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Recurrence of the use of “domestic drills” as surgical instruments in hospitals performing orthopedic surgeries: experience report

Recorrência do uso de “furadeiras domésticas” como instrumental cirúrgico em hospitais que realizam cirurgias ortopédicas: relato de experiência

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ABSTRACT

Introduction: The National Health Surveillance Agency, through Technical Note No. 40/2017, emphasizes that household drills used in orthopedic surgeries lack adequate safety mechanisms, as they do not allow for effective sterilization and do not ensure patient safety during surgical procedures. **Objective:** This study presented how a multidisciplinary team from the Health Surveillance addressed hospital establishments that were using domestic drills in orthopedic surgeries. **Method:** This is an account of the experiences of a team of health inspectors during inspections carried out in the first semester of 2023 at three hospitals in Ceará. For these inspections, instruments or guidelines based on Anvisa and the Ministry of Health regulations were used. **Results:** Inspectors found domestic drills in the sterilized material centers, which were exposed both in the disinfection rooms and in the storage and distribution rooms of the already processed instruments, available for immediate use in surgeries. **Conclusions:** This experience highlighted the need to train health inspection technicians in the state’s health services so that they could identify and differentiate the appropriate equipment used in surgeries.

KEYWORDS: Orthopedic Surgery; Surgical Instruments; Patient Safety; Health Surveillance Services

RESUMO

Introdução: A Agência Nacional de Vigilância Sanitária, por meio da Nota Técnica nº 40/2017, reitera que as furadeiras domésticas utilizadas em cirurgias ortopédicas não possuem mecanismos de segurança adequados, visto que não permitem uma esterilização eficaz e não garantem a segurança do paciente durante os procedimentos cirúrgicos. **Objetivo:** O estudo apresenta como uma equipe multiprofissional da Vigilância Sanitária abordou estabelecimentos hospitalares que utilizavam furadeiras domésticas em cirurgias ortopédicas. **Método:** Trata-se de um relato de experiência vivenciado por uma equipe de fiscais sanitários durante inspeções realizadas no primeiro semestre de 2023 em três hospitais no estado do Ceará. Para essas inspeções, foram utilizados instrumentos ou roteiros embasados na legislação da Anvisa e do Ministério da Saúde. **Resultados:** Nas centrais de material esterilizado, os fiscais constataram a presença de furadeiras domésticas, expostas tanto nas salas de desinfecção quanto nas salas de armazenamento e distribuição dos instrumentais já processados, disponíveis para uso imediato em cirurgias. **Conclusões:** Esta experiência ressaltou a necessidade de capacitar os técnicos em inspeção sanitária nos serviços de saúde do estado, a fim de que pudessem identificar e diferenciar os equipamentos adequados utilizados em cirurgias.

PALAVRAS-CHAVE: Cirurgia Ortopédica; Instrumentos Cirúrgicos; Segurança do Paciente; Serviços de Vigilância Sanitária

INTRODUCTION

Law No. 6.360, of September 23, 1976, determines the need for registration or authorization from the competent health agency for the use of products intended for health treatment. According to Article 25:

devices, instruments, and accessories used in medicine, dentistry, and related areas, as well as in physical education, beautification, or aesthetic correction activities, may only be manufactured or imported for consumption and sale after the Ministry of Health has pronounced on whether registration is mandatory[1].

The use of unregistered products exposes patients and health professionals to uncharted risks, since the product has not been assessed for safety and compliance with legal and regulatory requirements. The requirements for regularization with Anvisa vary according to each type of product and the risk involved in its use[2].

Despite existing health controls, there is still a risk of adverse events (AEs) occurring because of the use of these technologies. According to current regulations, AE can be defined as "a health problem caused to a patient or user as a result of the use of a product subject to health surveillance, under the conditions and parameters prescribed by the manufacturer"[3]. These events can cause sequelae or death in patients and workers, requiring notification by public health authorities[4,5].

The surveillance of medical devices is a topic that remains relevant. The growing use of new technologies, many of them innovative, introduces risks that are not yet fully established/known, making it possible for AEs and deaths to occur[2]. Although AEs are usually related to products with a higher risk class, they can also be observed in products with a lower risk class, which are currently subject to notification at Anvisa and exempt from revalidation[2,6].

As already pointed out, in Brazil, medical devices must be registered/notified to be marketed. In the context of health services, different technologies are available for the care process, which require services to manage these technologies from the moment they are purchased until they are withdrawn from circulation[1,3]. However, it is still possible to observe the use of unregulated products in the context of care, such as the use of domestic drills in surgery. Domestic drills are prohibited for clinical or surgical use, as the product was not designed to provide health care and does not offer the safety and performance defined in the regulations and standards, exposing the patient to risks not foreseen in the surgical process. There are also risks of contamination and post-operative complications, considering that this product was not designed to undergo cleaning/sterilization processes[7]. Surgical site infection can occur due to microbial contamination, varying according to the number of microorganisms, their virulence and the patient's immune status[8].

