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The work of the nursing auditor in orthetic processes and prostheses and special materials

ABSTRACT | The aim was to describe the role of the nurse auditor in the processes involving OPME in a public or private hospital environment. It is a theoretical-reflective study that proposes a discussion on the OPME processes in Brazilian territory, as well as the current legislation, both in supplementary health and in free and universal care practiced by the Unified Health System. There is a need for professionals trained, with technical competence and zeal for safety, to optimize the control of these materials, in addition to inhibiting doubtful and fraudulent practices. Contributing to the strict control and traceability of these inputs used, guaranteeing the service provided to the user and monitoring its quality. Therefore, it can be concluded that the role of the Nurse Auditor in the processes of use of OPME is essential for all stages of the process to be complied with and respected, in accordance with current regulations and legislation, both in public or private institutions. It was also found that there are few scientific publications nationwide on the subject.
Keywords: Nursing Audit; Prostheses and Implants; Orthotic Devices; Technology, High-Cost.

RESUMEN | El objetivo era describir el papel del auditor de enfermería en los procesos que involucran a OPME en un entorno hospitalario público o privado. Es un estudio teórico-reflexivo que propone una discusión sobre los procesos de OPME en el territorio brasileño, así como la legislación actual, tanto en salud complementaria como en atención gratuita y universal practicada por el Sistema Único de Salud. Se necesitan profesionales. capacitados, con competencia técnica y celo por la seguridad, para optimizar el control de estos materiales, además de inhibir prácticas dudosas y fraudulentas. Contribuyendo al estricto control y trazabilidad de estas entradas utilizadas, garantizando el servicio prestado al usuario y monitoreando su calidad. Por lo tanto, se puede concluir que el papel de la Enfermera Auditora en los procesos de uso de OPME es esencial para que se cumplan y respeten todas las etapas del proceso, de acuerdo con las regulaciones y la legislación vigente, tanto en instituciones públicas como privadas. También se descubrió que hay pocas publicaciones científicas en todo el país sobre el tema.
Descriptores: Auditoría de Enfermería; Prótesis e Implantes; Aparatos Ortopédicos. Tecnología de Alto Costo.

RESUMO | Objetivou-se descrever o papel do enfermeiro auditor nos processos que envolvem OPME em ambiente hospitalar público ou privado. Trata-se de um estudo teórico-reflexivo que propõe uma discussão sobre os processos de OPME em território brasileiro, assim como as legislações vigentes, tanto na saúde suplementar quanto no atendimento gratuito e universal praticado pelo Sistema Único de Saúde. Há uma necessidade de profissionais capacitados, com competência técnica e zelo pela segurança, para otimização no controle destes materiais, além de inibir a prática duvidosa e fraudulenta. Contribuindo no controle rigoroso e rastreabilidade destes insumos utilizados, garantindo o serviço prestado ao usuário e monitoramento de qualidade. Desde modo, conclui-se que a atuação do Enfermeiro Auditor nos processos de uso de OPME é primordial para que sejam cumpridas e respeitadas, conforme as normatizações e legislações vigentes, todas as etapas do processo, tanto nas instituições públicas ou privadas. Constatou-se também que poucas são as publicações científicas em âmbito nacional a respeito da temática.
Palavras-chaves: Auditoria de Enfermagem; Próteses e Implantes; Aparelhos Ortopédicos; Tecnologia de Alto Custo.

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INTRODUCTION

The great transitions that have occurred since the last century (XIX) to the present day have brought important impacts in the economic, political, social and cultural axes; including developments in technologies that have changed the profile and lifestyle of people, especially in the health-disease context[1].

From this demand, health-illness processes have undergone changes due to the complexes and multiple factors of these innovations[1].

Thus, in recent years, the morbidity and mortality profile of the Brazilian population is related to the increase in the number of deaths caused by chronic diseases. In this logic, cardiovascular diseases and their risk factors, high blood pressure and diabetes mellitus, reflect the lifestyle that people live[2].

Cardiovascular Diseases (CVD), classified as chronic diseases, are one of the biggest causes of death in the world population, generating social and economic impact. As consequences affected by these diseases, we can list: premature deaths, labor and inactive incapacities in the market, decrease of labor force of the active population, decrease of family income and expenses in public budgets with hospitalization, clinical and surgical treatment[3].

