Artigos

HEALTH TECHNOLOGY MANAGEMENT: EVALUATION OF ELECTROMEDICAL EQUIPMENT IN AN OPERATING ROOM UNIT.

RESUMO

Objetivo: discutir como se dá a gestão dos equipamentos eletromédicos em saúde, adotado pela unidade de centro cirúrgico de um hospital universitário estadual situado no município do estado do Rio de Janeiro à luz da RDC Nº2 de 25 de janeiro de 2010. **Método**: trata-se de um estudo descritivo, exploratório do tipo estudo de caso. Realizado em um hospital universitário do estado do Rio de Janeiro. Pesquisa autorizada através do CAAE 67955617.0.0000.5259. **Resultados**: os resultados permitiram construir a discussão do caso, levando em conta os pontos mais significativos e gerando então 2 categorias. Categoria 1: gestão de equipamentos eletromédicos. Categoria 2: relação e usabilidade de equipamentos eletromédicos. **Conclusão**: conclui-se que não há conformidade com a RDC Nº 2, de 25 de janeiro de 2010 com a ausência de diversos fatores exigidos pela resolução, porém o caminho a ser percorrido pela Unidade de Centro Cirúrgico.

DESCRITORES: Gestão de ciência; Tecnologia e inovação em saúde; Enfermagem; Avaliação da tecnologia biomédica.

ABSTRACT

Objective: to discuss how the management of medical electrical equipment in health takes place, adopted by the surgical center unit of a state university hospital located in the municipality of the state of Rio de Janeiro in the light of RDC No. 2 of January 25, 2010. **Method**: treatment a descriptive, exploratory study of the case study type. Held at a university hospital in the state of Rio de Janeiro. Search authorized through CAAE 67955617.0.0000.5259. **Results**: the results made it possible to construct the discussion of the case, taking into account the most significant points and then generating 2 categories. Category 1: management of electromedical equipment. Category 2: relationship and usability of electromedical equipment. **Conclusion**: it is concluded that there is no compliance with RDC No. 2, of January 25, 2010 with the absence of several factors required by the resolution, however the path to be followed by the Surgical Center Unit.

DESCRIPTORS: Management science; Technology and innovation in health; Nursing; Evaluation of biomedical technology.

RESUMEN

Objetivo: discutir cómo se lleva a cabo la gestión de equipos electromédicos en salud, adoptada por la unidad del centro quirúrgico de un hospital universitario estatal ubicado en el municipio del estado de Río de Janeiro a la luz de la RDC No. 2 del 25 de enero, 2010. **Método:** tratamiento de un estudio descriptivo, exploratorio del tipo de estudio de caso. Realizado en un hospital universitario del estado de Rio de Janeiro. Búsqueda autorizada a través de CAAE 67955617.0.0000.5259. **Resultados:** los resultados permitieron construir la discusión del caso, tomando en cuenta los puntos más significativos y luego generando 2 categorías. Categoría 1: gestión de equipos electromédicos. Categoría 2: relación y usabilidad de equipos electromédicos. **Conclusión:** se concluye que no se da cumplimiento a la RDC No. 2, del 25 de enero de 2010 con la ausencia de varios factores requeridos por la resolución, sin embargo el camino a seguir por la Unidad de Centro Quirúrgico.

DESCRIPTORES: Gestión de la ciencia; La tecnología y la innovación de la salud; Enfermería; Evaluación de tecnología biomédica.

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INTRODUCTION

Many transformations have occurred in nursing in parallel with political and social developments throughout time, in which I cite the decade of the 80's, which was marked by the advent of Law 7.498, of June 25, 1986, regulating the exercise of our profession.[1] What was observed from then on was a transition in the category that, in search of scientific recognition, aspired to be known as professionals who were not merely fulfilling prescriptions and executing tasks.

In this sense, in order to add a scientific character to an eminently practical profession, nursing turned to scientific research as the foundation of its knowledge/doing. Currently, nursing recognizes that there is no other way to grow and be recognized if not through constant research. Thus, it seeks to build and substantiate its knowledge in order to raise the status of nursing through discussions of its theories and their applicability.[2]

The aim is to improve the quality of the care provided, making reference to making all care provided to the population in need of health care more human, placing the triad of users, professionals, and managers as committed and co-responsible ethical protagonists.[3]

However, with the attempt to humanize care, the growing technological development in our practice scenario is becoming increasingly stronger, which can often pose great challenges for nursing care.

