REVIEW
https://doi.org/10.22239/2317-269x.01366

Functional evaluation of medical devices

Avaliação funcional de dispositivos médicos

Evelinda Trindade[I,*]
Elza Leiko Otubo Hayashi[I]
Stela Candioto Melchior[II]
Maria Glória Vicente[II]

ABSTRACT

Introduction: Acquisition of hospital medical devices and supplies without the analysis of quality and performance may result in the occurrence of technical complaints or adverse events, patients' or users' health risks, and characterizes misuse of public resources. **Objective:** This review studies functional evaluation of hospital medical devices, which may contribute for risk prevention. **Method:** A systematic literature review on instruments and tools for medical devices functional evaluation was performed in bibliographic databases [MEDLINE, LILACS, SciELO, Cochrane, ECRI] and the Ministry of Health website. **Results:** Ten publications contained the selected inclusion criteria [and were English and Portuguese publications from 2005 to 2019], comprising eight clinical studies on the functional evaluation of specific hospital medical devices and two reviews of conceptual aspects and methods for devices incorporation. **Conclusions:** While it is recognized that a growing number of health facilities conduct purchases pre-assessment, the paucity of published studies indicates insufficient process standardization and often requires efforts duplication. This article points out that the functional evaluation of medical-hospital articles can be a significant preventive strategy to verify their quality and performance, without disregarding that the topic deserves further study.

KEYWORDS: Technology Assessment Biomedical; Medical Devices Assessment Tools; Prequalification; Medical Devices

RESUMO

Introdução: A aquisição de dispositivos médicos sem a análise de qualidade e desempenho pode resultar na ocorrência de queixas técnicas ou eventos adversos, de riscos à saúde de pacientes ou usuários, além de caracterizar mau uso de recursos públicos. **Objetivo:** Este estudo revisa os conhecimentos sobre a avaliação funcional de dispositivos médicos que podem contribuir para a prevenção de riscos. **Método:** Uma revisão bibliográfica sistemática sobre instrumentos de avaliação funcional de dispositivos médicos foi realizada utilizando a estratégia de busca nas bases eletrônicas: MEDLINE, LILACS, SciELO, Cochrane, ECRI e *website* do Ministério da Saúde. **Resultados:** Dez publicações continham os critérios de seleção de publicações em inglês e português, no período de 2005 a 2019: oito estudos clínicos sobre avaliação funcional de dispositivos médicos específicos e duas revisões de métodos de incorporação e aspectos conceituais. **Conclusões:** Embora reconheça-se que um número crescente de estabelecimentos de saúde realiza avaliação prévia às compras, a escassez de estudos publicados denota a padronização insuficiente do processo e impõe duplicação de esforços. Este artigo aponta que a avaliação funcional de dispositivos médicos pode ser uma estratégia preventiva significativa para verificação de sua qualidade e desempenho, sem desconsiderar que o tema merece maior aprofundamento.

PALAVRAS-CHAVE: Avaliação de Tecnologia Biomédica; Fichas de Avaliação Funcional de Materiais; Pré-Qualificação; Dispositivos Médicos

[I] Faculdade de Medicina, Universidade de São Paulo, São Paulo, SP, Brasil

[II] Agência Nacional de Vigilância Sanitária (Anvisa), Brasília, DF, Brasil

* **E-mail:** evelinda.trindade@incor.usp.br

Received: Jul 16, 2019
Approved: Oct 18, 2019

INTRODUCTION

Today there is a profusion of medical devices (MDs) whose performance is unknown or partially known[1], and the requirements for technical and scientific expertise to use new health-related technologies and, in particular, to buy them, are growing exponentially. There is a plethora of brands and models, a great diversity of options, a large number of MDs and increasing complexity in the procedures in which they are used. MD purchases should therefore ensure patient safety and effectively meet their specific needs.

Knowing how to purchase MDs is a challenge, both in the private sector and in public administration. "There are blatant problems on three fronts of public administration: there is the use of technologies that have no proven efficacy, others with no effect or with deleterious results that continue to be used, and effective technologies that are scarcely used"[2]. This emphasizes the importance of specific and in-depth knowledge prior to acquisition and reveals the existence of an intrinsic network of interests, habits and customs that develops from their incorporation into clinical practice. There is also the impact of continuous increases in health spending and critical changes in population needs, as opposed to a decrease in funds allocated for healthcare[3].

