1. Higienizar as mãos
2. Colocar luvas de procedimento
3. Inspecionar minuciosamente a limpeza, integridade e funcionalidade dos produtos.
4. Embalar com invólucro recomendado
5. Lacrar com fita adesiva e no uso de papel grau cirúrgico usar seladora
6. Utilizar a "fita zebrada" nas embalagens de papel crepado ou manta de SMS. Na embalagem de papel grau cirúrgico o IQ Classe I vem impregnado
7. Identificar no lacre (fita adesiva) ou no rótulo ou nome do produto, data e nome do profissional que preparou (responsável pelo material).

10

Figures 3A and 3B. Chapter 3.

Monitorização do Processo de Esterilização

Teste biológico

1. Identificar o indicador biológico com data, identificação da autoclave (para serviços que tenha mais de uma autoclave), hora do processamento, lote, posição do pacote (ex. porta, meio ou fundo).

2. Colocar o indicador biológico no meio do maior *"pacote desafio"* das cargas processadas na UBS, identificando no lacre.

3. Esterilizar a carga de maneira ideal.

4. Deixar o teste esfriar por 10 min antes de retirar o indicador biológico.

Leitura do teste

- Ligar a incubadora e deixá-la aquecer por 1 hora;

- Colocar o tubete de plástico no local indicado na incubadora para que a ampola de vidro (interna no tubete de plástico) seja quebrada;

- Manter a tampa da incubadora sempre fechada para manutenção de temperatura apropriada para a incubação

- Proceder na mesma forma com um indicador que não tenha sido submetido ao processo de esterilização. Este indicador servirá como controle positivo e testará a incubadora, verificando se esta esta apresenta as condições ideais de temperatura e se os esporos daquele lote de indicadores são viáveis;

- Incubar o indicador biológico por até 48hs, verificando periodicamente se houve crescimento bacteriano. A cor do meio de cultura permanecerá violeta (negativo) ou amarela (positivo).

- Retirar as etiquetas dos tubetes de plástico para colar no livro de controle.

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Figure 4. Chapter 4.

DISCUSSION

It is important to highlight the importance of the service in the MSC, both regarding administrative and economic aspects, considering that the activities carried out in the unit require adequate physical and organizational structure to guarantee the quality of HP processing[9].

According to the "Manual of physical structure of basic health units: family health", the MSC is considered to be simple, and consists of an area for reception, cleaning and decontamination, and another area for sterilization and storage of sterile material with minimally established dimensions and recommendations about finishing touches and infrastructure, since it directly influences work efficiency and cross-infection control[7]. At this point, problems related with the physical structure occur due to physical space restriction, causing the contact between dirt and sterile items[11]. Activities in the MSC require planning and risk management, and this is only possible with adequate physical and operational structure[12].

RDC n. 15/2012 refers to health products as being critical, semi-critical and noncritical, according to the potential risk of infection transmission presented[7]. In this regard, there

is concern regarding the direct handling of contaminated materials, and the safety of the professional is emphasized in the recommendations of the Resolution on the use of PPE, designed to protect risks that may threaten the safety and the health of the workers[10].

The first step in product processing is cleaning, which is fundamental, since the presence of organic and inorganic waste compromises the efficiency of processes. In some PHCUs, professionals who are in charge of cleaning perform immunization and dressing activities simultaneously[12].

The preparation of products requires inspection, selection and storage in a sterile barrier system, as well as the identification of the sterilized products with labels[8]. The importance of choosing the sterile barrier system, whose function is to sterilize contents and to keep products sterile until their use, is emphasized here. The inadequate choice of storage for sterilization of thermo-resistant materials was approached in studies on sterilization in the PHCU[1]. The lack of identification observed in products can compromise the quality and safety of the patient. In the barrier system, surgical grade paper and creped paper are widely used in PHCU[13].

Disinfection is indicated for semi-critical products and may be carried out using chemical and physical methods. PHCU uses chemical methods with peracetic acid, indicated for high level of disinfection, eliminating all microorganisms in the vegetative form and some spores[8,12].

