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TECHNICAL COMMUNICATION

Post-market evaluation of medical electrical equipment

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Abstract

Purpose The present paper discusses the technical assistance for electrical equipment under sanitary surveillance by analyzing Brazilian regulations and legislation and proposes an improved post-market approach based on international standards.

Methods Brazilian legal and regulatory documentation was the basis of this research. The time span from 2000 to 2020 was used to review the legislation. The actual post-market practice in Brazil was examined in detail, and it was pointed out that there is a clear dichotomy between the legal foundation and the patient protective practice.

Results The Brazilian National Health Surveillance Agency regulates and the Brazilian National Institute of Metrology, Quality, and Technology owns the conformity assessment scheme of medical electrical equipment under a sanitary surveillance system. The conformity assessment is based on a certification process using technical standard series IEC 60601. The certification in its present form does not consider any active post-market surveillance, which is a potential risk for the final users because of the varied medical electrical equipment. From the consumer protection perspective, the objective responsibility of service providers includes accountability to the eventual harm caused by the equipment in normal operation. Therefore, a clear regulation or legislation on post-market technical assistance is of interest to the medical industry and technicians.

Conclusion The prospective assurance of the safety and performance of the well-being of citizens would be much more probable to be assured with the renewing of legislation on the post-market evaluation of medical electrical equipment, mainly if international technical standards are used. The dissemination of available medical electrical equipment technology would consequently help public health. Revising the post-market surveillance approach could lead to a better response to deal with medical electrical equipment maintenance issues.

Keywords Post-marked surveillance · Technical assistance · Medical electrical equipment · Regulations

Introduction

Post-market technical assistance is provided by several industrial sectors. The research presented in this technical communication focuses on the medical industry, particularly the equipment under sanitary surveillance, referred to as "medical electrical equipment" (MEE). This investigation compares ideal post-market surveillance (PMS) practice and the current scenario. Related legislations and technical standards are also presented and discussed.

An MEE aims to provide a safe and reliable diagnostic or treatment strategy. Technical standard series IEC 60601 is internationally accepted for ensuring the general requirements for basic safety and essential performance (IEC 2020). Numerous certification bodies worldwide assess MEE conformity based on such international technical standards. Presently, there are more than 70 valid technical standards in the series, including general, collateral standards, and particular standards (Costa-Felix 2018). The main purpose of a technical requirement is to ensure that appropriate MEE risk assessment (mechanical and electrical) is conducted by a metrology (accredited) laboratory. Theoretically, it precludes equipment that does not satisfy the requirements to be offered to the final users, i.e., physicians, clinics, hospitals, or any other health care unit or professional (Guerra-Bretaña and Flórez-Rendón 2018). However, the IEC 60601 series does not include PMS. Moreover, it is common to have a defined

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regulation prescribing who can technically and legally provide technical assistance for MEE.

The World Health Organization (WHO) has long been concerned about the MEE used in developing countries, such as Brazil. MEE demand periodic technical evaluation to ensure its basic safety and essential performance. Rational use and acquisition and maintenance of MEE are recurrent themes addressed by the WHO. Within this context, the WHO is concerned about the waste of resources caused by investments in medical devices that do not meet high-priority requirements (Chan 2010). The poor infrastructure in some countries may pose a risk to the appropriate use and maintenance of MEE, endangering the health and well-being of the citizens.