In addition, there is an increase in the number of individuals undergoing cardiological and vascular, electrophysiological, and hemodynamic procedures. As well as, angioplasties, open or percutaneous surgeries with the use of Orthoses and Prostheses and Special Materials (OPME), which will assist in the treatment and recovery of the disabled person affected by these diseases[3].

In this context, the scenario needs all the specific and technological knowledge to guarantee the adequate assistance provided, as well as the financial management and control. Thus, in health services, there is the indispensable figure of the nurse auditor, who has been contributing to financial control and to guarantee the quality of services provided and performed[4].

The nurse, through the Legal Exercise of the Profession, can participate in activities in institutions related to health, both in planning, as in the organization, coordination, execution, consulting, auditing and issuing of opinions, as regulated by Decree No. 9.4406, of June 8, 1987[5]. The nurse auditor is empowered to execute, in an autonomous way, the planning, execution and evaluation of services provided in the health area, as well as to prevent losses in assistance to the user, including in the financial and economic scope, according to Resolution No. 266, of October 5, 2001, from the Federal Nursing Council - COFEN[6].

By exposing the problem, this study aimed to answer the following questions: What are the processes that involve OPME in Brazil? What is the role of the nurse auditor in this scenario? Therefore, the objective was to describe the role of this professional in the processes involving OPME in a public or private hospital environment.

METHODOLOGY

This is a theoretical-reflective study that proposes a discussion about the OPME processes in Brazilian territory, as well as the current legislation, both in supplementary health and in free and universal care practiced by the Unified Health System (SUS). The survey was conducted from June 2019 to January 2020.

The inclusion criteria were: publications in national and international journals; OPME theme, studies carried out in Brazilian territory, in Portuguese, with complete texts of public availability; published from 2009 to 2019. The exclusion criteria for the present study proposal were: articles repeated in more than one database, which were considered only once, the editorials, and the studies that despite presenting the terms selected did not answer the guiding question.

Data collection took place in the following databases: academic Google, Scientific Eletronic Library On Line (SciELO) and electronic pages of the Ministry of Health and the National Agency for Supplementary Health (ANS). The descriptors were used: "Nursing Audit", "Orthosis", "Orthopedic Devices" and "High Cost Technology". It should be noted that the terms OPME (Orthosis, Prosthesis and Special Materials) and high cost health processes were used, as there are no descriptors for them.

DISCUSSION

With the change in the health care model, the State sought to promote actions aimed at these services, being guaranteed by constitutional law, to all Brazilians, access to the principles of universality, integrity and equity, promoted and carried out by public, private and contracted agencies , through SUS that was regulated by Law No. 8,080 of 1990[7].

The three spheres of government (Federal, State and Municipal) consolidate these SUS actions and govern their competences in controlling, inspecting, procedures and products within the scope of health, with direction of budgets, execution and financing expressed by Organic Law No. 8,142 from 1990[7].

The right to provide access to health for the population, through SUS, has enabled the increase of scientific and technological developments that develop and contribute in the health area, a place where financial resources are most directed, with high expenses, for the services provided with

quality and effectiveness. Thus, with the implementation of technological demands, it is essential to qualify managers with knowledge and control of resources[8].

In this context, the sanitary control and technical responsibility for materials and inputs related to the health area, started, starting with Law No. 5.990, of December 17, 1973[9], being strengthened by Law No. 9,782, January 26, 1999, constituting a set of actions that regulate, regulate, control and supervise the sanitary origin of materials related to the health area, with the purpose of promoting and guaranteeing population health[10].

The guaranteed form of highly complex treatment with hospital admissions associated with recommended interventions and the use of special materials required specific and complex actions to use this technological demand in health institutions[11].

The Interinstitutional Working Group (GTI), created by Interministerial Ordinance no. 38, of 8 January 2015; was instituted with the purpose of restructuring and making transparent all information related to the use of medical devices (OPME), from production to the final process, the user[12].

The referred GTI has the following definition "Orthosis: any permanent or transitory device, used to assist the functions of a limb, organ or tissue, avoiding deformity, or progressions and/or compensating for functional deficiencies. Prosthesis: any permanent or transitory device that completely or partially replaces a limb, organ or tissue". It is observed that health institutions, public or private, had a great increase in the use of OPME as a form of technological demand and aid in diagnostic and therapeutic interventions[12].

According to the study carried out by the GTI, nursing professionals are recognized for their activities in technological innovations and diagnostics and for the study and evaluation of cost-effectiveness in the processes involving the use of these OPME[12].