Sterilization is the process of destruction of all forms of microbial life[8]. The sterilization in the PHCU is conducted by moist heat under pressure, and the equipment used is the autoclave, suitable for thermo-resistant products[12]. Sterilization must take place according to the established criteria, which is essential to make sure procedures involving critical articles are not responsible for the transmission of pathogen infections to users[13].

In order to not compromise the effectiveness of sterilization, the maximum volume and arrangement of these materials within the autoclave chamber should be a careful process. These actions facilitate the penetration of the sterilizing agent, air removal and drying[14].

Storage conditions may interfere with the maintenance of product sterility, as recently sterilized material may be contaminated just before the established shelf life, depending on storage conditions and distribution to consumer units[11].

HP involves quality of service favoring the best implications to the user. Quality control will be satisfactory when the procedures adopted at each stage are in accordance with pre-established criteria, originating from scientific investigations and legislation[11].

Product processing should be a responsibility of trained nurses who provide guidance and supervision for all stages of processing[1].

FINAL CONSIDERATIONS

The elaboration of a guide involving the subject under study was valid in order to share fundamental theoretical content in a simple, illustrative and ludic manner addressed to professionals, highlighting the importance of their adherence to good practices for the processing of health products.

Experience has shown that the development of the guide was feasible, facilitating managerial methods and practical actions in nursing. It is concluded that technology can be used for the benefit of care.

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CRITERIA FOR EVALUATION OF NEW STERILIZATION TECHNOLOGIES

Critérios para avaliação de novas tecnologias para esterilização

Criterios para evaluación de nuevas tecnologías para esterilización

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ABSTRACT: Objective: To discuss criteria and methods that should ideally guide the evaluation of new sterilizing technologies. **Method**: Narrative review by means of search and interpretation of national legislation related to sterilization processes, as well as technical standards and documents that support constructive, functional, and safety aspects of sterilization technologies. **Results**: Topics relevant to the safety of sterilization processes, such as sterility testing, simulation of cycle under the worst load conditions, compatibility with sterile barrier systems, biocompatibility tests, process control, and economic evaluation, were discussed. **Conclusion**: The results will directly benefit three major segments: manufacturers while developing and requesting registration of new technologies; The National Sanitary Surveillance Agency when officially adopting a list of requirements with the manufacturer at the time of new equipment registration request; And health services, which will consume these new sterilization technologies.

Keywords: Sterilization. Methods. Technology. Science and technology legislation. Equipment technology and provision.

RESUMO: Objetivo: Discorrer sobre critérios e métodos que devem nortear a avaliação de novas tecnologias para esterilização. **Método:** Estudo de revisão narrativa mediado pela busca e interpretação da legislação nacional relacionada aos processos de esterilização, normas técnicas e documentos que embasam os aspectos construtivos, funcionais e da segurança das tecnologias para esterilização. **Resultados:** Foram discutidos tópicos relevantes à segurança dos processos de esterilização, como a prova de esterilidade, simulação do ciclo nas piores condições de carga, compatibilidade com sistemas de barreira estéril, testes de biocompatibilidade, controle de processos e avaliação econômica. **Conclusão:** Os resultados beneficiarão diretamente três segmentos principais; os fabricantes, no desenvolvimento e na solicitação de registro de novas tecnologias para esterilização; a Agência Nacional de Vigilância Sanitária, na adoção oficial de uma lista de exigências junto ao fabricante no momento de petição de registro de novos equipamentos; e os serviços de saúde, no consumo de novas tecnologias para esterilização.

Palavras-chave: Esterilização. Métodos. Tecnologia. Legislação em ciência e tecnologia. Tecnologia de equipamentos e provisões.

