

The Importance of Traceability of Implantable Medical Devices for Safety of Patients and Hospital Institutions: A Narrative Review

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Abstract— *Implantable medical devices are materials that assist or replace partially or totally for the purpose of preventing, treating, or compensating for a disease, injury, or disability. It is important to follow patient safety protocols such as effective communication, safe surgery and regulations to ensure the procedure free of risk and damage. To verify the predictors that guarantee safe use and comply with the safety of the patient and hospital institutions. This is a narrative study, which sought articles published in the past 10 years (2009 to 2019), in Portuguese, fully available. The following data platforms were consulted: BDEFN, LILACS and SciELO. Research was conducted through original articles, theses, dissertations, booklets, collegiate board regulations, regulation of ANVISA and handbook of good practices, all in the Portuguese language. The data were organized and presented in figures and tables. Of the 87 articles found, after reading the abstracts, 04 studies met the inclusion criteria and were thematically specified, classifying the knowledge elaborated on the subject. The research reflects on the importance of presenting labels and controlling the use of devices to ensure the safe use of the material. However, there were no Brazilian publications specifically on the theme and, in this sense, quantitative and qualitative researches on the subject should be developed.*

Keywords— *Implantable Devices; Patient's Records; Patient Safety; Traceability; Orthoses and Prostheses.*

I. INTRODUCTION

Hospital institutions aim to meet patients according to their needs and with hospital procedures and services at various levels of complexities. In many of these visits, patients are submitted to specific procedures in surgical

and hemodynamic centers, undergoing tests and procedures in which the use of orthoses, prostheses and special materials (OPSM) is essential, and this care aims to meet the patient with quality and safety. Thus, the quality of patient care and safety is fundamental to avoid errors,

adverse events and failures, thus increasing the credibility and reliability of care and the institution [1].

According to the World Health Organization (WHO), patient safety is the reduction of risk of unnecessary harm associated with health care to an acceptable minimum, considering constant components closely related to patient care. Currently, 4% to 17% of patients admitted to a hospital unit suffer events, which are not related to the underlying pathology [2].

Several aspects can be critical for adequate care, especially regarding the use of implantable equipment and devices that can adversely affect the patient's health conditions. Orthoses can be conceptualized as any permanent or transient material that assists the functions of a limb or organ, which does not require surgery. Prostheses are any permanent or transient material that replaces the entire or part of a limb, organ or tissue involved in a surgical act [3].

Brazil (2016) reports that special materials are understood as any material or device used in the implementation of OPSM that assist in the diagnostic or therapeutic procedure, not covering the criteria of orthoses or prostheses [3].

The Resolution of the Collegiate Board of the National Health Surveillance Agency n.185/2001 also defines that implantable medical devices are any medical product designed to be fully introduced into the human body or to replace an epithelial or ocular surface, through surgical intervention, with intended long-term permanence. Also considered an implantable medical product is any medical product intended to be partially introduced into the human body through surgical intervention with intended long-term permanence [4].

Orthoses, Prostheses and Special Materials are medical devices used for a range of health needs, such as pain relief, restoration of mobility, recovery or improvement of the function of an organ, diagnosis and aesthetic functions and the fields of application of these products are diverse and in almost all health areas. Due to its complexity, for the application of these products, a multiprofessional and multidisciplinary team is necessary, so that the risks of handling and using them are eliminated or minimized to the maximum, as the intended use purpose is reached safely. For the manufacture of these products, highly sophisticated technologies are used and strict quality controls are required [4].

Each or all of these have their own characteristics with a risk associated with use exposure. The risk corresponds to a probability of occurrence of an event, which may or may not cause damage to the collectivity and in the event

of the occurrence of any problem or complication related to the device. Thus, there is need to monitor this material, allowing the identification of particularities of the product and all its traceability [3].

Several resolutions seek greater control of the use and monitoring of the quality of these products, ensuring greater patient safety before a procedure that will use these materials, the correct supervision of materials, reception of the product, verification of registration, validity of legislation, enabling the safe conditions of use, integrity of the product packaging, the characteristics of the materials, whether they are reprocessed or single use, the control of occurrences of adverse effects and the control of the market are some objectives of traceability according to the Federal Council of Medicine (CFM) n°1804/2006 [5].