In Brazil, health surveillance is a work process that encompasses actions backed by legislation, regulations, and controls, conducted by multidisciplinary teams. The purpose is to act to control risk in the use of products and services, by means of health inspections and monitoring notifications. When a problem is identified, it is up to Health Surveillance (Visa) to take action, as defined by the legislation, applying penalties, removing non-compliant products from the market or those that pose a risk to public health[9,10]. Visa is also responsible for taking action in hospital environments to prevent the use of unregistered products by health professionals.

During health inspections of hospital health services, Visa observed the use of domestic drills in orthopedic surgeries. Professionals justified this practice due to the equipment's portability, ease of handling, and low cost. However, the use of this product raises ethical, safety, and regulatory issues that deserve attention.

The Brazilian National Health Surveillance Agency (Anvisa), in Technical Note No. 129/2008, ruled on the obligation to register "drills" for use in neurological and orthopedic surgeries, classifying them as "surgical equipment for orthopedics". In 2008, Anvisa issued Technovigilance Alert No. 939/2008, stating that "domestic drills" were not designed for medical use and their use in surgical procedures constitutes a health infraction with a high risk to health. Domestic drills have problems such as a lack of rotation control, the impossibility of proper sterilization, and the risk of contamination[7].

Technical Note No. 40/2017 reiterates that domestic drills used in orthopedic surgeries do not have safety mechanisms to prevent bones and tissues from overheating. In contrast, conventional surgical drills allow the surgeon to control the rotation of the drill, have cooling systems and sterilization mechanisms[7].

The use of domestic drills in surgeries goes against the technical standards for processing health products, as recommended by Anvisa's Collegiate Board Resolution (RDC) No. 15 of March 15, 2012. Cleaning internal surfaces is crucial for sterilization, and electrical safety is compromised by the use of water or steam during processing. In addition, the use of these drills in hospitals can generate contaminated aerosols, increasing the risk of infection[8].

The aim of this study is to show how a multi-professional team from Visa uncovered the use of domestic drills in medium and high complexity hospital environments, and that these products were used in orthopedic surgery. The study also alerts managers and health professionals to the standardization of medical products for surgical purposes, in accordance with current health legislation, while also discussing patient safety and quality of care.

METHOD

The work consists of a report on the experience of the Visa team in health inspections carried out during the first half of 2023 in three hospitals in the state of Ceará. These hospitals performed medium and highly complex surgeries on patients of different age groups with various pathologies affecting the musculoskeletal system, treating injuries affecting bones, joints, ligaments, muscles, tendons, and other related tissues.

The identification of inadequate equipment for performing orthopedic surgeries in these hospitals was carried out during inspections for the renewal of each establishment's health license. Visa's own instruments or scripts were used for these inspections, which were applied to hospitals with this care profile. The management team of each establishment, along with some professionals from the sectors inspected, accompanied the Visa team throughout the inspectors' work process. The inspection scripts contained information on the RDCs, ordinances, decrees, and technical notes issued by Anvisa, the Federal Councils of Medicine, Nursing, and other health classes, as well as the Ministry of Health, which could guide the entire team in carrying out the sanitary action promoted by the inspectors.

The health inspections carried out by the technicians of the Ceará State Health Department (SESA) are generally conducted by a multi-professional team of higher education professionals, with specializations in specific areas of activity, assigned to each technical inspection to be carried out. Generally, two or three technicians are assigned to the establishments, depending on the size of the health unit to be inspected. Inspections to renew the health license are carried out annually, but in the event of a complaint, unscheduled inspections become necessary. Inspections last between 6 and 8 hours, although there are establishments that need to be inspected for more than a day.

At the end of the action, the managers of all the sectors in each hospital unit were brought together to explain the evidence found and the recommendations suggested by the team, based on the legislation used to conduct the action. Documents relating to the non-conformities found in the units were generated.

RESULTS AND DISCUSSIONS

During the inspections carried out, the hospital units' operating rooms (OR) and Material Sterilization Centers (MSC) were inspected. However, when the inspectors entered the MSCs of these units, they noticed the use of domestic drills (Figure 1), which were seen both in the disinfection rooms and in the storage and distribution rooms for instruments that had already been processed and were available for immediate use in surgeries.

The Visa team immediately reported the finding of this equipment and carried out a comprehensive search in the other sectors of the establishment to check whether this product was also available in other areas. Subsequently, the morbidity and mortality indicators for orthopedic surgeries were analyzed, based on the reports issued by the Hospital Infection Control Commission (CCIH). We also reviewed the safe surgery protocols adopted, the standard operating procedures (SOPs), and information from medical records that could indicate the use of this equipment.

The presence of domestic drills in the surgical environment highlighted the need for action by the health inspectorate, which played an interventionist, legalistic, and educational role. It is important to note that the role of each team of inspectors varies according to the organizational structures present at the three levels of management of the Unified Health System (SUS), and is influenced by the political, social, and economic context. Such intervention is necessary in the event of any non-compliance identified in healthcare establishments[11].