RESUMEN: Objetivo: Discurrir sobre criterios y métodos que deben guiar la evaluación de nuevas tecnologías para esterilización. **Método:** Estudio de revisión narrativa mediado por la búsqueda e interpretación de la legislación nacional relacionada a los procesos de esterilización, normas técnicas y documentos que basan los aspectos constructivos, funcionales y de la seguridad de las tecnologías para esterilización. **Resultados:** Fueron discutidos tópicos relevantes a la seguridad de los procesos de esterilización, como la prueba de esterilidad, simulación del ciclo en las peores condiciones de carga, compatibilidad con sistemas de barrera estéril, pruebas de bio-compatibilidad, control de procesos y evaluación económica. **Conclusión:** Los resultados beneficiarán directamente tres segmentos principales; los fabricantes, en el desarrollo y en la solicitud de registro de nuevas tecnologías para esterilización; la Agencia Nacional de Vigilancia Sanitaria, en la adopción oficial de una lista de exigencias junto al fabricante al momento de petición de registro de nuevos equipos; y los servicios de salud, en el consumo de nuevas tecnologías para esterilización.

Palabras clave: Esterilización. Métodos. Tecnología. Legislación en ciencia y tecnología. Tecnología de equipos y provisiones.

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INTRODUCTION

The challenging mission of the Sterile Processing Department (SPD) is to turn critical, used products into clean, sterilized products with preserved function. It therefore needs sterilization equipment that is absolutely safe as to elimination of microorganisms and which can preferably be installed in the health service aiming at practicality and total process control.

In addition, it is desirable that cycles be fast enough to meet the high demand and dynamics of care units, especially the surgical center; have no limitations on penetrability of the agent in medical devices; be compatible with sterile barrier systems available in the market; have low toxicity, be monitorable by biological and chemical indicators — especially type 5 or 6; and have affordable acquisition, installation, operation processes, besides the possibility of periodic qualification. These characteristics should guide the assessment of new sterilizing technologies in the field of health either by the Brazilian Health Surveillance Agency (ANVISA) at the time of its registration for marketing purposes, or by the SPD responsible technician in order to support its acquisition.

Analyzing product offer throughout evolution, especially surgical techniques, the significant increase of health products with thermosensitive characteristics is notable, leading to a need of new technologies for low temperature sterilization. The saturated steam autoclave currently meets demands of heat-resistant products at the SPD, with continuous improvements such as the coupling of fractional vacuums, leaking tests, and devices that remove non-condensable gases from the steam before entering the inner chamber. The same cannot be claimed for healthcare thermosensitive products, once the equipment must operate at low temperatures with a chemical agent.

The first equipment to sterilize thermosensitive medical devices in nationwide health services was ethylene oxide, followed by hydrogen peroxide gas plasma, low-temperature steam and formaldehyde. Although these technologies are regulated by the Ministry of Health through ANVISA in Brazil, each of them poses limitations, which impels the industry to invest in new technologies.

Although ethylene oxide's penetration is considered the gold standard, according to requirements of the Joint Interministerial Ordinance of Ministry of Labor and Employment (MTE) and Ministry of Health (MS) nº 482, 1999, it is currently to the charge of outsourced companies that fully meet legal requirements[1]. Although the other two technologies may be allocated at the SPD, they require caution due to the limitations they impose, features related to dissemination and compatibility with raw materials of medical devices and barrier systems.

New health technologies should be evaluated for efficacy, comparative effectiveness, and economic aspects in compliance with methodological guidelines proposed by the Brazilian Network for Health Technology Assessment (REBRATS), which is linked to the Ministry of Health[2-4]. However, such methodologies have general application and do not apply only and specifically to sterilization equipment.

So far, there is not a clear definition of criteria and methods to be officially adopted by ANVISA for the evaluation of new equipment for sterilization. In view of the above, we question what these would be. Thus, our study proposes to discuss sound criteria and methods that should guide the evaluation of different aspects before the approval and use of new technologies for sterilization in health services.

METHOD

Narrative review based on search and interpretation of the national legislation related to sterilization processes, national and international technical standards and documents that support constructive, functional and safety aspects of sterilization technologies. The aim was to establish the tests and minimum criteria for a new sterilization technology to be considered safe for use in health services.