From this, there are two steps to this control. The primordial phase that is related to the registration of the product and the knowledge of manufacturing conditions, which is understood as a step before commercialization. The second phase is related to the use that affects the problems to the use of the product, also known as "Technosurveillance", after marketing [6].

The Handbook of Good Management Practices of the OPSM of the Ministry of Health [MS] (2016) defines that traceability is the ability to trace a history, application or location of an item through previously recorded information, as well as related information and its identification and coding, generating knowledge about its origin and its final destination. The information should be inserted in the patient's medical records, delivered to the patient and in the tax documentation, which generates collection to the material, aiming at a supporting effect [3].

For Prestes and Rangel (2007), the definition of medical records provided for in CFM resolution n. 1,638/02, being conceptualized as an individualized document consisting of a grouping of recorded information generated from facts, events and situations about the patient's health, of a legal, confidential and scientific nature, which enables effective communication between members of the multidisciplinary team and the continuity of care provided to the individual [7].

Despite its importance and usefulness for the other functions, the elaboration and general care with such document are often omitted by the health professionals who write on it and, when they point, they invariably do so with negligence, with illegible letter and without the chronological sequence. A well-prepared medical record indicates not only the seriousness of the professionals, but also a true instrument of judicial defense [7].

The correct management of Implantable Medical Devices (IMDs) and the reports made in the medical records are important points for ensuring safety and exempt non-conformities, thus being important to give visibility to this theme, since the traceability of implanted medical devices is a factor that directly interferes with patient safety and, when not well performed and regulated, can produce complications to the patient, family, hospital institution and to whom provided the product.

From this perspective and the reflective exercise of investigating health issues from the field of management and control of implanted devices, as well as the recognition of the importance of traceability labels, the present study of narrative literature review was motivated. Therefore, this study aims to verify the predictors that guarantee safe use and complies with the safety of the patient and hospital institutions.

II. METHODS

This is a narrative literature review with a qualitative approach, which has a comprehensive character and proposes to portray the development of a given theme, from a theoretical or contextual point of view, through analysis and interpretation of the existing scientific production. This synthesis of knowledge from the description of comprehensive themes favors the identification of knowledge gaps to support the execution of new researches. Furthermore, its operationalization can systematically occur with methodological rigor [8].

To guide this review, the following question was formulated: "What is the importance of traceability of hospital medical devices for safety of the patient and hospital institutions?". The Virtual Health Library (VHL) was accessed in the databases: Latin American and Caribbean Literature (LILACS), Nursing Database (BDENF), as well as in the Virtual Library: Scientific Electronic Library Online (SciELO).

Through advanced search, using the delimiting terms of the search, "traceability"; "implantable devices", "patient safety", "patient records" as descriptors by the integrated search with the Boolean operator AND and to achieve the purest and most reliable refinement and data collection in a period indexed from the years 2009 to 2019, generating a content based on scientific evidence. This process involved activities of investigation, identification, study, mapping and analysis.

After this stage, the articles were directly read by the abstract, observing that no articles published in Brazil were found with these descriptors, in addition to documents that directly address this subject.

The inclusion criteria defined for the selection of articles were: original articles, published in Portuguese, whose object of study is of interest to this narrative review and fully available free of charge in electronic format in the database, portraying the theme on the importance of traceability of implantable medical devices, in an indexed period between 2009 and 2019, as well as theses, dissertations, booklets, collegiate board regulations, regulation of ANVISA and good practice handbook [3].

The exclusion criteria defined were: articles published with complete content not available virtually or in journals not edited Brazil, experience reports and other integrative reviews or that did not have all the inclusion criteria.

The selection of studies was based on the Preferred Reporting Items for Systematic Review and Meta-Analyses - PRISMA, a four-step flowchart, with the objective of assisting in the development of articles [9]. The search strategies used on the databases were presented in the flowchart (Figure 1).

