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Iatrogeny in the Brazilian scenario: Medical Technologies that can prejudice in patient treatment.

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Abstract. Medical technology plays a fundamental role in supporting medical practices, from diagnosis to the patient's rehabilitation phase, but the iatrogenic potential of the equipment must also be admitted. Resumption of iatrogenesis in a damage, material or psychic that is emitted to the patient during medical treatment and opposite to medical error, this term is related to a necessary procedure for the improvement of the patient, being considered an inevitable fact, an investigation of the iatrogenic consequences generated equipment by doctors was indispensable to verify which factors can motivate this type of complication. The lack of basic infrastructure for the adaptation of devices in hospitals affected not only patients but also employees, the lack of training and investigation of technical problems are factors that directly influence this occurrence. This study addresses the subject in order to investigate the factors that are capable of causing iatrogenic consequences generated by medical equipment, it also points out problems that need to be investigated for improvement during use by health professionals, developing an analysis that makes it possible to assist in this problem in the hospital environment. Therefore, in order to carry out the study, the applied methodology was a bibliographic review, analyzing and collecting data on the risks caused by medical technology in the hospital environment, following the method, the search resulted in a few articles that included and emphasized the use of technologies medical, but after obtaining the data it was possible to develop two graphs that analyze the incidents that occurred and the impact of medical technologies on these incidents. In view of this, the present recommends the study through a hospital management the application of resources focused on medical technologies, with a specialist to identify problems. It is important to emphasize that an analysis of this theme is beneficial for the performance of managers, relating medical equipment to iatrogenic consequences.

Keywords. Medical support, Iatrogeny, Iatrogenic consequences, Medical error, Hospital infrastructure.

Introduction. Medical technologies that cause harm to the patient is a form of iatrogenesis, which is summed up in a negative result of medical practice in treatment done correctly or afterwards. Iatrogeny derives from the Greek: “iatro” has the meaning of doctor, medicine, medicine, “geno” which generates, produces and “ia” means quality.

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Even in Ancient Greece, where Hippocrates acted as an important figure in history of medicine, there was already a recognition of the potential harmful effect of a person's actions during a treatment. Over years, there have been developments in several techniques that have gradually diminished this potential, but iatrogeny it is still incident in several cases.

Studies reveal that the largest share of patients who are affected by iatrogenesis are elderly, according to Carvalho Filho and Dallanora (2006) a study generated by the Harvard Medical Malpractice Study in a review of 30,000 medical records from 51 hospitals in New York revealed that patients over 65 years of age had an incidence of iatrogenesis twice as high compared to patients younger than 44 years, the reason for this discharge is due to the elderly being submitted to a multidisciplinary team and due to the fragility they are this patient care is more prone to iatrogenic errors.

There are numerous factors that can be considered predisposing to iatrogenesis, hospital environment is a coefficient and for that reason protocols for preventive measures within a hospital must be followed, thus adopting safety measures that preserve health of patients, ANVISA provides a manual safety in hospital environment that requires multidisciplinary treatment for decision making to be effective across the hospital.

Technological advances in healthcare area have expanded a lot in recent years, and medical and hospital equipment is increasingly used not only for diagnosis of patients but also for their treatment, health technology according to National Health Service of England - NHS (2006), means any intervention used to promote, prevent, diagnose or treat diseases, or to promote rehabilitation or long-term care.

Some studies prove complications due to technological advances within the hospital, several problems can be caused when medical equipment is used, such as: misuse of the equipment, lack of corrective and preventive maintenance, lack of adequate training for professionals in the field and even the unnecessary use of equipment.

An ANVISA safety manual (2015, p. 39) identified that about 35% of adverse events identified in a university hospital were related to use of medical equipment, the conditions that cause this high number of iatrogenic complications should be studied, adapting practices and necessary measures, developing methods, with intention of preventing and minimizing more and more this type of incident.

Objectives. Investigate what factors are capable of influencing constant iatrogenic conditions generated from use of medical technologies, and thus develop a study that makes it possible to help reduce this problem in hospital environment.