Process of acquisition and control of the use of OPME and its traceability

In Brazil, spending on the use of OPME in 2014 exceeded R$ 19.7 billion, this is due to the recurring technological advance in the area of health related to these products, which help in diagnoses, treatments, therapeutic rehabilitation and boost markets and suppliers in attention to the development, manufacture and commercialization[12].

The concern of the managers of health institutions to effectively and efficiently meet the guarantee of the quality of care provided and to maintain the cost-benefit ratio, which burdens the financial sector, requires organization, seriousness and knowledge to meet the entire health care flow. process, in addition to the ability to impartially manage harassers (suppliers and manufacturers) who wish to induce professionals to direct the request for their materials, thus injuring the competition for the best materials and with quality[13].

It is noteworthy that in the SUS the OPME table of the Procedures Management System (SIGTAP), established by Ordinance GM / MS No. 2,448, of November 6, 2007, contains the descriptions, compatibility and values of the materials, among others[14].

The OPME acquisition process includes several phases, starting with technical specifications until confirmation of use, verification of the veracity of the information and the good acquisition of the product; with traceability and patient/user care[12].

The acquisitions of OPME are the responsibility of the hospital manager or responsible, according to highly complex procedures or diagnostic assistance, from the making, commercialization and registration[15]. In hospital institutions, the process involving the use of OPME focuses on flow management, aiming to ensure the control and monitoring of these inputs. Ordinance SAS/MS No. 403, of May 7, 2015, currently revoked by Ordinance SAS/MS No. 1,302, of August 1, 2017, regulates the stages of the entire process, which are addressed in this study: acquisition/purchase, supply, distribution, use, control and traceability of OPME[16].

One of the recommendations of the GTI is to carry out an analysis of the institutional profile regarding the need to acquire OPME, considering the scientific evidence and the control of technovigilance, avoiding any type of conflict of interest. Therefore, it is necessary to establish a specific commission for technical analysis, performance, quality and product traceability[16].

In addition, purchases/acquisitions must be adequate with the characterization of the object and budgetary resources, and appropriate to standardization; compatibilities; without indication of brands, specifications, technical assistance and maintenance; guaranteed by quantities by technical estimates and without deterioration by storage; and with beacons of registration of compatible prices in the market and free competition[17].

Regarding the acquisition, the health institution must carry out a forecast of the quantity of material to meet its demand, hospital and outpatient, with planning in the technical specifications and quality parameters of the OPME, which must be registered with the National Health Surveillance Agency - Anvisa[16].

It is important to note that, in the public sphere, any process involving works, services, advertising, purchases, concessions, permissions, and any actions contracted with third parties, must be governed by Law No. 8,666, of June 21, 1993, which contemplates the general rules and bidding rules and administrative contracts[17].

In this logic, the Term of Reference (TR), a document that expresses the information of the object to be contracted, in this case, OPME, serves as the basis for the acquisition of the same and must contain clearly and objectively the information about the material, according to the rules of the Federal Attorney General (AGU). The TR should, for example, contain clauses that bind the supplier on the lending regime to his obligation to carry out the exchange of components that have not been used, after its validity and/or the end of its warranty[16].

Finally, bids will be held in the form of Auction, preferably electronic, and processed in the Price Registration System to ensure that what is in the TR is fulfilled. The formalization of the winner is carried out through a contract and the acquisition by issuing the Note of Commitment (NE). The NE and the Invoices (NF) must contain all relevant information and conformities, so that they are registered in the Federal Government Integrated Financial Administration System (SIAFI), for later settlement of the NF[16].

The materials intended for use in health must contain a technical record for purposes of registration with Anvisa, with information on: if the material is only an accessory or component, trade name, composition and identification with traceability labels, in accordance with the Regulations of the Collegiate Board (RDC) No. 14, of April 5, 2011[18].

These labels should contain a summary of all material information, namely: batch; registration of the material with ANVISA; trade name, manufacturer or importer code and product code in the system, in addition to a wrapper specifying its shape and instructions for use, with respect to RDC No. 14/2011[18].

As for the receipt, the acquired OPME should be stored in properly prepared warehouses or deposits, with access restricted to the circulation of people, which may be permanent or temporary[16].