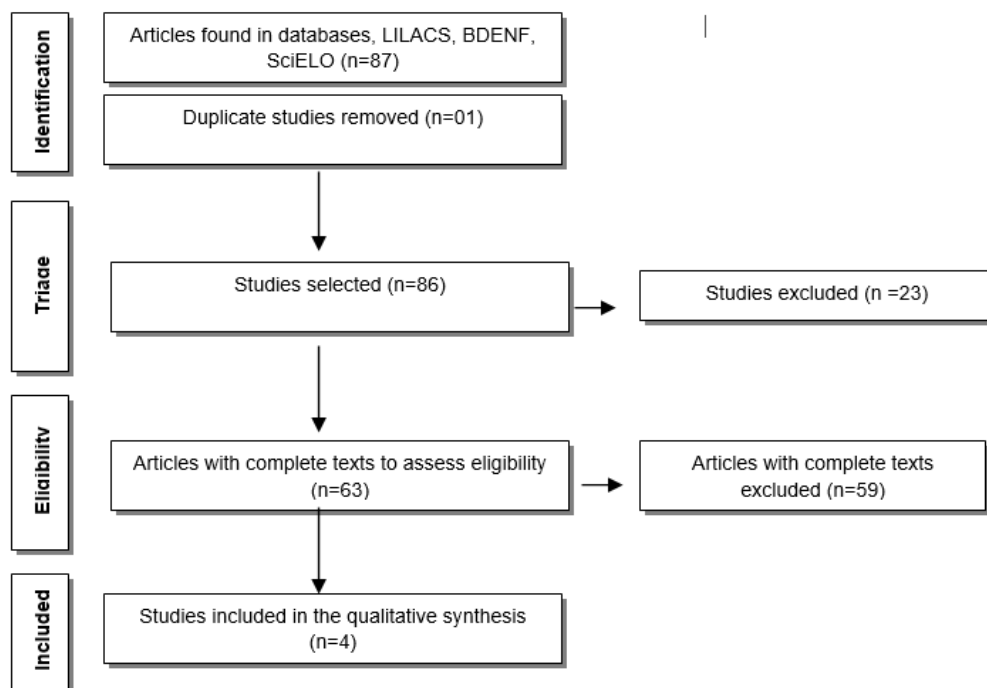


Fig 1: Flowchart of the selection of studies. Recife, Pernambuco (PE), Brazil, 2020.

Adapted by PRISMA [9].

Source: Created by the authors.

III. RESULTS AND DISCUSSION

The presentation of the results and discussion of the obtained data was performed descriptively, with categories listed for discussion, enabling the reader to evaluate the applicability of the elaborated review, in order to achieve the objective of this method, that is, positively affect the understanding of the objectives of this study.

Two phases were performed to obtain the results. The first phase was the search for articles, which returned 87 scientific productions using the aforementioned descriptors. Of these, 66 presented complete text and met the inclusion criterion related to the language, which was Portuguese.

Of these 66 selected productions, 64 met the inclusion criteria when classified as article. Of these, 01 was available in more than one database, justifying its exclusion, remaining 63. After reading the titles and abstracts of these productions, 59 were excluded for not answering the guiding question of this study. Therefore, 04 remained, which became part of the analysis of this narrative review study.

After the selection of articles, a second phase began, in which there was a direct reading of the works of master's dissertations, institutional booklets, regulations of the National Health Surveillance Agency (ANVISA), sources

of regulations of medical and nursing councils, books, technical standards and handbooks of good practices in OPSM [2,3,5].

Data analysis was through Minayo's theme technique (2007), which is the discovery of the meaning cores, which consist of the communication about periodicity or the presence of some meaning for the object that will be explored. This method of analysis consists of three stages: pre-analysis, which is the organization of the obtained data; the exploration of the material, which classifies the elements in order to reach the core of the understanding of the text through the formulation of categories and the treatment of the obtained results and interpretation, which articulates the data assimilated to the theoretical framework, aiming to answer the research questions [10].

The results of these studies show that the subject is scarcely discussed and has been complemented with norms and handbooks. The table describes the titles, authors and objectives of the article that composes the sample of this work.

Table 1: Results found in studies according to title, authors, year of publication, and objectives that make up the sample. Recife, Pernambuco (PE), Brazil, 2020.