In the public sector, two legislations recommend and regulate the systematization of technology incorporations: Law n. 8.666 of June 21, 1993[4], and Law n. 10.520 of July 17, 2002[5]. The former established rules for public procurement processes and administrative contracts[4] and the latter established a bidding procedure for the purchase of common goods and services[5], with performance standards that can be set in a call for bids. The critical and in-depth knowledge of the technical features, performance standards, quality and intended purposes enables the specification of the MD in the design of calls for bids. These technical criteria also guide the stages of classification, assessment and selection of the products to be purchased[6,7].

An additional challenge is the tight deadlines within which these assessments and decisions must be made. To address this need, short assessments have been made at the hospital or institution level (mini-assessment). A mini-assessment or mini-HTA is a list of questions (checklist) of the prerequisites and consequences of using health technologies[1,8].

Functional assessment is one of the steps of these short assessments[1,6]. It refers to the acquisition of knowledge prior to the purchase of specific MDs through prequalification and standardization or approval of products and brands. Functional assessment includes checking compliance with current health requirements, history of technical complaints and adverse events associated with the MD, identification of the health program of which it is part, interaction with existing technological alternatives, additional staff training needs, impact on other related health programs and "functional testing". This functional test is performed by the relevant user(s) and guided by evaluation sheets that include the parameters expressed in applicable technical standards, in which the evaluator record whether or not the MD is compliant with the requirements[6,7].

Although functional assessment is a fundamental process, there are few experiences published internationally[6] and in Brazil[6,7]. Therefore, the objective of this review was to summarize the published assessment tools that can support this process and to analyze the underlying conceptual approaches in the published examples, with a view to disseminating methods and enhancing the functional assessment of MDs.

METHOD

We searched the following bibliographic databases: (i) Latin American and Caribbean Health Sciences Literature (LILACS), (ii) Scientific Electronic Library Online (SciELO), (iii) Cochrane Plus Library, and The Cochrane Library/Systematic Reviews, using the following indexed terms: "*Avaliação de Tecnologia Biomédica*" (Biomedical Technology Assessment) and the free terms: "*artigo médico-hospitalar*" (medical-hospital device) and "*ficha de avaliação*" (assessment sheet) or "*formulário de avaliação*" (assessment form) or "*instrumento de avaliação*" (assessment tool). In MEDLINE the following indexed or free terms were used: "Technology Assessment Biomedical", "Equipment and Supplies", "instrument", "tool", "medical device", which contained at least one of the three word roots of the following expressions "purchas*, acquir* or procur*". The terms were also searched on the institutional websites of the Brazilian National Health Surveillance Agency (Anvisa) and of the Emergency Care Research Institute (ECRI). In the latter, research included the following databases: Healthcare Risk Control, Medical Devices System and Health Technology Assessment Information System. The selection of studies was limited to the last 15 years, from 2005 to 2019 (because of the evolution and changes in technologies and technical standards), restricted to publications in Portuguese or English, containing the terms of interest and addressing MD assessment for acquisition. The criteria for choosing languages was based on the trajectory in Health Technology Assessment of English-speaking countries and the interest in including studies conducted in Brazil (Portuguese language).

The studies were collected in sequential order and the search was refined with subsequent concepts, like a cascade. Quotations with abstracts were placed in a supporting text document. This enabled us to revise these texts with the text searcher by selecting the key concepts. Only those studies containing the keywords were retrieved in full, and then a second scan was performed to check whether the assessed object was in fact an MD. The studies were analyzed by two researchers through a structured instrument addressing their design, the population investigated, the object studied, the instrument applied or exemplified, as well as the analysis, results and conclusions as presented by their authors. Divergences in item abstraction were resolved by consensus and ratified with reviewers.

The assessment tools presented in the studies were the unit of analysis for reviewing the dimensions and categories of topics considered relevant to prequalify MDs before their acquisition. Qualitatively, these reflect the conceptual dimensions that build the aspects that integrate the quality of the MD, according to their authors.