The incorporation of new technologies plays a relevant role in the success of a patient's treatment and hemodynamic support. However, to base care only on electromedical equipment may put an end to humanization in sectors where the use of these devices is more frequent.[4]

Therefore, in view of the above, we refer to patient safety, especially when the overvaluation of technology is cited. About 35% of iatrogenic complications are related to the use of medical equipment, according to the Agência Nacional de Vigilância Sanitária (ANVISA), which defines iatrogenic complication as a disorder resulting from a diagnostic or therapeutic procedure.[5]

With the increasing need of managers of the Sistema Único de Saúde (SUS) for relevant information about Avaliação de Tecnologias em Saúde (ATS), in 2003 the Ministério da Saúde (MS) created the Conselho de Ciência, Tecnologia e Inovação (CCTI), whose main function was to create the Política Nacional de Ciência, Tecnologia e Inovação em Saúde (PNCTIS).[6]

Given the increased use of electromedical equipment, the MS launched the Resolution of the Resolução da Diretoria Colegiada (RDC) No. 2 of January 25, 20106, which provides for the management of health technologies in health facilities. Article 4, item XI of this resolution aims to establish minimum criteria for technology management to be followed by health facilities. Thus, it aims to ensure traceability, quality, efficacy, effectiveness, and safety in the use of technologies within a hospital.[7]

This study is justified by the search for the relationship between the necessary use of electromedical equipment and patient safety, which is very present in today's large hospitals through the management of their technologies.

As a guiding question, we obtained: how is the management of electromedical equipment in the Unidade de Centro Cirúrgico (UCC) of a state university hospital located in the city of Rio de Janeiro?

To meet the questions this study aims to discuss how is the management of electromedical equipment in health, adopted by the surgical center unit of a state university hospital located in the municipality of the state of Rio de Janeiro in the light of the RDC No. 2 of January 25, 2010.

METHOD

To support this study, the descriptor vocabularies used were MeSH (MEDLINE/PubMed) and DeCS (BIREME/BVS) and the descriptors: Management of Science, Technology and Innovation in Health, Nursing and Biomedical Technology Assessment. The terms were combined using the Boolean operators AND and OR in the databases: SciELO (Scientific Electronic Library Online), LILACS (Literatura Latino-Americana e do Caribe em Ciências da Saúde) and BDENF (Base de dados em enfermagem). This is a clipping of a research using case study as methodology with content analysis. Where informal case studies are appropriate for clinical practice, when it is desired to analyze or describe a particular situation, identify problems in particular fields, observe changes, and explore causes.[8]

In this way one keeps an open mind by visiting the multiplicity of dimensions present in certain case study situations, since reality will always be complex, and it is viewed as a qualitative research study.[9]

The research setting was the UCC, which has 16 operating rooms in a state university hospital in Rio de Janeiro; this hospital has a large technological park, which made it possible to carry out the study.

This research was done using a self-administered questionnaire that was generated from a cutout of the technology park research tool[8]. Inclusion criteria were: unit coordinator nurses, with more than five years in the position, who had answered the Informed Consent Form. Excluded from the study were: routine, on-duty and resident nurses. Nurses on leave for any reason whatsoever.

The data were produced and analyzed with the authorization of the institution for access to professionals and through CAAE 67955617.0.0000.5259, respecting all the indications of Resolution 466/2012 of the Conselho Nacional de Saúde (CNS), which reports: the incorporation from the perspective of the individual and collectivities the four basic references of bioethics:

autonomy, non-maleficence, beneficence and justice, among others, and aims to ensure the rights and duties that concern the scientific community, research participants and the State.

The data collection was carried out in the coordinator's own room, guaranteeing privacy and tranquility to the interviewee and not bringing any kind of benefit to the participant, and the only risk was embarrassment.

Thus, the type of analysis that I used in this study was the thematic type, where the discovery of the nuclei of meaning that are compositions of the communication, whose presence or repetition is relevant to the study. In other words, a set of communication analysis techniques aimed at obtaining, through systematic and objective procedures to describe the content of the messages, indicators (quantitative or not) that allow the inference of knowledge about the conditions of production/reception (inferred variables) of these messages.[9]

The analysis of themes according to Bardin[9] has three logics: pre-analysis; exploration of the material; treatment of the results, inference and interpretation. Where six techniques of content analysis are also cited: categorical analysis, evaluation analysis, enunciation analysis, expression analysis, expression analysis, relationship analysis, and discourse analysis.[9]

RESULTS AND DISCUSSION

The results allowed the construction of the case discussion, taking into account the most significant points that are the approximation of ideas within the questionnaire, generating from then on 2 categories and other subcategories. The following categories then emerged: **Category 1 -** management of electromedical equipment. **Category 2 -** electromedical equipment relationship and maintenance.