TITLE	AUTHOR/YEAR OF PUBLICATION	OBJECTIVES
A1 - Incidence of in-hospital adverse events in the state of Rio de Janeiro, Brazil: evaluation of patient medical record [11].	Pavão et al., (2011)	To evaluate the quality of information in the medical records of three teaching hospitals in the state of Rio de Janeiro, which participated in the baseline study to estimate the incidence of adverse events (AE) and the importance of developing measures aimed at improving the quality of the medical record, as these will reflect on the quality of patient care.
A2 - Nursing care and the focus on patient safety in the Brazilian scenario [12].	Silva, et al., (2016)	To analyze the contribution of nursing to patient safety in Brazil. The study highlights the existence of positive actions and the reduction of incidents concerning patient care and safety.
A3 - Assessment of the care process with orthotics, prosthetics and special materials [1].	Moraes C.S; Rabin E.G; Viegas K., (2017)	To highlight the evaluation of potential flaws in the OPSM care work process in a high-complexity hospital. It stresses points in the process that can be critical and important for adequate care and that any failure in one of these steps can result in the absence of OPSM availability and affect directly and negatively on the patient's health condition.
A4 - Patient safety approached from the rights of users [13].	Benrens, R., (2019)	The article highlights the lack of protection and respect for the user's rights, the evidence that the participation and the possibility of the patients' participation in the treatment and the rights justifying it.

Source: Created by the authors.

As for the objectives of the authors, even with different themes, somehow, all of them focus on patient safety, thus linking the other themes as importance of the report in medical records and that, through these records, adverse events can be observed and methods can be traced for the quality of care and reduction of risks and the patient's right. However, there are still few publications, agreeing with Moraes, Rabin and Viégas, (2018), the importance and need for researches contributing to this process [1].

For a more detailed view, Table 2 shows the titles, authors and objectives of dissertations clearly addressing the flawed points and gaps of nonconformities.

Table 2: Results found from dissertations according to title, authors, year of publication, and objectives that make up the sample. Recife, Pernambuco (PE), Brazil, 2020.

TITLE	AUTHOR/YEAR OF PUBLICATION	OBJECTIVES
D1 - Assessment of the care process with orthotics, prosthetics and special materials [14].	Moraes, C.S., (2014)	The work analyzes the failures in the OPSM process of a hospital and the impact of these failures regarding the lack of registration, standardization of materials and pre and post audit analysis.
D2 - The traceability of implantable medical devices and the unique identification system: A bibliometric study [6].	Cabral, J.A., (2019)	The work shows the importance of systematizing and analyzing nationally and internationally the importance of DMI's traceability and the Unique Device Identification, showing the increase on this theme.

Source: Created by the authors.

The two authors are complementary by mentioning failures at the beginning of the device management process until the final process, bringing inconsistency and risk to patients and hospital institutions.

From the analysis of the themes of the articles, dissertations, ANVISA regulations, CBRs, publications of public consultations, good practice handbook, books and booklets, three thematic categories emerged.

Ensuring surgical health products that meet the safety of patients and hospital institutions:

IMDs have had an important rise in health and this is punctuated by the increased number of elderly people, incidents of violence and occurrences and accidents in general. In the past, the ease of use of these devices was unmeasured, because these materials were not subject to an evaluation and certification of their consumer, the prices charged in the market changed and ended up affecting and reaching public or supplementary health costs [15].

According to Brazil (2015), this ease gave scope for the occurrence of crimes of component tampering and falsification of materials in the manufacture of products, causing adverse effects and serious health complications, ranging from simple damage to irreversible losses, fraud of indications to unnecessary surgeries and materials with incorrect indication, changes of records in medical records in the quantity used, use of expired materials, fraud in budget and bids and overbilling, thus violating the principles of safe surgery and compromising patient safety [15].

These practices violate the ethical and professional code and are characterized as a heinous crime by the Brazilian Penal Code, Law n. 9677 of JULY 2, 1998, Art. 273, item 1B.

The fundamental principles of the code of medical ethics, cites medicine, which cannot, under any circumstance or form, be exercised as a trade, and medical work cannot be exploited by third parties for profit, political or religious purpose. The doctor is forbidden to practice or indicate unnecessary acts or prohibited by the legislation in force in the country and exaggerate the severity of the diagnosis or prognosis, complicate the therapy or exceed the number of visits, consultations or any other medical procedure, thus providing a mercantilist exercise [15].

According to the fact, in recent years, the use of these materials was hesitated by economic and financial unrest and, for safe processes of the devices, there was need to have a responsibility behavior of all those involved in the process of these products, from their manufacture, storage, use to their disposal [15].

In view of the above case, measures were taken to contain the health risk and guarantee the safety of users of these materials, the collection of devices with questionable quality, impositions for the implementation of good practices through regulations, clarification and guidance for the activation of technosurveillance [3].