RESULTS

In the MEDLINE database, there were 10,760 references to "Technology Assessment Biomedical", 1,231 of which were also indexed with "Equipment and Supplies". Of these, 540 had ("instrument" OR "tool") free terms, and five, published after 2005, met the inclusion criteria. In the LILACS database there were 135 references, and three studies were selected. Other titles and abstracts did not meet the inclusion criteria. In the SciELO database/Journal of Public Health/Brazil, there were 140 references, three of which had already been selected from the LILACS database. In The Cochrane Library/Systematic Reviews base, no papers containing the inclusion criteria were found. On Anvisa's website, only one publication addressed MDs and an assessment tool among references in technovigilance support materials[7]. A later study, recently conducted and not yet indexed, was found within the Sentinel Network.

The Chart presents the ten studies identified, according to the study design.

Of the ten studies, eight are observational, seven of which (numbers 2, 3, 5, 7, 8, 9 and 10) are comparative and prospective clinical trials testing criteria for the purchase and use of specific products. Study 4 was organized in four laboratory centers for experimental use of specific products. All eight studies applied questionnaires and measured specific safety and effectiveness parameters, with presentation of results applied by means of qualitative scores or scales. The other studies (1 and 6) are conceptual studies about the process to optimize purchases and assessment instruments, without presenting applied results.

Studies 2 and 7 were conducted in England, where the health system is a mixed public-private system with a predominance of the public sector and where there is intense health technology assessment for the purpose of healthcare planning. To this end, one of these studies (7) assessed MDs that are already established, low-cost, and commonly used: diapers, which impact the planning of healthcare programs because of their likelihood of being heavily used. One of the two studies conducted in Brazil (9) also assessed a low-cost, commonly used, high-volume product: a parenteral infusion set.

Study 2 in England, Study 3 in Israel, and Studies 4 and 8 in the United States assessed high-cost and relatively innovative MDs. The process of procurement of high-cost products has also been reported in Italy (5) and Mexico (1), in an effort to improve procurement processes and optimize fund allocation.

The study done in Israel (3) stands out because it assesses a complex and innovative technology: a radio frequency pen that captures the electromagnetic response of cells, differentiating normal tissue from tissue with cancer. Although the radio frequency pen is a healthcare device, we chose to include it as an example of innovative technology, given the cancer epidemiology.

Both assessments of low-cost, common-use and high-volume MDs (7 and 9) were based on conceptual dimensions of health risks, safety and outcomes given by their performance, presenting similar analysis categories from different perspectives. In the English study on diapers (7), the major perspective was the final impact of MD performance on the quality of life of its users. The categories of analysis included in the assessment instrument were: effectiveness, durability, usability, acceptability or preference. The effectiveness of the diapers was assessed by physical-technical requirements, listed in the guiding questions. Participants used two or three types of daytime products and four or five of those for nighttime use, either disposable or washable, in different versions according to the participant's gender. Each item of the instrument addressing aspects of performance, impermeability and usability categories presented a categorical scale of five ratings, ranging from excellent to very poor. In the Brazilian study (9), the dominant perspective was risk management for patients and users. The categories of analysis of the instrument reflected the same dimensions already published in the highlighted examples of the Prequalification Manual (6). In the instrument submitted to the opinion of 81 hospitals of Anvisa's Sentinel Network and finally validated by five judges, each attribute assessed was rated according to a continuous scale (from very poor: 0.00 to excellent: between 4.51 and 5.00). This enabled us to check the brand's performance and compare it to the other five brands of the two types of sets, either simple or with reservoir.

Four studies addressed the assessments of innovative high-cost MDs with potential high volume of use. Studies 2 and 8 focused on dressings and primarily addressed their safety dimension. The objective method of the first of these studies (2) measured the density in cumulative incidence curves of surgical site injuries over the period, such as skin blisters when removing the dressing, enabling the comparison between established routine technologies and the innovative product. The second of these studies (8) also used objective measurements through a tensiometer that checked the peel force required to remove the adhesive as an indicator of adhesion effectiveness and measured clinical requirements as indicators of the safety dimension.