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Theoretical Foundation. According to Silva (1977), there are different definitions of iatrogeny, however they are based on the same principle, he mentions Quiroga who describes iatrogeny "as a consequence of its therapeutic, diagnostic and animistic action for the patient", any medical intervention, being correct or not, is capable of resulting in a harmful consequence to patient.

In the last decades, studies have been evaluating the risks that patients are submitted to within hospital environment, even though they know that purpose of a hospital is to ensure that services provided are of quality and effectiveness, it is necessary that projects for the prevention of accidents become a priority, integrating all environmental professionals, because with a multiprofessional team capable of offering safety to the patient, the risks of accidents decrease.

Occurrence of iatrogenesis is predominant in elderly patients, the research generated by Harvard Medical Practice Study, in addition to revealing this higher incidence also indicates that up to 70% of events caused lower disabilities six months ago, but that up to 2.6% generated permanent disabilities and 13.6% led to death, while another study revealed that among 120 medical records analyzed, 70 suffered an iatrogenic complication representing 58.3% of cases and among these 35.8% complications suffered were classified as potentially preventable.

As mentioned, iatrogenic complications are generated from different situations, psychological factors contribute to health professionals feeling overwhelmed by emotional impact, countless circumstances where the doctor finds himself exceeds limits and affects the staff that encompasses various conditions clinics. In a study Magnavita and Fileni (2013) found that public servants had cases of anxiety rates in up to 43.7% of professionals and 43.9% were diagnosed with cases of depression.

Burnout syndrome is a pathological syndrome resulting from prolonged occupational stress and affects different groups of professionals in the hospital environment, in Brazil, Ordinance / MS nº 1,339 / 1999 considers a disease, and is present in list of mental disorders and behavior associated with work, according to Ministry of Health is an emotional disorder with symptoms of exhaustion, stress and physical exhaustion and can generate profound depression. According to Gracino, M. et al. (2016, p. 253) "It was highlighted that quality of doctor-patient relationship influences all dimensions, and there is less and less time devoted to this relationship, which can further increase the incidence of this syndrome."

When investigating burnout syndrome, it was possible to identify that doctors showed emotional exhaustion when subjected to absence of breaks, excessive shifts, deprivation of family life, inadequate staff, absence of equipment and ideal conditions for performance, another significant factor is the lack of specialized education. "Pseudovocations can culminate in fragile, hostile, erradic, and therefore iatrogenic, identities." (TAVARES, 2007, p. 182).

After the ANVISA manual (2015) reported the proportion of iatrogenic occurrences caused by medical equipment, it was also possible to identify that 42% referred to equipment used to control drug substances, among them the study mentioned infusion pumps, perfusers, nebulizers, gas anesthesia equipment, etc. However, an analysis showed that out of 145 incidents that

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occurred in an Intensive Care Unit (ICU), up to 30% of the occurrences were due to the misuse of medical equipment and 96 incidents caused by medical equipment up to 48% injured patient.

The lack of training of professionals for the handling of medical technologies or inadequate training in the handling of them happens after the reported occurrences, a risk control for the use of medical equipment should always be evaluated, providing the worker with training that establish qualification and thus limiting the exposure of the same to the workers risks and also of patients.

The damage caused by iatrogenesis is involuntary, therefore, it is not possible to measure possible consequences for patient, however, it is important to highlight psychiatric implications that in most cases are caused after iatrogenic error, this fact occurs because of patient's expectation that his disease is cured or significantly improved.

What is done by health professionals is a perspective, where situation in which the patient is found is analyzed, thus being able to elaborate the most appropriate conduct to be followed, Aníbal Bruno says that predictability "[...] gives the limit of the agent's responsibility for results that result from his lack of initial diligence. Only for predictable results will the agent answer. ".

In relation to iatrogenic damage and legal doctrine, as cited by Carvalho (2009, p.5).

> The absence of specific legal frameworks, coupled with lack of a more direct analysis on part of the doctrine and of national courts, is that this line of separation between legal effects resulting from the almost illicit - iatrogeny - and the civil illicit - responsibility has been blurred. doctor.