Another factor addressed by the WHO is the unequal distribution of MEE worldwide, particularly regarding new technologies. Such a scenario may occur in rich and poor countries. In numerous countries, more frequently in developing ones, unequal regional distribution is of serious concern. As an example, Chan (2010) reported that the availability of mammography equipment, a major breast cancer screening tool, is 1 per 47,000 people in high-income countries. Comparatively, there is only 1 for 5.7 million people in low-income countries, more than 100 times worse. The availability of computed tomography scanners is 1 per 170,000 people in high-income countries, whereas there is 1 per 3.8 million in low-income countries. As another example, approximately 30 developing countries do not have radiotherapy equipment for cancer treatment (Chan 2010). Recently, COVID-19 disclosed that mechanical ventilators meeting the international standard ISO 80601-2-12 (ISO 2020) were insufficient to assist the population of several countries. The public health emergency of international concern due to COVID-19, as officially declared by the WHO, in a recent update, has directly influenced the Brazilian regulation for lung ventilators. The Brazilian National Health Surveillance Agency (Anvisa) published on 19 March 2020 a resolution of the board of directors, RDC 349/2020, allowing manufactures to produce and commercialize lung ventilators without certification according to the terms of reference of the Brazilian Conformity Assessment System (SBAC; see INMETRO 2012, 2020a, b; ANVISA 2020a, b). Although this example does not apply to PMS, it is notable that MEE legislation can be easily improved if there is evidence of necessity.

In Brazil, the legislation defines who is responsible for post-market technical assistance: the manufacturer or a delegated representative. Nevertheless, it is common practice to have other servicing companies offering to repair or to test the integrity of an MEE during its cycle of life. The regulation disclosed in RDC 02/2010 (ANVISA 2010) states that it should be ensured that the minimum technical requirements are achieved by a health tech or health care facility. A health care establishment should have specific procedures for this purpose. Furthermore, any stage of management can be outsourced, provided there is no legal impairment. Outsourcing must be conducted by a formal contract. Outsourcing of any management activity does not exempt the contracting health establishment from responsibility to the health authority. Complementary, the liability to manage that activity is on a professional with a technical capability officially recognized by a professional organization. In Brazil, recognized professionals assuming such responsibilities are biomedical engineers working as clinical engineers (CONFEA 2018) at a health care facility or professionals with a specialization course in clinical engineering (CONFEA 2016).

It is worth studying this dichotomy in the background of the technical requirements for basic safety and essential performance of MEE. Neither the delegated servicing office nor another maintenance office can be satisfactorily competent if they cannot perform technical testing in accordance with technical documents, such as international standards or specifications. This implication was studied, and a trade-off approach is proposed in this document.

In this paper, the technical assistance for electrical equipment under sanitary surveillance is presented and discussed. Brazilian regulations and legislation were analyzed, and a better post-market approach based on international standards was proposed. Besides, some international approaches for PMS for MEE are presented and discussed.

Methods

Brazilian legal and regulatory documentation was the basis of the research. The time span from 2000 to 2020 was used to review the legislation. The Brazilian national regulations from Anvisa were analyzed, and all the related documents were also revised. Furthermore, two specific international standards that could be included to enhance the national regulation if adopted by the stakeholders were studied and their potential technical quality improvements are disclosed.

The main legal document is the resolution of the board of directors, RDC 16/2013, whose objective is to define good manufacturing practices and establish the MEE manufacturers liable for post-market evaluation (ANVISA 2013). However, RDC 16/2014 also provides a tacit authorization to other players through its definition of independent technical assistance (ANVISA 2014). However, such resolutions do not impose requirements for technical assistance. An important enhancement in the legal basis would be the insertion of mandatory technical aspects, such as those presented in technical standard IEC 62353 (IEC 2014). More specifically, for ultrasound physiotherapy systems, for instance, the recently revised edition of technical specification IEC TS 62462 guides to test the equipment after maintenance routine or servicing (IEC 2017). It is a supplementary technical specification that can be used to assess the conformity of MEE in a PMS scheme.

Another important technical issue is that according to resolution RDC 25/2001, used or refurbished MEE may not be commercialized in Brazil (ANVISA 2001). This suggests that an owner (a health professional, clinic, or hospital) cannot dispose of its property. This resolution is under review, and an important question to be addressed is how to ensure that the technical specifications of MEE are maintained even after several years of use. A proposal on this subject is presented in this paper, aiming to aid regulatory agencies to improve their public health regulation.