The third study assessed endoscopic and automated suture instruments for use in minimally invasive endoscopy and video-assisted surgery (4). These products are relatively new and innovative, but above all, they are rapidly evolving with increasing costs. The complexity of every component that is added makes these products technically difficult to assess. In this study, in four experimental workstations, eight sets of these devices from different manufacturers were compared by standardized functional testing. Orally and in real time, an interviewer applied the standardized instrument to each test, questioning the dimensions of safety and performance,

Chart. Papers included according to year, country, author and research design.

Year, country	Author(s), title, bibliographic citation	Structured abstract
1. 2005, USA	Spears et al. *New tool assess medical device for patient safety. The risk management reporter - ECRI. 2005;4(5):11-12*[9]	**Design:** Amendment of the instrument recommended for the process of MD assessment prior to acquisition. **Population:** Hospitals of the BJC Healthcare Group of St. Louis - Missouri. **Object:** Healthcare products purchasing process. **Instrument:** Questionnaire with six sections taking into consideration the patient safety component: aspects of clinical use and effectiveness, risks and problems reported, cleaning and infection control, environmental safety and waste. **Analysis and Results:** Conceptual study of the instrument without presentation of applied results. **Conclusions:** The tool developed to assess MDs is similar to the **mini-assessments** previously recommended by DACCEHTA, 1994, but its sections explicitly indicate what hospital sectors should support the purchase orders.
2. 2006, England	Chang et al. *CUSUM: A tool for early feedback on performance?* BMC Med Res Methodol. 2006 Mar 2;6:8[10]	**Design:** Prospective observational clinical study in a single center on the case series of a single surgeon. **Investigated population:** Twenty patients operated for total hip or knee replacement arthroplasty. **Object:** Dressings, blue gauze and *Tegaderm*. **Instrument:** Perioperative blister incidence score, blisters under dressing until discharge. **Analysis:** Cumulative sum curve of incidence density in relation to acceptable thresholds in the service. **Results:** Incidence of less than 10% of blisters on the perioperative site compared to 10% acceptable in the service. **Conclusions:** Cumulative sum curves of incidence density of a parameter measuring product performance against relevant and acceptable thresholds can visually signal trends in quality deviations.
3. 2007, Israel	Karni et al. *A device for real-time, intraoperative margin assessment in breast-conservation surgery*. AM J of Surgery. 2007;194:467-73[11]	**Design:** Prospective multicenter clinical study of radiofrequency wave reflex diagnostic method compared to the gold standard: histology. **Population:** Fifty-seven patients who underwent partial mastectomy in the intraoperative period. **Object:** Disposable probe transmitting console-captured radiofrequency signals with software/algorithm that suggests presence or absence of malignancy. **Instrument and Analysis:** It is considered true positive and concordant for malignancy if, in the excised and immobilized tissue, the margins presented > 22% of points captured at distances ≤ 0.1 cm from the corresponding stained margin in histological examination. **Results:** The probe detected additional positive margins in real time in 19/22 patients in whom the surgeon could not see them with the naked eye. In the absence of a pathologist and simultaneous freezing examination, these patients would have to be reoperated on. However, it did not detect three other patients with malignancy in margins detected in the simultaneous freezing examination. **Conclusions:** Trials designed to study the performance of a new diagnostic product compared to the gold standard enable better understanding of the potential benefits.
4. 2007, USA	Burns et al. *Assessment of medical devices: How to conduct comparative technology evaluations of product performance*. Int J Techn Assess Healthcare. 2007;23(4):455-63[12]	**Design:** Qualitative comparative, quasi-experimental, prospective and multicenter assessment. Each study site was organized into four laboratory stations for experimental surgeries, each with a standardized set of MDs for the different procedures. **Population of evaluators:** Forty-five surgeons, free from declared conflicts of interest, of the relevant subspecialties in local hospitals, in number, age and level of training representative of the Group Purchasing Organization's base area, comparable to their distribution in the American Medical Association's Masterfile. Each surgeon, upon operating at the four laboratory stations, tested 40 of the 52 brands/products under study. **Object:** A minimum of 50 ready-to-use samples donated and delivered by the eight manufacturers to each of the test hospitals, including suture threads and needles, video surgery devices (clip applicators, endoscopic and internal staplers, trocar and disposable clamps for biopsy). **Instrument:** Questionnaire addressing assessment parameters of ergonomics, functionality, overall performance, clinical equivalence and their relative ranking, applied in real time and noted down immediately by the respective study station technician. **Analysis:** Comparison of scores from 1 to 7 to the most satisfactory in Likert scales on each assessment parameter and ranking of overall performance; in the responses of the evaluators matched by gender, age and correlated with their background. Variations within repeated expressions of surgeon preferences, intra-observer, were controlled by covariance analysis with regression technique under random effects model. **Results:** One manufacturer consistently stood out with high ratings, two others achieved the same low scores on all products and among all evaluators. These results did not vary in the fixed or random effects models. **Conclusions:** Under structured assessment, the manufacturer variable has greater influence than the characteristics of the evaluators.