As mentioned, iatrogenesis arises from a beneficial intention of health professionals, therefore, it does not cause a civil liability of same, being consequent to a correct procedure, in accordance with all norms and fundamentals acquired during the teaching by science of their professional area.

It is important to highlight the difference between iatrogenesis and medical negligence, when the damage can be avoided and patient did not obtain adequate care, it is considered negligence, according to OECD (2006) that damage that might not have occurred if the doctor had provided other medical care to patient or medical care that consequently the result would be satisfactory in relation to the chosen one.

For Riú (1891, p. 50), "[...] iatrogenesis is associated with a non-punishable syndrome characterized by inculpable damage to patient's body or health as a result of a therapeutic application." Given that iatrogenic injury is due to the use of necessary techniques, there are no grounds for civil liability.

In this context, Gonçalves (2010, p. 261) expresses: "The iatrogeny" does not entail the doctor's civil liability, an expression used to indicate the damage that is caused by the doctor, that is, damage caused by a medical act in healthy people or sick, whose work is unpredictable or unexpected. "
Some studies show that the occurrences of adverse effects involving medical technologies occur with respect to equipment itself, these being due to failures during its operation or inappropriate

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use by the team of professionals, it is inevitable to mention that one of the main solutions to minimize this type situation is the constant evaluation of medical technologies and the specialized training of the entire professional team.

Elpern, E et al. (2013, p. 30 -37) A study was carried out in which 108 patients who received a CPI device (intermittent pneumatic compression) were observed. In this project, it was identified that 49% of the applications resulted in errors, and about half of the errors were related to the incorrect positioning at the time of applicability. As it was possible to identify the training of equipment, it must involve the entire medical team and training must be periodic, thus maintaining a standard conduct and aiming at a quality service.

The National Policy on Health Technology Management (PNGTS) is responsible in Brazil for addressing failures that are presented by medical equipment, with the aim of maximizing health benefits to be obtained from these resources, data from a multinational study point to that up to 112 equipment failures were identified that compromised patient safety.

According to the study produced by Ribeiro, G et al. (2017) nurses described some problems experienced in daily life:

> "These batteries are a problem [...] you can't trust these devices too much, they also stop working on their own." (Nurse 1).
>
> "[...] I hope that they arrive soon [new monitors], because the defects of the devices and this horrible maintenance end up disturbing people." (Nurse 2).

It is observed that iatrogenic complications can result from various situations, medical equipment is part of 35% and this study aims to determine the factors that cause this problem, analyzing ideal solutions for the improvement of this problem.

Methods. The methodology used to carry out this study is a bibliographic review, with the purpose of interpreting the study of an object, analyzing and collecting data on risks caused by medical technology in hospital environment, then defining existing risks, where research shows problems generated from equipment installation to handling by medical teams. The study initially included all the studies found on the topic iatrogeny in the form of a scientific article, in electronic virtual library database that includes: SciELO, PubMed and Google Scholar, restricting analysis to articles written in languages: English and Portuguese. Over the course of the investigation, more than 100 articles were found, during the period from September 1 to October 15, 30 articles were selected for pre-analysis, among them divided into thematic groups, the first focused on the reasons that cause iatrogenesis and the second highlighted how to minimize these occurrences, it is important to note that the only study directly related to theme was the ANVISA manual, which was the main one taken into consideration. Applying knowledge acquired during the course to understand complications caused by technological advances in medical equipment and in an attempt to identify and manifest solutions so that

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incidents have a lower rate than records of the latest analyzes. There is a scarcity of data that investigate these factors in view of this. The present study is expressive for the development of solutions that assist in the reduction of iatrogenic complications.

Results and Discussion. Following defined method, the search resulted in few articles that included and emphasized use of medical technologies that cause losses in the treatment of patients. Analyzed articles were separated into thematic groups, first group focusing on reasons that cause iatrogenesis and the second highlighting how to minimize iatrogenic occurrences.

Main study taken into account was in relation to safety in hospital environment, developed by ANVISA, including data from studies that presented medical technologies as a major factor of iatrogenic consequences, and shows some conditions that are responsible for developing this problem more often.