Thus, it is possible to promote an increase in technical notifications of products and adverse events in the NOTIVISA (Health Surveillance Notification System) system, the creation of the sentinel network and the grouping of registers divided by groups and subgroups, since the existence of the huge variety of categories and subcategories of identification of these products is a complicating factor, either in the regulatory sphere or in health services, actions were promoted in order to avoid surgeries with products of non-conforming characteristics for their use and damage to the patient [3].

The table below synthetize regulatory resolutions regarding the promotion, protection of patient safety and traceability of IMD materials. These CBRs are published by ANVISA in the Official Gazette and are available at the electronic website of the National Agency [4].

Table 3: Anvisa's Collegiate Board Resolution (CBR). Recife, Pernambuco (PE), Brazil, 2020.

ANVISA COLLEGIATE BOARD RESOLUTION	THEMATIC
CBR N. 56 OF APRIL 06, 2001	Establishes essential safety and efficacy requirements to be met by health products.
CBR N. 185 OF OCTOBER 22, 2001	Approves the Technical Regulation contained in the annex of this Resolution, which regulates the registration, alteration, revalidation and cancellation of the registration of medical products at the National Health Surveillance Agency - Anvisa.
CBR N. 156 OF AUGUST 11, 2006	Defines and regulates medical products with forbidden and allowed reprocessing.
CBR N. 2605 OF AUGUST 11, 2006	Establishes the list of single-use medical products with forbidden reprocessing.
CBR N. 185 OF OCTOBER 13, 2006	Deals with the regulation of economic information and health products, checking the market price, the intended number of patients, the price of the domestic and worldwide market.
CBR N. 59 OF AUGUST 25, 2008	Institutes the technical regulation with the general requirements for grouping in families and orthopedic implant systems for registration purposes.
CBR N. 2 OF JANUARY 25, 2010	Provides for the management of health technologies in health facilities.
CBR N. 14 OF APRIL 5, 2011	Institutes the technical regulation with the requirements for grouping materials used in health for registration with ANVISA and adopts traceability labels for implantable products.
CBR N. 63 OF NOVEMBER 25, 2011	Provides for Good Operating Practice Requirements for Health Services.
CBR N. 23 OF APRIL 4, 2012	Provides for the mandatory execution and notification of field actions by health product registration holders in Brazil.
CBR N. 36 OF JULY 25, 2013	Institutes actions for patient safety in health services

Source: Created by the authors.

These regulations, technical standards and the handbook of good practices ensure the use of these materials, preventing the patient from undergoing a new procedure, and, after his/her hospital discharge, a better quality of life with a warranty of the implanted product. The adequate control and efficiency of OPSM are significant for ensuring adequate care and a legal obligation of health operators. The adherence of measures that ensure that traceability labels with the necessary information follow ANVISA standards belongs to them, and patients are allowed to know about the technical specifications of OPSM, the tracking from its manufacture to its final use, enabling information whenever necessary if there is need to investigate an adverse event or product life [2].

The importance for increasing safety in medical hospitals and health professionals:

Patient safety is the responsibility of hospital units and all health professionals that provide direct care. Even before a patient’s admission to perform a surgical procedure, a process is already in progress and, when there is admission for the performance of this procedure, there is a complement of this care until the hospital discharge [1].

For Moraes (2014), the sectors involved are the preoperative authorization center, scheduling, OPSM center, responsible for receiving and returning the devices, sterilization center, operating room, hemodynamics, postoperative authorization and hospital technology and there are a variety of critical processes for this care and any failure in one of these steps can directly affect the patient’s care and procedure and hospital expenses, thus causing a high cost to the institution [14].

In view of the above, initial failures of technical knowledge of the responsible for the surgical scheduling and the incorrect indication of the product by the doctor in the scheduling, the material inaccurately registered in the system, information unavailable for the areas involved, failure to identify the product received, wrong or incomplete material are extremely important points for breaching patient safety, thus, for institutions that work with implanted devices, there is need to maintain an effective cycle, a controlled management with all the requirements of current legislation [14].

The registration of the products present in any of these stages of management will be denied in case of non-complied conditions, requirements or procedures for such purposes provided for by Law, regulation or instruction of the competent body, according to Law n. 6360 of SEPTEMBER 23, 1976, in Art. 15.

In order to have greater control over these aforementioned processes, addressing crucial points and educating the relationship of these processes provides a greater guarantee of the safety of the procedure performed and patient safety through traceability of materials. These controls are obtained in the pre-audit, device management and post-audit phases, according to the table [2].