Continue

Continuation

Year, country	Author(s), title, bibliographic citation	Structured abstract
5. 2007, Italy	Balestra et al. *AHP for the acquisition of biomedical instrumentation*. Conf Proc IEEE Eng Med Biol Soc. 2007;2007:3581-4[13]	**Design:** Real-life observational study applying the Analytic Hierarchy Process – AHP method before acquisition. **Population:** Two cardiology clinics of a hospital in Turin, Italy. **Object:** Applied potential of the AHP method as a subsidy for selection of implants for acquisition. **Instruments:** Survey among users with the list of technical and work characteristics of the proposed deliverables for prioritization. **Analysis:** Comparison of user-marked prioritization scores, ranking of importance with Expert Choice™ software and comparative visual graphs, performance diagrams. **Results:** The assessment of pacemakers and defibrillators by AHP enabled the construction of visual models that are easily comparable and explainable to users, ranking the proposed implants for the bid choices. The analyses enable error checking, document consistency and grade consensus, facilitating the bidding and procurement process.
6. 2008, Brazil	Brazil. *Prequalification of medical and hospital articles: Preventive health surveillance strategy/ Anvisa/MS - Brasília, 2008*. National Health Surveillance Agency/Brasília[7]	**Design:** Review of the post-marketing preventive strategies adopted by five hospitals for the healthcare product assessment process before acquisition. **Population:** Brazilian public university hospitals belonging to the Sentinel Network and the National Health Surveillance Agency Materials Group. **Object:** Harmonize the minimum requirements for Good Prequalification Practice for the healthcare product procurement process. **Instruments:** Annex with examples of specific questionnaires by large classes of medical and hospital devices. **Analysis:** Conceptual study of the process without presentation of applied results. **Results:** Description of common processes, legislation, precedent of jurisprudence and regulation related to the purchase of medical and hospital devices marketed in Brazil, as well as the step by step adopted in the prequalification routine. **Conclusions:** The National Health Surveillance Agency's Materials Group presents the experiences, context, structural and instrumental aspects, and work process flows for prequalification legal, technical, and functional testing, reviewed in light of relevant product surveillance literature in health and provides templates for Material Assessment Sheets.
7. 2008, England	Fader et al. *Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product design*. Health Technology Assessment, 2008; Vol.12: N. 29[14]	**Design:** Comparative qualitative assessment, divided into three 1, 2 and 1 week studies. **Investigated population:** The first two studies with 85 community members with urinary or fecal incontinence, or both, and the third with equal conditions addressing 100 long-term inpatients or, if they were unable, their caregivers. **Object:** Absorbent day or night products, 12 tests (three products in four different models), 14 tests (three or two products in five different models) and one (one product in four different models), respectively. **Objective:** Check the performance and cost of the products used. **Instrument:** Questionnaire applied in individual interview, addressing aspects of performance, durability, leakage, safety, acceptability or preference. **Analysis:** Quali-quantitative stratified by weight of product used (indicator of incontinence severity), scores 1 to 3 for the most severe leaks and number of exchanges, correlated with total preference scores of 0% to 100% visual scale acceptability (Likert), including ease of exchange, time to exchange, ease of use, with or without costs. **Results:** This study demonstrated different needs by gender; men need more or more absorbing products. Needs for daytime, nighttime or under different circumstances were also different by people. **Conclusions:** Within the budget of the English healthcare system it may be more cost effective to allow users to choose between day or night model combinations or different circumstances. Existing products do not meet all needs and their impact on the life of these incontinent patients needs to be measured.
8. 2008, USA	Murahata et al. *Preliminary studies on the relationship among peel force, quantitative measures of skin damage and subjective discomfort*. Skin Research and Technology, 2008; 14: 478-83[15]	**Design:** Comparative qualitative and quantitative assessment, divided into five groups according to the time of exposure to the product: 30 min in group 1; 6 h, 24 h, 48 h and 72 h in group 2 to 5, respectively. **Population:** Groups 1 to 3 with six individuals each, and seven individuals in groups 4 and 5, in which the six objects were concurrently applied to the skin of the 32 patients' abdomens. **Object:** Standard samples (1 x 2.5 inches and similar thickness) of six commercially available adhesives. **Instruments and Analysis:** Measurement of peel force with tensile testometer with clip clamp at 90°, connected to the computer; measurement of evaporated moisture loss (skin barrier function indicator) by means of a calibrated probe connected to the evaporimeter; dye-free skin erythema grading and quantification of irritated cells on the surface tested by dye uptake evaluated with xenon reflex chromatometer; and oral question about perceived discomfort on a scale from 0 to 5 = severe discomfort. **Results:** The peel force gradually decreases after 30 min with no difference between the products except one that adheres by more than double from the start, but all have 25% (100 g mass force) at 72 hours at the end. The discomfort scores are parallel except for the most adherent product, which consistently obtained the lowest score. Other measures do not differ among products. The sensitivity of the chromatometer needs further study. **Conclusions:** Objective parameters can be quantified and correlated to subjective measures, like discomfort.