Still according to the study, about 30% of complications in an ICU are generated from misuse of medical equipment, realizing that lack of correct training for employees who use medical technologies is a major issue to be improved. and discussed within hospital environment.

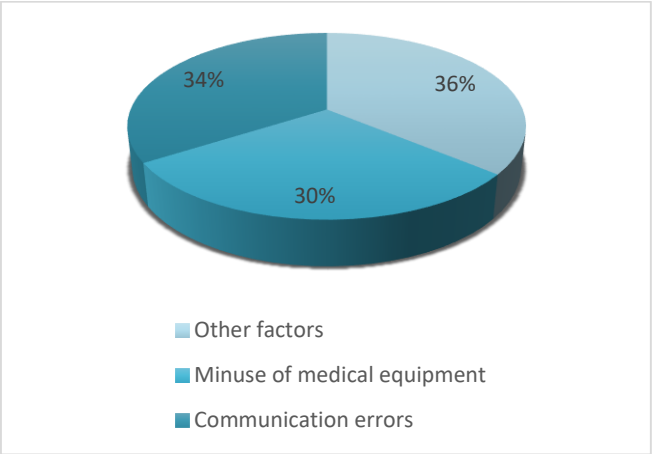

Figure 1 - Analysis of incidents that occurred in an ICU in brazilian scenario.

Within this study, it is also possible to verify dehumanization during doctor-patient approach, greater advance of technology, especially within Intensive Care Units (ICU) where there is a need to use perfect technique, professional cancels contact with patient, causing greater impact during the period that patient is hospitalized and may generate greater incidents.

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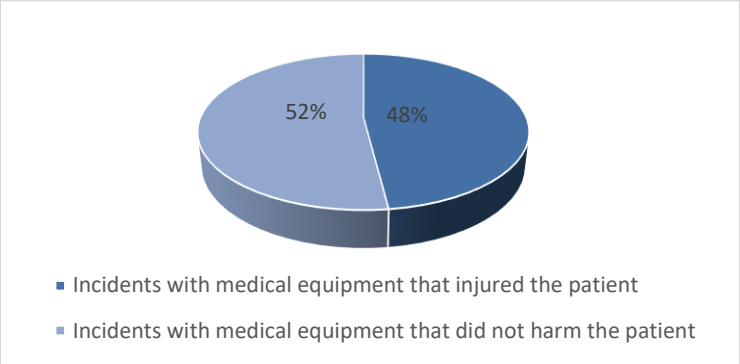

Figure 2 - Incidents performed using medical equipment in the ICU in brazilian scenario.

According to safety manual in hospital environment of ANVISA (2015, p. 39) in a university hospital, it was possible to identify that about 42% of errors that cause iatrogenesis are related to drugs and this is due to the equipment that controls doses of medicinal substances such as infusion pumps, which is a device that delivers fluids containing nutrients or drugs directly to patient's body in controlled quantities, this equipment has been observed in some studies and it can be said that its errors can be caused due to malfunction, inefficient programming or difficulty in selecting infusion options.

The American Society of Health - System Pharmacists - ASHP. (AMERICAN ASSOCIATION OF HOSPITAL PHARMACISTS, 1993) classified types of medication errors found and according to the specification:

> 1. Prescription errors: incorrect selection of the medication [...] dose, infusion speed and inappropriate instructions for use made by the doctor; illegible prescription that may be misleading.
>
> 2. Errors in administration technique: [...] incorrect infusion rate.

In order for this type of error to be mitigated Mavilde L. G. Pedreira et al. (2005, p. 55-61) mentions that intelligent infusion pumps were designed, even if it is still little used in health institutions, they can prevent errors and improve the quality of service, optimizing time and increasing patient safety.

It is essential to analyze that reduction of errors, as their prevention must be based on real causes, and that we can see that the errors generated in health system are due to the poor organization and implementation of medical technologies, and they can also manifest themselves failures through defects or equipment malfunctions, showing damage that can impair interaction with the professional compromising proper use.