In addition, information should be recorded in the institution's systems, through the breakdowns of the NE, with specifications of the materials, codes, expirations, lots, quantities, NF and NE values, NF numbers, National Register of Legal Entities (CNPJ) of suppliers, corporate name of suppliers and manufacturers, so that the veracity of the information is verified[16].

It should be noted that in the central warehousing sector, OPME will be analyzed and immediately processed, so that they can respond to requests promptly and quickly. In addition, upon being referred to the operating room, the monitoring of the OPME must be carried out by a circulating professional in the room, who will investigate its use, checking the inputs used and registering on specific consumption forms of the institution, item by item. In addition, unused OPME should return to the central warehouse, a place of strict control and storage[16].

Regarding the use, all OPME and Implantable Medical Devices (DMI) should be under the supervision and responsibility of the Technical Director of the health institutions and the doctor who indicated and performed the procedure, as regulated by the Federal Medical Council (CFM) , through Resolution No. 1,804, December 20, 2006[19].

Also, according to the Resolution of the Federal Council of Dentistry (CFO), no. 115, of April 3, 2012, it is also up to the surgeon specialist to determine the use of OPME in its procedures and compatible instruments, according to specificity, size, type and the material[20].

Therefore, the supply of OPME must be done upon the request of the professional who will perform the procedure and who needs to use it, up to 48 hours in advance, when elective, containing all patient data in a specific form of the institution, such as: name complete, medical record, specified material, name of the procedure and name of the responsible professional[16].

Within the scope of SUS, patients who are hospitalized must have a Hospitalization Authorization (AIH) that justifies the need to use OPME, with the appropriate codes that meet the requirements of surgical procedures[16].

The registration of use and consumption control must be made by describing the materials used, attaching the traceability labels, keeping the packaging wrappers in the specific form. Subsequently, the registration must be forwarded to the sector responsible for checking and billing the items used together with the AIH[16].

In private institutions, the National Health Agency (ANS) determines and makes available the use of OPME with surgical intervention or not, according to the interventions, in materials included in the list of Procedures, so that health plan operators assist their beneficiaries as requested by the assistant specialist[21].

According to the Regulatory Normative (NR) No. 428, of November 7, 2017, for the provision of OPME of the procedures provided in the ANS List, the requesting professionals, these: assistant doctors or dentists, must perform the material descriptions , with the characteristics, quantities and marks of the materials in a specific form for each health insurance company or operator[22].

The respective form must contain the clinical justification of the applicant, the use and the need for OPME, in addition to the information of at least three different brands duly recognized and approved by Anvisa and that meet the technical specifications; so that a quote is made with the suppliers and, thus, elect those who have the best condi-

tions to meet the specificities of the applicant's procedure. At this stage, there is also a need for prior authorization from the operator to perform the procedure[21].

NR 424, dated June 26, 2017, also signals that when there is a difference between the operator and the assistant professional, in the availability of the material requested for technical-assistance use in carrying out the event in health or surgery, it should - to compose a board of professionals to guarantee the resolution of the demand[21].

This board will be constituted by the requesting physician or dental surgeon, a member of the operator and a tiebreaker, who will adopt criteria of release and evaluation on the use of the use and supply of OPME, according to what is on the list of List of Procedures and registration with Anvisa, except for urgent and emergency procedures[21].

However, the traceability of all OPME must be considered as a guarantee of safety for the user. In this scenario, some equipment, devices and supplies used in medical, dental, prevention, treatment and rehabilitation and that use forms of preservation and sterilization in their conservation are prohibited from being reprocessed, according to the regulations of the Collegiate Board No. 156, August 11, 2006[23].

It is also worth mentioning the need to make available at least 03 OPME tags to be mandatorily attached to the medical record, the consumption form, and the General Operational Registry (RGO). They must contain a summary of all technical information pertinent to registration with Anvisa, such as lot, numbering, trade name and manufacturer, according to Resolution RDC No. 14, of April 5, 2011[18].

Resolution RDC No. 232 of 20 June 2018, on the other hand, regulates the labels of specific materials, such as coronary stent implants and hip and knee prostheses. These OPME's must contain traceability bar codes with identification information, expiration date and serial or batch number, in order to facilitate identification and electronic reading[24].

Also in accordance with this RDC, the labels must be attached, at least, to the medical record, the document or card to be delivered to the patient and on the product invoice. In addition, suppliers are required to feed the National Implant Registration (RNI) system with the information from these OPME[24].