Category 1 - management of electromedical equipment

Subcategory 1.1: Equipment management

Study findings point out that the maintenance/engineering service is outsourced and that within the hospital unit, it has specific management, with a physical area intended for the maintenance of the electromedical equipment. The absence of information about the unit having some internal norm and/or protocol so that it is possible to carry out the equipment management activities, leads to cancel the next question, which would be how these norms and/or protocols are operationalized.

Therefore, the data shows that the management does not use indicators in its work processes but has an updated and organized technical collection. Another fact pointed out is the lack of continuing education for the professionals who operate the electromedical equipment, nor training to identify the simplest and most common problems.

When we approach the programs for management of waste disposal of electromedical equipment such as: mercury, batteries, fluorescent lamps, carcasses, parts or pieces of

equipment, chemicals from X-ray processors and laboratory reagents it is clear that the hospital treats the disposal in a correct way as recommended by ANVISA.

Subcategory 1.2: Equipment Acquisition and Exclusion

With regard to equipment acquisition and exclusion, data indicate that there is no committee or commission of professionals in the hospital unit in the stage of evaluating technologies to be handled. Above all, there is no standard operating program or criteria for health technology management, and it is also noteworthy that there is no defined workflow for the stages of the process. Therefore, it equals the lack of consultation with the unit for the decision of acquisition or exclusion of electromedical equipment.

Subcategory 1.3: Electromedical equipment use

Research data about the quantity of equipment is sufficient for the service demand. For sure, it highlights that the most necessary equipment to be used in the UCC are:anesthesia equipment, c-arm, surgical microscope, x-ray equipment, bispectral index monitor, video-surgery component devices, thermal blanket and compressor.

Besides, in relation to accident risks, it is evident that there is no methodology for this purpose, but there is risk management, which contradicts the previous question.

It also shows that the unit makes available enough personal protective equipment for both users and employees, and there is no evidence in the hospital of any movement towards hospital accreditation. When investigated about technovigilance, it shows knowledge and reporting of adverse events as well as technical complaints.

Subcategory 1.4: Equipment maintenance

In this subcategory, information is obtained that the work order system is electronic and that it is owned by the hospital through the intranet. Also regarding maintenance, there is a list of materials acquired in the form of lending, the following equipment was mentioned: thermal blanket compressor and video surgery equipment, and that the unit itself has control of such equipment and it is evident that the maintenance management does not have a warehouse for the replacement of such parts, which sometimes means that the equipment has to leave the hospital unit for maintenance. I even evidence that there is no standard operating program for maintenance, however there is metrology applied for validation/measurement/calibration of equipment and that in its majority only corrective maintenance is performed.

Category 2 - List of electromedical equipment and maintenance

The following is the list of equipment available for use in the UCC, its respective quantity, and whether there is preventive and/or corrective maintenance as seen in Chart 1.

Table 1 - Ratio versus equipment maintenance

EQUIPMENT	QUANTITY	PREVENTIVE MAINTENANCE	CORRECTIVE MAINTENANCE
Hemodynamics (digital)	2	External service	External service

Infusion pump	450	Does not have	External service
Multiparametric monitor	20	Does not have	External service
Bispectral Monitor	12	-	External service
Lung Ventilator	1	Does not have	External service
Oxycapnograph	10	Does not have	External service
Bench Autoclave	0	-	-
Steam Autoclave	3	Does not have	External service
Hybrid Autoclave	0	-	-
Hydrogen Peroxide Autoclave	0	-	-
Ethylene Oxide Autoclave	0	-	-
Thermodisinfector	1	Not installed	Not installed
Ultrasonic Cleaners	3	Does not have	External service
Trachea Dryer	1	Does not have	External service
Automatic External Defibrillator	1	Does not have	External service
Pulse Oximeter	20	Does not have	External service
Anesthesia Devices	15	Does not have	External service
Surgical Tables	12	Does not have	External service
Surgical Lights	12	Does not have	External service
Surgical Microscope	3	Does not have	External service
Electric Scalpel	14	Does not have	External service
Video Endoscopy/Laparoscopy	3	External service	External service
C-arm Surg	3	Does not have	External service

The Endoscopy/Laparoscopy video equipment was informed that it is used in the lending modality and the coordination of the UCC and Central de Material e Esterilização (CME) sector did not highlight any equipment not listed in the existing form or in the sector.