Continue

Continuation

Year, country	Author(s), title, bibliographic citation	Structured abstract
9. 2009, Brazil	Kuwabara CCT. *Risk Management in Technovigilance: Application of the Six Sigma concepts and Delphi technique for the design and validation of a medical-hospital device assessment instrument*. Doctoral Thesis in Fundamental Nursing - University of São Paulo - Ribeirão Preto College of Nursing, 2009: 296 p[16]	**Design:** Quali-quantitative exploratory study and method development. **Population:** Brazilian public university hospitals belonging to the Sentinel Network of the National Health Surveillance Agency. **Object:** Prequalification of venous infusion equipment. Instruments: Specific questionnaire for this class of MDs. **Analysis:** Study of the process and presentation of the applied result. **Results:** Prequalification instrument for the acquisition of venous infusion equipment agreed with 81 hospitals and validated in Londrina, Brazil, by five judges who rated the attributes listed on a scale from 1: very poor to 5: excellent, comparing the six unidentified brands, three of simple models and three of models with reservoir. On average, the judges rated four brands as excellent and two as good. **Conclusions:** The designed instrument has greater detail on legal attributes than the Sample Material Assessment Sheet for venous infusion equipment available in the Prequalification Manual for medical-hospital devices: Preventive health surveillance strategy (Anvisa/MS - Brasília, 2008). The consensual instrument has the same items for the assessment of technical attributes as the example of venous infusion equipment provided in the previous publication.
10. 2017, Mexico	Lingg et al. *Attitudes of orthopedic specialists toward effects of medical device purchasing*. Int J Technol Assess Health Care. 2017 Jan;33(1):46-53[17]	**Design:** Qualitative assessment of the process of purchasing high-risk implants in Mexico's public hospital structure. **Population:** Representative sample of orthopedists in hospitals, stratified by state, sector, level of care and professional experience. **Object:** Pattern of centralized purchasing decisions in Mexico. Instruments: Specific question for this class of MDs and for these specialists as to which criteria demonstrate the success of the purchasing process or not. **Analysis:** Study of the process and presentation of the applied result. **Results:** An instrument answered by 31% (out of 600 eligible users) demonstrated that they want greater participation and involvement to avoid having to experience events of material failure; restricted effectiveness of MD; acquisition of obsolete MD technology; incomplete supply of implant/instrument sets; late delivery of implants and instruments. Decisions should be based on multiple criteria, including short-term clinical impact (e.g., primary implant stability) and long-term clinical impact (e.g., product lifetime or patient survival with implant).