The procedures performed in SUS and in Supplementary Health must be registered with the RNI with information on surgical interventions and location of the materials used, products, services and professionals involved, in order to minimize risks to the user and contribute to possible corrections[12].

For procedures using non-surgical OPME, it is recommended that the user should be accompanied by a rehabilitation team, to avoid possible complications. In addition, your dispensation must be recorded on a specific form with recommendation for use and with the signature of a user or guardian to later be attached to the medical record[12].

The Nurse Auditor in the OPME Process

The nurse who has knowledge of the audit processes is able to inspect the quality provided of the materials related to the procedures and with amounts charged to the user, thus certifying their reliability[4].

In this way, nursing care practices provided to users contribute to the control of expenses and losses of materials, supplies and equipment, guaranteed through practices that determine effectiveness, effectiveness and quality and that are capable of reducing doubts related to procedures, thus favoring financial control and unnecessary disallowances[25].

Due to the high complexity of the procedures and, consequently, the use of OPME, care is required to minimize possible errors and high costs, both for the institution and for the user. In this sense, the nurse has competence and security in the stages of the high cost process, with strict and meticulous control, preparation, use, checking, return and billing of the same[11].

It should also be considered that the nurse working in the audit area, who has technical knowledge in line with technological innovations, is able to evaluate the care provided to the user and the financial and accounting control(4). Thus, this professional attest and guarantees the quality of the service provided through the analysis of medical records, including recognizing errors and placing the educational practice in the corrections pointed out, reducing the risks to users and losses to the institution.

In this scenario, studies still point to the existence of an eminent deficiency of nursing notes in the care provided in the operating room, making the analysis of the audit team difficult. It is known that nursing acts in the care provided to the patient during the operation and that the patient's stay is relatively short; factors that can contribute to the non-prioritization of annotations(26). Thus, this problem has major impacts on the quality of the information recorded and on ensuring patient safety.

Despite this, the literature portrays the advances, above all, technological ones that have enabled improvement and development in health, however, there is still evidence of the disparity in prices in the commercialization of OPME and abuses aimed at profit to the professionals involved[27].

In line with this prerogative, research has reflected the importance of the role of nurses in a health institu-

tion and in everyone through skills and technical competence, including as coordinators for areas that require high complexity[25].

It is noteworthy that all the processes involving OPME are considered to be of high cost for any institution, therefore, the nurse's performance will fulfill all phases of the processes, from conservation, handling, returns to billing, through analysis of the appropriate use and ensuring safety and quality of care[11].

Still, other authors point out the problem faced by public hospitals in relation to the complete provisioning for acquisition and meeting the demands, as they do not have tools capable of assisting them in forecasting the demand estimate, in addition to the lengthy bidding processes that, for in turn, influence the availability of materials in these deposits[28].

Thus, currently, information technologies are great allies to audit processes, as they ensure agility in research and demands[29]. In this context, nurses with their technical and care skills contribute to maintaining a link between the institution's technologies and financial resources; acting in an agile way in the processes and guaranteeing the privacy and security of information, of the users and of the health institution.

CONCLUSION

The present study enabled the analysis of the processes that involve the use of OPME as an aid in health interventions, technological advances and its application, favoring the recovery of the patient, with improvements in health and quality of life.

It is known that the nurse auditor is a professional capable of evaluating the practices of care assistance, including the return of unused inputs, through analysis of medical records, RGO and material consumption. Thus, this professional contributes to the minimization of possible undue and fraudulent practices and corroborates the control of expenses in health institutions through the adequate practice of financial and accounting management, with due payment to the user or the health and settlement service. to the supplier.

When examining the medical record and checking the OPME labels, attached to the medical record as proof of use, the nurse auditor strengthens the performance of the health team in ensuring the quality of care provided to the user, in the security of traceability and in the veracity of information of product. In addition, if it is necessary to carry out a repair or replacement, due to material failure, traceability facilitates localization, thus guaranteeing the user the right to resolve the fact.

Considering the high cost materials, due to their applications in highly complex interventions, this study, with technical-scientific basis, showed the importance of the nurse auditor's performance, from the acquisition and control to the traceability of OPME.

Although the dissemination through the media is increasing, with regard to fraudulent activities involving OPME, there was a shortage of national and international scientific production in relation to the subject addressed. Thus, it is recommended to produce studies involving the performance of auditors in all phases of the process, both in public and private institutions.

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