Sterilization tests

Considering that bacterial spores are recognized as the most resistant and feasible microbial form for handling in non-specialized laboratories, they should be part of the process in a sterilization test. Viruses, oocysts of the subclass *Coccidia*[5] or prions are certainly greater specific challenges than bacterial spores, but the risk posed (in the case of prions), the absence of officially standardized methods (in the case of *Coccidia*) and non-availability of specialized laboratory infrastructure for virus testing (although there is an official European methodology) cause these to not

be officially included in most countries in the process of approval of new technologies with purposes of sterilization in health services.

In Brazil, the sterility test report to be presented by the manufacturer of a new technology must follow the standards established by the National Institute for Quality Control in Health (INCQS), Fundação Oswaldo Cruz (FIOCRUZ), which integrally complies with the Association of Official Analytical Chemists International (AOAC)[6], official methodology of the Food and Drug Administration (FDA).

The traditional AOAC[6] methodology addresses two bacterial spores to be tested: Bacillus subtilis, American Type Culture Collection (ATCC) 19,659 and Clostridium sporogenes, ATCC 3,584. Tests should be performed with two types of carriers: 120 porcelain carriers purchased from Fischer Scientific Co™, No. 7,907, and another 120 carriers made with approximately 6.5 cm of surgical silk thread nº 2 for each test microorganism. All cultures and their subcultures (total of 240 cultures for each test microorganism) should be put in initial 21-day incubation, followed by heat shock at 80°C and complementary 72-hour incubation. After these procedures, if there is not recovery of 100% of test samples, the technology for sterilization under evaluation is considered effective. The challenge of spored microorganisms carried by penicylinders and surgical silk thread nº 2 should be validated against the hydrochloric acid HCl at 2.5N concentration, subjected to contact with acid for 2, 5, 10 and 20 minutes. For inoculum reliability, the spores must stand for at least two minutes and can withstand for more than 20 minutes.

As a result of an outbreak of rapidly growing bacteria (RGB) infections related to invasive procedures in health services across almost all Brazilian States, with peak in 2006, ANVISA's General Management of Sanitation (GGSAN), determined the inclusion of Mycobacterium massiliense, strain INCQS 00594,[7] as a test microorganism in the evaluation of sterilization products through Resolution of the Collegiate Board of Directors (RDC) nº 35, 2010[7]. INCQS has not yet expressed its opinion on this inclusion in the group of test microorganisms to assess new sterilization technologies. However, reports must attest to minimal sterilizing effectiveness against spores of *Bacillus subtilis*, *Clostridium sporogenes*, and now also *Mycobacterium massiliense*.

Tests on devices simulating the penetration of sterilizing agent under the worst load conditions

To evaluate the penetration of the sterilizing agent in products, standardized devices and tests should be used. Considering the direct contact between sterilizing agent and surface required by low-temperature methods, the test device should reproduce the challenging conditions related to air removal and sterilizing agent penetration, whether by length, lumens, blind bottom, recess, or articulation.

For saturated steam, tests on devices that simulate steam penetration in the worst loading conditions are already well established. The same cannot be claimed for low-temperature equipment, though.

One of the tests proposed to verify air withdrawal and penetration of the sterilizing agent at low temperature consists in sterilization of an approximately 90-cm long tube with a 0.65-cm internal diameter and sealed end, where a biological indicator containing the spore that is most resistant to the sterilizing agent and a chemical indicator (preferably type 5 or 6, specific to sterilization method) are placed[8].

The American National Standards Institute / Association for the Advancement of Medical Instrumentation (ANSI / AAMI) Standard ST41:2008[9] establishes a test to monitor sterilization equipment in which biological indicators are placed inside a plunger syringe. These syringes are placed on a tray and packaged with a sterile barrier system, thus forming the challenge package.