Source: Prepared by the authors.
USA: United States of America; MD: medical devices; AHP: Analytic Hierarchy Process; Anvisa/MS: Brazilian National Health Surveillance Agency/ Ministry of Health.

functionality, usability, ergonomics, human factors and clinical equivalence. The correlation between the answers to the different questions, characteristics of the participants and of the manufacturer provided greater insight into the justifications of these preferences and highlighted the importance of the in-depth technical knowledge of the specific user to perform the assessment. The fourth study stands out for its diagnostic device assessment design (3), which measured sensitivity against the gold standard or the technology established in the routine. In this case, the pen has a transmitter of the radio frequency emitted by the equipment and a colorimetric sensor, which also depends on the application of a third technology, a dye. Together, these elements form the assessment of a diagnostic program. The innovative MD makes the program more flexible and easy to apply in the context of routinely complex, frequently used care programs that require multiple professional teams and extended response times. In a broader and more generic approach to instrumenting examples of qualifying processes for better procurement, but also assessing examples of high-cost, high-volume-potential MD-specific purchasing processes in Italy (5) and Mexico (10), respectively, similar initiatives were adopted for pacemakers and defibrillators (5) and for orthopedic implants (10), through specific questionnaires about technical specs, requirements and criteria prioritization.

DISCUSSION

Upon assessing or performing MD functional tests, studies emphasize the need for systematized training according to each type of product, aiming to clarify the purpose/use of the MD to be tested and the main points to be observed, as well as the guidelines for filling out the instrument. The real-time oral interviewing approach can be an enhancement to this process in case of assessment of innovative technologies with little evidence, high risk potential and where many evaluators are required. Consideration of aspects of compliance with technical standards, where applicable, is considered unavoidable in most publications we reviewed. The use of a structured instrument for functional assessment of MDs enables the recording of remarks made by users, and the quantification and qualification of the evaluators' responses. This documentation may allow further analysis of their evolution, use review or confrontation against quality deviations, alerts, recalls or adverse events, enabling the management of the technology in the service[1].

Despite the fact that this is a reasonably accepted practice and performed in the daily routine of the technical teams responsible for issuing technical reports, standardization and planning for the acquisition of MDs[18], there is a shortage of publications regarding prequalification or functional assessment of MDs.

This review is therefore limited by scarce documentation, and in Brazil this is probably due to the current oral culture that prevails in the country. Furthermore, other aspects of the clinical assessment of products that are more oriented to the well-being and quality of life of their users are important, but were addressed in only two studies. Questions like the safety of patients or users, inherent risks in certain MDs, the evolution of spending on MDs, as well as the consequent increase in hospital costs and the impact on the healthcare provided to the population are a constant concern[2]. However, these topics also have a small number of publications and form a knowledge gap that needs to be filled by further studies.

CONCLUSIONS

The studies we analyzed indicate concern with the safety, quality and cost of healthcare technologies. The systematized assessment that uses instruments with standardized questions and addresses core technology issues, related to the prerequisites and consequences of the use of said technology, enables deeper analysis to support decision making in the approval, or not, of the adoption of these technologies by healthcare services. This practice can mean healthcare savings and waste prevention.

The design and use of instruments or Functional Assessment Sheets specifically for each group or category, accompanied by technical assessment criteria, create opportunities for training and raising awareness of human resources about the required effectiveness and safety criteria. Thus, in addition to being a tool for performing functional MD testing prior to acquisition, these instruments, combined with other safety practices, contribute to the safe and effective care of patients in healthcare facilities. What is more, they can be shared with other stakeholders and optimize the work of technical teams in prequalification, procurement and provision of care.

The data presented here are not exhaustive and demand further research and other perspectives on the subject, in order to contribute to the best practices for medical device assessment.