The use of domestic drills in surgical procedures is an extreme example of inadequate practice that can result in serious consequences for patients and the establishment that uses them. As well as being considered non-compliant because they are not registered with Anvisa, this equipment does not meet the technical standards of good practice for processing health products, as indicated by Anvisa RDC No. 15/2012, since it is difficult to remove organic matter during the sterilization process in autoclaves, due to its dimensions which are incompatible with the machinery used for sterilization[12]. The inappropriate use of this instrument in surgical procedures violates any ethical basis, since there is a lot of scientific evidence of the damage that can be caused to the surgical site[13,14].

Serious infections, such as those caused by the bacterium *Clostridium tetani*, can occur due to poor sterilization of the equipment. Sporulated bacteria can proliferate in the domestic drill,

Source: Photo courtesy of the author's work archive Girão AC.

Figure 1. Example of a domestic drill found in hospitals by the Visa team.

releasing toxins into the tissues during surgery, causing serious organic complications for the patient[15].

The use of domestic drills in surgical centers can lead to the opening of a Sanitary Administrative Process (PAS), regulated by Federal Law No. 6.437, of August 20, 1977. If the inspector identifies a serious and imminent risk, he can partially or totally interdict the establishment. The PAS is initiated by issuing a Notice of Infraction (AI), which is the start of the process[16,17,18].

The Visa team intervened, banning the use of this equipment and adopting appropriate legal measures, following administrative protocols. Technical reports were generated, and the importance of reporting AEs was emphasized, in addition to proposing patient safety training for the MSC, CCIH teams, clinical engineers, and OR professionals, with the aim of preventing recurrences.

In Brazil, the incidence of AEs in hospitals is mainly related to surgery, followed by clinical procedures. Research indicates that the most frequent AEs are related to: patient falls, incorrect administration of medication, failures in patient identification, errors in surgical procedures, infections, and inappropriate use of medical devices and equipment[19,20].

The challenges for improving the AE reporting system in Brazil include: a) speeding up the implementation of the National Patient Safety Program; b) strengthening Patient Safety Centers (NSP) with multi-professional teams; c) promoting a culture of safety; d) evaluating the current system to promote professional learning and the improvement of organizational systems and processes; e) changing the institutional culture, strengthening the notification process; and f) generating constructive feedback for notifiers, providing recommendations and guidelines to improve the notification process and contribute to the prevention of future AEs[21].

Surgery accounts for a large proportion of adverse outcomes, making patient safety a critical issue. Surgical complications contribute significantly to the occurrence of avoidable deaths and injuries. To prevent such situations, it is imperative to invest in adequate healthcare infrastructure, promote education about the risks associated with the use of inappropriate instruments, and place safety as a priority in the practice of healthcare services. In addition, it is crucial to educate the population about the dangers related to the use of inappropriate instruments in medical procedures[22,23,24].

In the process of investigation, it was identified that several factors contributed to the services' use of domestic drills in surgeries, such as: the pressure for quick, low-cost solutions and the lack of adequate training on the part of health professionals[24,25]. To prevent the inappropriate use of domestic drills in surgery, it is essential to invest in healthcare infrastructure that provides adequate access to quality surgical instruments and complies with Anvisa legislation (Figure 2).

The study has limitations because it is an experience report from a small sample of hospital units in the scenario described. It does not refer to a field study that demonstrates the sequelae or expresses the intensity of surgical infections resulting from the use of these surgical instruments in patients undergoing surgery with this equipment.

However, it leaves a warning to improve surveillance of AEs that may arise in orthopedic and neurological surgeries, considering the possibility of using an inappropriate device. In addition, it makes it possible to encourage Visa inspectors to carry out scans in various hospital units and clinics in other states of the country, in view of the possibility that this problem may also be recurring in other health services.

CONCLUSIONS

This experience by the Visa inspectors triggered the initiative to verify the occurrence of this practice in other hospitals that perform neurological and orthopedic surgeries, with the aim of definitively abolishing the use of domestic drills in the state of Ceará. In addition, the inspectors' attention

Source: Photo courtesy of the author's work archive Girão AC.

Figure 2. Some examples of perforators used in orthopedic surgery, recommended by Anvisa.

was drawn to the possible use of other equipment, such as wire cutters, screwdrivers, and other household tools during surgical procedures. There is no justification for using these products in surgical procedures, given the risk associated with this practice. It should also be noted that this type of product is not subject to health surveillance and does not meet minimum safety and efficacy requirements for use in healthcare.

This intervention by Visa led to the need to train other health inspectors in the state, so that they could learn to identify and differentiate the correct equipment used in surgery.

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Authors' Contributions

Girão AC, Pinto JR - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the paper. Fernandes EP, Costa Aguiar IY, Almeida Costa S, Pinto RMF – Writing of the paper. All the authors approved the final version of the paper.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.