In addition to lumens with and without a blind bottom and other internal spaces, sterilizing superimposed surfaces such as surgical instruments' articulations, grooves, and racks is also a major challenge in low-temperature processes. Thus, it is reinforced that devices used in the validation of any sterilization process must be able to support challenging conditions in comparison to medical devices used in healthcare assistance. In other words, a technology intended for the sterilization of endoscopes, for example, must challenge the complex conformation of this device and be proven safe for daily life.

Tests of compatibility with sterile barrier systems

A critical aspect that must be evaluated in processes of new sterilization technologies approval is related to the

sterile barrier system, that is, the physical and structural behavior of materials used for medical devices packaging.

The sterile barrier system ensures sterilization until the moment of use and promotes the transfer of contents by an aseptic technique[10]. Therefore, validation of packaging process is also crucial to ensure the integrity of the sterile barrier system until it is used[11].

The current context of sterile barrier systems involves a diversity of color options, dimensions, weights, hermeticity, and biobarrier property/effectiveness characteristics. It is recommended that the manufacturer of new sterilization technologies perform functional, macroscopic analyses, as well as maintenance of bio-barrier and sterilant residues remaining in the package so that the initially validated properties are rigorously maintained.

Events such as discoloration, physical changes, loss of peculiar resistance, deterioration of the seal, and mischaracterization of product identification after the cycle are important indicators of non-compatibility with the sterilization method.

Biocompatibility tests

Safety in sterilization processes depends not only on the guarantee of sterility but also on the absence of toxic effects whenever the medical device comes in contact with the patient during invasive procedures, since sporocidal activity presupposes toxicity of the sterilizing agent. In addition to sterilization employing chemical or physical agents to destroy microbial cells, the device must be free of chemical residues that compromise its use at the end of the process, just as the raw material must maintain its initial biocompatibility. The same is valid for sterile barrier systems, since they must be permeable by the sterilizing agent.

To meet this demand, specific tests are carried out to quantify residues and to evaluate the biological response induced by medical devices, according to their nature and time of contact with the tissues[12].

Considering the nature of the device in contact with tissues (superficial contact by external or implantable communication) and the time of contact, which is sorted as limited (<24 hours), prolonged (>24 hours to 30 days), and permanent (>30 days), safety assays may include: cytotoxicity, intracutaneous sensitization, irritation or reactivity, systemic toxicity, subacute and subchronic toxicity, genotoxicity, hemocompatibility, and implantation. Selection criteria of appropriate tests are described by ISO 10993-1[12].

For sterile barrier systems that do not come into direct contact with tissues, absence of cytotoxicity must be assured as they come into direct contact with medical devices until they are used.

In addition, material safety data sheet (MSDS) must be presented, as well as compliance with provisions of Decree 2.657, from July 3, 1998,[13] which promulgates International Labor Organization (ILO) convention 170 regarding chemicals safety at work.

Sterilization process control

The ANVISA Resolution of the Collegiate Board of Directors 15[10] requires that the physical parameters of a sterilization cycle be recorded at each cycle. Thus, one of the main requirements for the regularization of new equipment is monitoring all critical variables of the process with a printed data record, indicating — preferably at the end of the cycle —, whether variables' values meet acceptance criteria, also informing if it was satisfactory or not, based on this information. This is a requirement for the physical indicator to be valid and which can be used as a counterproof to a chemical or biological indicator. Another relevant aspect is the possibility of monitoring variables by instruments that are independent of the equipment, since they must be qualified every 12 months, and calibrated as frequently as determined by the manufacturer, in periodic maintenance. In addition, if the installation site changes, goes through intervention that changes critical parameters as of evaluation of changes implemented in qualification, or presents suspected flaws, it should be requalified. Besides such monitoring, chemical and biological indicators should be used at each requalification[10].

The Brazilian legislation[10] also establishes that the control of sterilization processes be carried out upon each load, in a challenge test package with chemical integrators type 5 or 6 — previously characterized as "class" by ISO 11.140-1[14], revised in 2014.