Table 4: Regulatory instructions and good management practices for IMDs. Recife, Pernambuco (PE), Brazil, 2020 [2,3].

HEALTH AUDIT AND REGULATION STEPS	HEALTH AUDIT AND REGULATION PROCESSES
PRE-AUDIT	Verify if the requested procedures are included in the ANS list; Check if the material is compatible with the procedure to be performed; Analyze if the procedure is compatible with the clinical case; Check if the listed materials are technically equivalent; Research on products by ANVISA (product models, process, product origin, risk class and validity), ANS and evidence-based studies.
OPSM MANAGEMENT	Verification of the material ordered with the material delivered, documented and registered. Electronic receipt presentation and supply authorization. Check and record the information of receipt number, code, quantity, validity, lot, value, CNPJ, legal names of the manufacturer and suppliers.
POST-AUDIT	Registration of doctors in a surgical report and in the patient’s record, mandatory use of traceability labels and packaging in each document and receipt. Carry out in-place audit for verification and control.

Source: Created by the authors.

The access to these IMDs, aid equipment and accessories in establishments must be checked and documented. They must be delivered with Auxiliary Electronic Receipt (Danfe) and Supply Authorization (SA), belonging to the person responsible for this function to make the provisional or definitive reception according to Articles 15 and 73 of Law n. 8,666/1993. After the reception, the information recommended in the organizations containing receipt, code, quantitative, validity, lot, value, CNPJ and legal names of the manufacturer and supplier must be recorded [3].

This activity ceases the risk of incomplete information, avoiding using divergent material, ensuring the possibility of a safe procedure, unifies and facilitates communication between all involved, avoiding possible failures in this stage [1,14].

Health professionals, such as the doctor, are responsible for the procedures performed, the use of implanted devices and the prohibitions according to the CFM (2000); Brazil, (2006) and Brazil, (2010). Nursing professionals are responsible for most of the actions and care provided to the patient, obtaining an excellent condition for reducing incidents and complications and better contributing through control and checking, reducing possible failures [5,12,16,17].

According to the Brazilian Society of Nurses of Surgical and Sterilization Center, to check the implantable

materials necessary for the procedures and verify the availability and functionality of materials, instruments and equipment for performing the surgical act are the nurse's function. The MSC nurse must define and regulate deadlines for receiving sterilized and reprocessing products, and the nursing technician is responsible for checking these materials, availability, the guarantee of records and the traceability of the implanted IMDs [1].

The IMD used should be recorded by all healthcare professionals related to the procedure, in the room expense report, in the surgical description and in the patient's medical records, and this information should contain quantity, size, traceability labels contained in the product packaging and in Danfe. The surgical description is the responsibility of the professional who performs the surgical act and should contain the steps performed and the relationship of the IMDs [3].

Inadequate documentation or lack of information in the medical records may be related to an adverse event, because it is responsible for providing the necessary information for the specific and appropriate care of each patient [11].

Identification labels are fundamental as a supporting document for the implantation of the devices. The supplier must give possession of 05 traceability labels with the essential information for tracking and should be fixed in the patient's medical records, delivered to the patient, attached in the receipt documentation, made available to the supplier and surgeon. The information must contain the name or business model, identification of the manufacturer or importer, product code or voucher in the system, making number and Anvisa registration number (2017) according to CBR n. 14, of April 5, 2011. When there is incompatibility or excessive amount used between the uses of OPSM, the professional should report a mandatory technical and plausible justification [18].

The IMDs with non-complied packaging, such as deteriorated, open or contaminated not used in the surgical procedure, should have their loss justified [3]. According to Art. 4, the attending physician, directly responsible for the procedure, is obliged to communicate to the technical director any defects or failures in the quality of the product or in his/her implanting instruments.

The post-procedure conference is carried out through an audit, being essential to ensure the veracity of the information, observing legible surgical description, imaging examinations, the conference of the attached label, which must be identical to the authorized material [3].

The importance of product control for health after registration, market control and patient rights:

Ramos (2017), mentions that the control of health products and their traceability are extremely fundamental and important for patient safety. The lack of this control provides a huge gap for the reverse objectives. Performing unnecessary implants, employing more expensive technologies, even without recommendation for use or bringing necessary benefits, using unnecessary quantity of products and defrauding reports to collect unused products are events that evidence the lack of quality of the procedure and risks to the patient [15,19].