The UCC is characterized as a hospital unit with intensive use of health technology and outstanding vocation for pioneering the adoption of new techniques, equipment and products for health care.[10]

It is also one of the areas with the highest hospital costs and billing. For these reasons, it receives great pressure to incorporate new technologies, exerted by manufacturers, by health professionals, and even by the patients themselves, who wish to have access to innovative procedures in their care.

It is such a specific sector that its work can generate repercussions in two other sectors such as: Post-anesthesia recovery and CME, which are fundamental for the good and continuous flow inside the surgical center.

Based on the RDC No 2 of January 25, 2010, the minimum criteria that must be followed by health institutions for the management of health technologies is determined, ensuring traceability, safety, effectiveness and efficacy, from entry into service until obsolescence.[6]

At this point, we can characterize the definition of technologies according to the MOH: medications, materials, equipment, and procedures, organizational, educational, information, and support systems, and care programs and protocols, by means of which health care and attention are provided to the population.[11]

Category 1, which deals with the management of electromedical equipment, should be carried out by professionals with a college degree and with active registration in their council, which tells us that it is allowed as long as there is no legal impediment for the engineering/maintenance sector to be outsourced, that a systematic record of the execution of activities of each stage of management is made available, ensuring (elaborating, implanting, and implementing) continued education.[6]

Regarding continuing education, it was informed that it is not implemented in the hospital, not even as training for identification of simple and common problems, which goes against article 12 of the RDC No. 2, January 25, 2010, which states that the institution must develop, implement and implement continuing education program for the correct management of technologies.

It also describes the disposal of waste in detailing what the management and technology management plan is about, aiming at protecting workers, preserving public health and the environment, and patient safety. And that the physical structure for equipment maintenance should be in accordance with the RDC No. 50 of February 21, 2002.[12]

The health service should implement a management plan for health service waste, meeting the requirements of the RDC No. 306 of December 7, 2004, whether for disposal of mercury, batteries, fluorescent lamps, carcasses, parts or pieces of equipment, chemicals from x-ray processors, and laboratory reagents.

The biggest concern in the country related to the management of electromedical equipment is with the purchase, leaving neglected maintenance in other plans, leading to a technological cultural issue. This causes low quality with interruptions in the equipment's operation.[12]

According to what was described by the coordination in subcategory 1.2, there is consultation with equipment management when there is a need to acquire new technology and equipment, but they are done without planning and without traceability, as described in article 2 of the RDC number 20106.

Depending on the size or quantity of use, there is a need for building or readjusting physical areas and human resources, waste treatment, and periodic maintenance so that the functionality and purpose of the process are fulfilled.[12] It is not enough to have a team to perform equipment maintenance; the level of knowledge is important for the service and for the usefulness of this equipment in supporting health care.[11]

The hospital's internal maintenance service borders on unfeasibility, making it necessary to hire external services to meet the need and demand for electromedical equipment maintenance in high complexity.[11] The hospital management team must have in its possession or prepare specific technical documentation related to the equipment, must have equipment for testing and calibration aiming at evaluation and maintenance, the possibility of acquiring parts and that it is relatively close to the manufacturer and/or technical representative, keeping the human resource trained and qualified to perform this task.

In addition to the hospital health team participating in the acquisition process or even the obsolescence of some electromedical equipment, it should also participate in the maintenance service for the development of criteria, technical requirements, and compliance verification.[11]

The training of nurses to develop materials management is about preparing them for the tasks that are legally directed to them, that is, the tasks that they will develop either in hospitals or in basic health units.[13]

The nursing team has direct and very intense contact with health technologies, even with those in which the definition of the assistance adopted for the patient does not come from the nurse. It is because of this proximity with technologies that nursing is able to perceive the difficulties in applicability, usability, and the possible risks that they can bring to the professional or the patient being cared for.[10]

Another important piece of information in this process is the definition of POP for the fluidity of the work, and it is important to evaluate the observation of calls to the maintenance service for a certain type of equipment, making it possible to verify localized problems such as lack of training in maintenance, negligence, carelessness during maintenance, or even the obsolescence of the equipment.[14]

All health care managers need reliable and detailed information that will allow them to make rational, coherent, and transparent decisions when establishing priorities in the incorporation of technologies, with the goal of obtaining the maximum benefit with the available budget.[10]