According to researches carried out so that installation of medical technologies in hospital is safe and effective, it is necessary to fulfill some requirements since the correct installation of electricity, classifying general areas of hospital and defining each sector so that, at time of installation of the equipment, compatibility either in accordance with standards and technical specifications.

Also according to research, we identified that preventive maintenance mainly in equipment that is used in critical areas such as in the Intensive Care Unit - ICU sector must occur periodically, following factory

standard of all equipment, as well as it is also important to restrict the modifications that support each equipment and the procedures should only be carried out with the authorization of maintenance sector.

But it is also necessary that corrective and predictive maintenance, where the equipment is repaired after an episode of failure and when it is flexible with regard to programming, that is, from the identification of malfunction indicators, respectively, must be made.

According to the ANVISA safety manual (2015), equipment of greatest concern at time of installation until its continuous use in hospitals are those that emit X-rays and gamma rays, and for this reason there are instruments for radioprotection and time control of exposure that are indispensable to assist in the exemption of damages and risks to the health of patients and employees, the shielding of the X-ray room is mandatory as well as there are a series of measures provided for by the National Nuclear Energy Commission that regulate aspects related radiological protection.

Thus, the iatrogenic consequence can also be generated by this equipment if the set of factors established by regulatory standards are not applied or if the patient is subjected to examination several times for some eventuality.

The use of medical equipment in hospital environment is essential, but incidents that occur while using them are a problem for the safety of everyone who is present, according to Ribeiro, G et al. (2016, p. 1942 - 50) Problems can occur in four ways: patient-device, device-device, professional-device, environment-device.

Therefore, as studies have shown lack of continuous training with whole team, the lack of maintenance, whether corrective, predictive or preventive, lack of basic structure and infrastructure, jeopardize hospital security causing iatrogenic damage, this perspective should be analyzed by an entire professional team in order to avoid this issue present in health area.
Clinical engineering, according to Potter (1970) is the “bridge” between science and ethics, and seeks to provide and implement a Management Plan for all technology used in health services, this includes that all essential items analyzed for reduction of iatrogenic consequences to be properly planned, it is important to note that since 2010 ANVISA has published a resolution in the Official Gazette (RDC nº 02/2010), where it is determined that there is a higher level professional for the management of technologies.

Conclusion. Thus, it is permissible that medical technology is extremely relevant within hospital environment, acting on technical assistance performed on patients, in the execution of exams, in the agility of procedures and during the rehabilitation procedure of patients, and for this reason it is essential that together equipments hospital has a support network for the professionals that support the training of employee, it is emphasized importance of periodic verification of the correct functioning of equipment, as well as fulfillment of the maintenance in accordance with provisions of supplying companies.

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The incidents evidenced in this study are visibly caused by situations of equipment malfunction or errors in use of the equipment by professional, another condition not previously mentioned, but which was mentioned in other studies are problems in equipment batteries, it is presented in several hospitals due to lack of evaluation by technical team and the lack of maintenance staff to evaluate performance of equipment, all of these points are relevant during the analysis of iatrogenic consequences.

Effective tools in the prevention of iatrogenic errors should be prioritized in hospital and it is necessary to use resources that work directly with professional, highlighting flaws present in the system, making it possible through these resources to identify the main point where it is possible to apply a error reduction program.

The present study is expressive for the development of innovative solutions that somehow help to reduce iatrogenesis caused by medical technologies, thus improving quality of life of patients. There is a scarcity of research that investigates conditions that motivate this inciden through equipment, therefore, during the study it was possible to obtain specific points in which performance of a clinical engineer is able to minimize and prevent simultaneously with hospital team, an appropriate practice clinic.

It is recommended through hospital management to strengthen the application of resources focused on medical technologies, in order to identify problems such as equipment malfunction, hospital infrastructure, lack of specific training for professionals, lack of maintenance services. adequate and aligned with what the suppliers establish improper development of a project, misuse of equipment. I believe that the analysis of this theme is beneficial for the performance of managers, relating medical equipment to iatrogenic consequences.

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