For the Institute of Supplementary Health Studies (2018), it is clear that management efficiency reflects in the control of waste and allows greater investments for the benefit of the assistance itself, diagramming the use of a certain input, or preventing mistaken or hasty indication, while still providing assistance when necessary [20].

The patient has the right to have access to the necessary information and health care services, consent or refuse voluntarily and with adequate prior information regarding the diagnostic and therapeutic procedures to be performed, have a second opinion or opinion of another professional at any stage of treatment and may change doctors or institutions, if not feeling safe, and have access to clear and accurate notes in the medical records of all relevant information about his/her health. Patient rights are basic rights known by users of health services, offering safe and quality care [4].

According to the WHO recommendation in resolution adopted at the 55th and continued at the 57th World Health Assembly, Brazil instituted the National Patient Safety Program (PNSP). The program was created by Ordinance 529/2013 of the Ministry of Health, and, among its objectives, presented in article 3, item II, is involving patients and family members in safety actions [21]. One of the main guidelines of this program is the establishment of protocols by the health service, including patient identification, surgical safety and incidence notification.

Implants can be permanent or removable and the risks associated with their insertion can be during surgery with the placement or removal of IMDs, infection, reaction to the materials of the devices or implant failure, thus the absolute control of these IMDs allows issuing a Technosurveillance alert [2].

Brazil (2017), aiming at quality control and care safety, the implanted OPSM must be permanently monitored. The professional must record the occurrence in an appropriate form when the IMD present some quality change, so that the supplier allows exchanging or returning and the

institutions must communicate the occurrence and these failure events to ANVISA through the notification system of this body [4].

“NOTIVISA is a computerized system to receive notifications of adverse events and technical complaints of products and services under sanitary surveillance” [4].

NOTIVISA received only information associated with the use of products under health surveillance, but with the publication of CBR 36/2013, which establishes patient safety actions, the system began to receive notifications of incidents and adverse events not only associated with the use of products, but also related to the provision of health care. Complaints of adverse events such as failures during the surgical procedure and technical complaints associated with deviation of product quality, counterfeit product, unregistered product, irregular advertising, companies without COA, are notified in order to reduce fraud, avoiding the compromise of quality and patient safety, as well as promoting actions to protect public and private health [4].

The absolute control of these products through mandatory registration in ANVISA and traceability provides the investigation if the occurrence is isolated or of a whole making, resulting in a request for the return of a making or an entire line of products made by the manufacturer [21].

For Bergamine (2019), it is not uncommon for the patient to undergo a new surgery and not know what type of device has been used, and, to avoid this type of exposure, traceability labels are necessary because it allows the localization of information about the product, minimizes losses and costs for the institution, reduces the risk if there is need for new devices and serves as a support in case of an eventual indemnification. The traceability label is also important until after hospital discharge, because it serves as a means of proving that the patient has a device once one may need to present this information [21].

IV. CONCLUSION

This study showed that a safe procedure is fundamental for the patient's quality of life and the responsibility of hospital institutions.

Nursing care is indispensable to promote this type of care, because it is the link of information among other health professionals, bringing possibilities that can lead to changes in the process and outcomes. It is essential to follow patient safety protocols according to their steps and we can observe in this study that effective communication

and safe surgery are important points when an institution actively works with IMDs.

Seeking the best result before the use of these devices, there is need to maintain a clear, truthful and accurate information that meets all the requirements of the current legislation, and, through the traceability of these implants, control policies and improvements can be outlined for the patient.

Therefore, controlling, evaluating, investigating, certifying and documenting are actions that avoid incidents related to adverse events and problems of composition, raw material and product quality, and, once notified, ensure legal support of health professionals and hospital institutions. They also enable parameters for the control of material in the market, avoiding possible complications, and serves to outline goals and public health policies to cease these incidents.

The doctor is responsible for informing the patient of the need to implant the devices and the procedures that will be performed, in addition to explaining the particularities and their routines after the procedure, as well as guiding with essential information and without any doubts, ensuring that the patient and his/her family have a safe return to home, since the patient has the right to receive the traceability label as a document supporting the use of the material or as information whether a new procedure is necessary.

The research reflects on the importance of presenting labels and controlling the use of devices for patient safety, health professionals and hospital institutions, suggesting quantitative and qualitative researches on the subject.

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