However, there is not always solid evidence of the efficacy, effectiveness, and efficiency of these new health technologies. Therefore, their benefits, risks, and costs must be weighed. ATS consists of a methodology that produces technical support for the manager to make a rational and transparent decision regarding the incorporation of a given technology.[10]

Regarding category 2, which addresses the relationship and usability of electromedical equipment, I bring that in 2009 ANVISA published the RDC No. 67, which determines what techno-surveillance is about, where it says that it is the system created for surveillance of adverse events and technical complaints of health products in the post-marketing phase and determines deadlines and describes the mandatory notifications, leading to a more qualified and assertive management.[15]

All professionals should be guaranteed the use of EPI compatible with the activities developed and ensure the systematic monitoring and risk management of health technologies in order to minimize or reduce the occurrence of adverse events (AE). The establishment must also notify the National Health Surveillance System of EAs and technical complaints involving health technologies.

The availability of EPI to employees is also to think about electromedical equipment, because thinking in the line of reasoning that health technologies help professionals to take conducts in alignment with the clinical part of the patient, the so-called lack of equipment can become a risk to the continuous care that we nurses provide to patients 24 hours a day, a safe care.

Also, the resolution that deals with the management of health technologies in the UCC is adequate regarding the use and availability of EPI as described in its article 14, which says that the hospital must ensure the safety of the professional, either individually or collectively6.

The use of electromedical equipment is inserted in the context of the RDC No. 2 of January 25, 20106, more specifically in the management plan which determines the execution of the steps from planning the entry of the equipment to its use. For it is almost impossible to visualize health care without the use of some of these technologies that we have available today.

Regarding maintenance management, all electromedical equipment must undergo quantitative inspections, qualitative inspections, and preventive maintenance, which is not performed in this hospital unit, with tests instituted by the institution and based on the manufacturer's manual.[11]

Performing maintenance is an extremely important factor, both for the hospital and for the patient; performing this maintenance will make assistance safer and, consequently, make institutional costs decrease.

In addition to usability, the management and maintenance of electromedical equipment are of paramount importance in the current reality that we live in, because at some point, with the great use, this equipment will become obsolete and a new process must be initiated for new acquisitions.

There are several questions about the excessive use of technology in the surgical area and its impact on health care costs, without the corresponding benefits to the patient. And these issues need to permeate the whole society so that professionals and users of the health system become more critical of health care practices.[10]

CONCLUSION

There is still a wide range of problems related to the management of health technologies, and we as nurses should study this topic more and publish articles that contribute to clinical

practice. With this in mind, ANVISA, through RDC No. 25 of January 2010, established the actions that guide the management of health technologies.

It is also concluded that the operationalization, although complex and laborious, is possible from the massive awareness of professionals about the importance of GTS, especially with regard to the aspects of management, maintenance, acquisition and obsolescence of technologies.

This awareness must occur through events and continued education that also does not occur in this hospital unit, demonstrating that there is a law determining how the management of health technologies must be done and the benefits that this will bring to the assistance and the hospital unit.

The management of electromedical equipment constitutes itself in the mapping of equipment from acquisition to obsolescence, in the performance of the service, implementation of routines, maintenance, analysis of the quality of the service provided by third parties, validations, calibrations, investigation of adverse events, creation of standard operating program and hospital accreditation.

As for the objective of the study, it was satisfactorily met, based on the data obtained and compared to Resolution No. 25 of January 2010. Through this research I was able to know how the UCC performs the management of electromedical equipment, where I visualize the work done by the coordination of the unit that is in the sense that there is the proper control of its technological park, having noted on a spreadsheet of Microsoft Excel software which and how many electromedical equipment it holds to work, understands and acts in the correct disposal, that when there is need for acquisition of some type of equipment the competent management is consulted through OS, tells us that there are asepsis programs for each type of material, that it complies with EPI coverage and that it has control of the technovigilance notifications. It also tells us that it is unaware of an ongoing hospital accreditation process.

On the other hand, based on the analysis performed in the UCC, the absence of several factors leads to non-compliance with the RDC No. 2 of January 25, 2010, such as the lack of a standard operating program as stated in the fifth article, indicators of work processes as stated in the ninth article, the lack of continuing education and the need for further training in the area as stated in the twelfth article, even consulting the management for the acquisition of equipment there is no committee or specific methodology for this procedure as stated in the sixth article.

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