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

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

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

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

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

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

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INTRODUCTION

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

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

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

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

IMPORTANT CONCEPTS AND PRINCIPLES ON THE HEALTH TECHNOLOGY ASSESSMENT

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

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

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

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

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

To perform the HTA, some methodological principles are fundamental:

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

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

HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FINAL CONSIDERATIONS

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

REFERENCES

1. Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização (Sobecc). Práticas recomendadas Sobecc. São Paulo: Manole; 2013.

2. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Glossário temático: economia da saúde. Brasília: Ministério da Saúde; 2005. 60 p.

3. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Diretrizes metodológicas: elaboração de pareceres técnico-científicos. 4ª ed. Brasília: Ministério da Saúde; 2014. 80 p.

4. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Política Nacional de Gestão de Tecnologias em Saúde. Brasília: Ministério da Saúde; 2010. 48 p.

5. Segatto C. Os falsos doentes de R$ 9,5 milhões: os bastidores de uma das maiores fraudes já descobertas no Brasil envolvendo ações judiciais para fornecimento de remédios de alto custo. Revista Época [online]. 2016 jun. 22 [citado 2016 jul. 21]. Disponível em: http://epoca.globo.com/vida/noticia/2016/06/os-falsos-doentes-de-r-95-milhoes.html

6. Carmo SGD, Amâncio T. Investigação aponta fraude em compra de material para cirurgia no HC. Folha de S. Paulo [online]. 2016 jul. 18 [citado 2016 ago. 29]. Disponível em: http://www1.folha.uol.com.br/cotidiano/2016/07/1792811-investigacao-aponta-fraude-de-r-135-mi-no-tratamento-do-mal-de-parkinson.shtml

7. Pivetta M. A prova final da fosfoetanolamina: testes clínicos em seres humanos devem atestar se o composto pode ser útil no tratamento de algum tipo de câncer. Revista Pesquisa FAPESP [online]. 2016 [citado 2016 jul. 11];243:16-23. Disponível em: http://revistapesquisa.fapesp.br/2016/05/17/a-prova-final-da-fosfoetanolamina/

8. Toma TS, Soares AC, Bortoli MC, Pirotta KCM, Venâncio SI, Derbli M, editors. Avaliação de tecnologias e inovação em saúde no SUS: desafios e propostas para a gestão. São Paulo: Instituto de Saúde [online]; 2015 [citado 2016 ago. 02]. p. 13-100. Disponível em: http://www.saude.sp.gov.br/resources/instituto-de-saude/homepage/temas-saude-coletiva/pdfs/ats_inova_saude_capa_miolo.pdf

9. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Diretrizes metodológicas: elaboração de revisão sistemática e metanálise de ensaios clínicos randomizados. Brasília: Ministério da Saúde [online]; 2012 [citado 2016 maio 30]. 92 p. Disponível em: http://rebrats.saude.gov.br/diretrizes-metodologicas

10. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Diretrizes metodológicas: estudos de avaliação econômica de tecnologias em saúde. 2ª ed. Brasília: Ministério da Saúde [online]; 2014 [citado 2016 jun. 04]. 132 p. Disponível em: http://rebrats.saude.gov.br/diretrizes-metodologicas

11. Brasil. Lei n.º 12.401, de 28 de abril de 2011. Altera a Lei n.º 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde – SUS. Diário Oficial da União; 29 abr. 2011 [citado 2016 ago. 07]. Disponível em: http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2011/Lei/L12401.htm

12. Petramale CA. Conhecendo a CONITEC. Webconferência Conitec em Evidência de 29 de agosto de 2016 [online]. [acesso 2016 set. 04]. Disponível em: https://www.youtube.com/watch?v=TtAXnIb0yZ8

13. Quanto custa a sua saúde? Revista Exame. 2015 maio;1090 [citado 2016 mar. 17]. Disponível em: http://exame.abril.com.br/revista-exame/edicoes/1090/

14. Kolata G. Why "useless" surgery is still popular. The New York Times [online]. 2016 ago. 03 [citado 2016 ago. 28]. Disponível em: http://www.nytimes.com/2016/08/04/upshot/the-right-to-know-that-an-operation-is-next-to-useless.html?_r=0

15. Kise NJ, Risberg MA, Stensrud S, Ranstam J, Engebretsen L, Roos EM. Exercise therapy versus arthroscopic partial meniscectomy for degenerative meniscal tear in middle aged patients: randomized controlled trial with two year follow-up. BMJ. 2016;354:i3740. DOI: http://dx.doi.org/10.1136/bmj.i3740

16. Thorlund JB, Juhl CB, Roos EM, Lohmander LS. Arthroscopic surgery for degenerative knee: systematic review and meta-analysis of benefits and harms. BMJ. 2015;350:h2747. DOI: http://dx.doi.org/10.1136/bmj.h2747

17. Kallmes DF, Comstock BA, Heagerty PJ, Turner JA, Wilson DJ, Diamond TH, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med. 2009;361:569-79. DOI: 10.1056/NEJMoa0900563

18. Silva LA, Andriolo RB, Atallah AN, da Silva EMK. Surgery for stress urinary incontinence due to presumed sphincter deficiency after prostate surgery. Cochrane Database Syst Rev. 2011;(4):CD008306. DOI: 10.1002/14651858.CD008306.pub2

19. Psaltikidis EM, Bustorff-Silva JM, Resende MR. Efficiency of the artificial urinary sphincter in the treatment of post prostatectomy urinary incontinence. Health Technology Assessment International Annual Meeting [online], Oslo (Noruega), 2015 [citado 2016 mar. 17]. Disponível em: http://pt.slideshare.net/REBRATSoficial/ht-ai-2015-poster-238-efficiency-of-the-artificial-urinary-sphincter-49783062

20. Brasil. Ministério da Saúde. Departamento de Ciência e Tecnologia, Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Prostatectomia radical assistida roboticamente. Boletim Brasileiro de Avaliação de Tecnologias em Saúde. 2012;7(20).

21. Yaxley JW, Coughlin GD, Chambers SK, Occhipinti S, Samaratunga H, Zajdlewicz L, et al. Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. The Lancet [online]. 2016 jul. 26 [citado 2016 jul. 19];388(10049):1057-66. Disponível em: http://dx.doi.org/10.1016/S0140-6736(16)30592-X

22. Psaltikidis EM, Resende MR, Bustorff-Silva JM. Efficiency analysis of surgical staplers compared to manual suture for open and laparoscopic surgery. Value Health. 2015;18(7):A543. DOI: http://dx.doi.org/10.1016/j.jval.2015.09.1722

23. Canadian Agency for Drugs and Technologies in Health (CADTH). Non-manual techniques for room disinfection in healthcare facilities: a review of clinical effectiveness and guidelines. Rapid Response Report. Canadá; 2014 [citado 2016 jun. 23]. Disponível em: https://www.cadth.ca/about-cadth/what-we-do/products-services/rapid-response-service

24. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Analyse comparative de la pasteurisation et de la désinfection thermique dans un laveur-désinfecteur: dispositifs d'anesthésie et de soins respiratoires. ETMIS. 2009;5(7).

25. Psaltikidis EM, Leichsenring ML, Nakamura MHY, Bustorff-Silva JM, Passeri LA, Venâncio SI. Desinfetantes de alto nível alternativos ao glutaraldeído para processamento de endoscópios flexíveis. Cogitare Enferm. 2014;19(3):465-74. DOI: http://dx.doi.org/10.5380/ce.v19i3.35455