REFERENCES

1. Hayashi ELO. Fichas de avaliações de materiais: bases para uma metodologia de avaliação funcional em artigos médicos hospitalares [dissertação]. São Paulo: Universidade Federal de São Paulo; 2009.
2. Ministério da Saúde (BR). Departamento de Ciência e Tecnologia. Secretaria de Ciência e Tecnologia e Insumos Estratégicos. Avaliação de tecnologias em saúde: institucionalização das ações do Ministério da Saúde. Rev Saude Publica. 2007;40(4):743-7. https://doi.org/10.1590/S0034-89102006000500029
3. Trindade E. Incorporação e avaliação de novas tecnologias no sistema de serviços de saúde brasileiro: estudo de caso na área de cardiologia [tese]. São Paulo: Universidade de São Paulo; 2006.
4. Brasil. Lei N° 8.666, de 21 de junho de 1993. Regulamenta o artigo 37, inciso 21, da Constituição Federal, institui normas para licitações e contratos da administração pública e dá outras providências. Diário Oficial União. 25 jun 1993.
5. Brasil. Lei N° 10.520, de 17 de julho de 2002. Institui no âmbito da união, estados, Distrito Federal e municípios, nos termos do artigo 37, inciso 21, da Constituição Federal, modalidade de licitação denominada pregão, para aquisição de bens e serviços comuns, e dá outras providências. Diário Oficial União. 18 jul 2002.
6. Hayashi ELO, Novais MAP, Trindade EM, Varela OS, Zucchi P. Fichas de avaliações de materiais: bases para uma metodologia de avaliação funcional de artigos médico-hospitalares. Rev J Health Med Review. 2015;1(1)13-31. https://doi.org/10.21902/jhmreview.v1i1.325
7. Agência Nacional de Vigilância Sanitária - Anvisa. Manual de pré-qualificação de artigos médico-hospitalares: estratégia de vigilância sanitária de prevenção. Brasília: Agência Nacional de Vigilância Sanitária; 2010
8. Kidholm K, Ehlers L, Korsbek L, Kjaerby R, Beck M. Assessment of the quality of mini-HTA. Int J Technol Assess Health Care. 2009;25(1):42-48. https://doi.org/10.1017/S0266462309090060
9. Spears C, Caleca B, Bruns A. New tool assess medical device for patient safety. Risk Manag Rep. 2005;4(5):11-2.
10. Chang WR, McLean IP. Cusum: a tool for early feedback about performance? BMC Med Res Methodol. 2006;6(1). https://doi.org/10.1186/1471-2288-6-8
11. Karni T, Pappo I, Sandbank J, Lavon O, Kent V, Spector V et al. A device for real-time, intraoperative margin assessment in breast-conservation surgery. Am J Surgery. 2007;194(4):467-73. https://doi.org/10.1016/j.amjsurg.2007.06.013
12. Burns LR, Bradlow ET, Lee JA, Antonacci AC. Assessment of medical devices: how to conduct comparative technology evaluations of product performance. Int J Techn Assess Healthcare. 2007;23(4):455-63. https://doi.org/10.1017/S0266462307070547
13. Balestra G, Knaflitz M, Massa R, Sicuro M. AHP for the acquisition of biomedical instrumentation In: Procedings of 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; Lyon, France. Piscataway: Institute of Electrical and Electronics Engineers; 2007.
14. Fader M, Cottenden A, Getliffe K, Gage H, Clarke-O'Neill S, Jamieson K et al. Absorbent products for urinary / faecal incontinence: a comparative evaluation of key product design. Health Technol Assess. 2008;12(29). https://doi.org/10.3310/hta12290

15. Murahata RI, Taylor MG, Damia J, Grove GL. Preliminary studies on the relationship among peel force, quantitative measures of skin damage and subjective discomfort. Skin Res Technol. 2008;14(4):478-83. https://doi.org/10.1111/j.1600-0846.2008.00320.x

16. Kuwabara CCT. Gerenciamento de risco em tecnovigilância: aplicação dos conceitos seis sigmas e técnica delphi para o desenvolvimento e validação de instrumento de avaliação de material médico-hospitalar [tese]. Ribeirão Preto: Universidade de São Paulo; 2009.

17. Lingg M, Merida-Herrera E, Wyss K, Durán-Arenas L. Attitudes of orthopedic specialists toward effects of medical device purchasing. Int J Technol Assess Health Care. 2017;33(1):46-53. https://doi.org/10.1017/S0266462317000101

18. Rogante MM, Padoveze MC. Critérios de avaliação dos principais produtos médico-hospitalares. In: Rogante MM, Padoveze MC, organizadores. Padronização, qualificação e aquisição de materiais e equipamentos médico-hospitalares. São Paulo: EPU; 2005. p. 59-72.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.