Ideally, new technologies should be marketed only after development and availability of chemical indicators:

- Type 1 (which differentiate products that are or are not exposed to the sterilizing agent without signaling the effectiveness of sterilization);

- Type 2 (specific tests for particular conditions that are essential to the success of a given method);
- Type 3 (which react in the presence of one critical process variable);
- Type 4 (which react in the presence of more than one critical process variable);
- Type 5 (which react to all critical process variables);
- Type 6 (which emulate the sterilization cycle, reacting to all critical process variables at shorter variation intervals)[14].

Specific and/or validated biological indicator should also be required, as it is one of the important pillars in the evaluation and monitoring of sterilization cycles[12]. In addition, the most challenging step of a sterilization process must be defined while qualifying the equipment, so that the biological indicator and the load-clear test package are properly positioned during the cycle. As the indicator must be packaged so it promotes challenging process conditions[10], the manufacturer must present its own commercially available challenge package or compliance with packaging guidelines by SPD itself at the time of registration request.

Economic evaluation of sterilization technologies

Economic aspects are fundamental in the decision-making process to incorporate a new technology. Despite this, the literature still lacks both national and international publications addressing cost-related evaluations of equipment, products, and sterilization processes. The few publications available speak to costs of reuse of single-use medical devices, where manufacturers do not recommend this process compared to disposal, and also studies that evaluate costing systems applied to CME[15,16]. Worthy of note is Canadian Technology Assessment, which has calculated the costs of pasteurizers compared to washer-disinfector machines to reprocess respiratory care devices. Results of operational costs/year were very similar: C$ 10,657 for washer-disinfector machines versus C$ 9,425 for pasteurizers. The study highlights the different applications of washer-disinfector machines as a differential benefit in parallel to pasteurizers[17].

Studies addressing cost-effectiveness should be more explored by professionals involved with medical devices, since high cost is a constant challenge for health care services. Results of such analyses provide important managerial tools, enabling a technical basis for negotiations, technological management at SPD, and optimization of financial resources[18].

There are several methodologies available for economics-related studies with health technologies, and they may be based either on the principles of health economics or cost accounting. Comparative economic evaluations are preferred, that is, studies that analyze costs and results of new technologies as opposed to those already available in the national or international market for the same purposes[3,18,19].

The correct identification of cost components in a process is a fundamental step for all methodologies. In the case of sterilization technologies, they should at least include the value of equipment and accessories acquisition, use and cost of all necessary inputs, expenses with environmental adjustments for installation, personnel dedicated to operating the equipment, value destined to team training, environmental impact, maintenance and monitoring costs[3-4,16,18].

Data for economic evaluation is retrieved from detailed sources that are compatible with the context of technology application, thus avoiding inference and fictional data. Therefore, when deciding whether to incorporate a technology in a particular health service, knowing the institutional demand, the operational capacity of each equipment model, and the forecast of cycles/day is fundamental.

Caution must be taken when interpreting data from health technologies economic studies; avoiding generalization of results from assessments carried out in different contexts is important, as there may be important variations related to work processes and local costs. It is recommended that studies with this scope be also evaluated for quality through an instrument developed for such purpose[20].

Very optimistic statements also require cautiousness, for example, upon incorporating a certain technology, promise of arsenal minimization, team reduction, cancellation of contract with outsourced companies, minimum time of product return for use, and others. Cost-related evaluations allow us to anticipate future reality; but not accurately, in view of possible uncertainty of parameters and analytical models adopted[3].

CONCLUSION

Having patient safety as the guiding principle of health care, be it direct or indirect, this study discussed criteria

and methods for the evaluation of new equipment for sterilization in the health field that will directly benefit three main segments:

1. The manufacturers, when developing and requesting registration of new sterilization technologies with ANVISA;
2. ANVISA, with the official adoption of a list of requirements for manufacturers at the time of request of registration of new sterilization equipment aimed for health services; and
3. SPD, when consuming the new technologies for sterilization in health care.

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