Results

To solve the technical aspects of appropriate evaluation of an MEE after its commissioning, the following actions are proposed to the Brazilian biomedical engineering community as the first steps to a supervised discussion:

1. "Technical assistance for MEE" should be defined as service provided by a professional (an individual, an office, or a laboratory) certified following technical standard IEC 62353 (IEC 2014) and suitably accredited as a metrology laboratory according to IEC 17025. The individual must have professional skills under Brazilian legislation (CONFEA 2016; CONFEA 2018).
2. A mandatory maintenance and repair procedure should be established for MEE, considering the particularities and technical complexity of each MEE according to IEC 62353 ("All maintenance, inspection, servicing, and repair done following the manufacturer's instructions" to "maintain the conformity to the standard used for the design of the equipment."). The repair and maintenance should be done by "technical assistance for MEE," and competent authority (Anvisa) should register and follow up the maintenance records for all the MEE. This could be achieved, for instance, by an online system in which each medical facility or health professional uploads the maintenance records about its medical devices. This functionality could be added to the existing passive technical surveillance system of Anvisa (ANVISA 2020b).
3. RDC 25/2001 (ANVISA 2001) should be reviewed, allowing used and refurbished MEE to be commercialized in Brazil, provided their maintenance records are following the mandatory procedure, including the conformity assessment done by "technical assistance for MEE." Whenever specific technical standards exist, for instance, for ultrasound physiotherapy systems, the conformity assessment should include it (IEC 2017).

Although the three recommendations are addressed mainly to Brazilian regulatory agencies, they were based on an extensive discussion of interest to the overall field of biomedical engineering. The present technical communication was based on the scenario in Brazil. However, the guidance provided by the discussion can be expanded to other countries or economies, including regional blocks such as the European Community (Pane et al. 2019) and Mercosul. The adoption of such proposed actions internationally would be of interest, based on the fundamental arguments that motivated the research reported in this technical communication. The particularities for each MEE risk class should be considered (Zippel and Bohnet-Joschko 2017).

Discussion

In Brazil, the legislation itself has a drawback, as it does not allow wide access to MEE, restricting the access to used or refurbished equipment. Resolution RDC 25/2001 completely restricts their commercialization in Brazil (ANVISA 2001). The first argument is that used equipment could lead to incorrect use of the technology, which is not necessarily true. Used or refurbished MEE must be as reliable as a new brand product; otherwise, it will not be safe for its intended use. As mentioned before, the series of standards that are extensively accepted to technically ensure the safety of MEE is IEC 60601, which has to be proven by the manufacturer. However, it must be noted that numerous mandatory tests required by the application of IEC 60601 are destructive, or at least lead to stress to the MEE such that they are not safe for use after the complete evaluation (IEC 2020; Costa-Felix 2018) 00. It is important to consider this issue. This suggests that IEC 60601 is unsuitable for evaluating equipment after its commissioning. In this view, IEC TC62A (common aspects of electrical equipment used in medical practice) developed a technical standard disclosing the methods for conducting recurrent tests and tests after repair for evaluating the MEE that are in use (IEC 2014). This standard defines how the risk management process defined by a manufacturer can be achieved and accomplished during the proposed lifetime of the MEE, including after maintenance and repair. Adopting these technical standards in the regulations would avoid, or at least diminish considerably, the risk of using any unreliable MEE.

Another regulatory issue in Brazil is the existence of two conflicting ordinances. The point of conflict is the definition, authorization for operation, and surveillance of technical assistance (repair and maintenance offices). According to resolution RDC 16/2013, technical assistance is defined as the maintenance or repair of a finished product to return it to its specifications. The resolution specifies that each manufacturer shall establish and maintain procedures to ensure that the finished products submitted to the technical assistance by the manufacturer or its representative satisfy the specifications. Therefore, it is explicit that the responsibility of the technical

assistance is unique to the MEE manufacturer unless it officially authorizes a representative to do so. However, resolution RDC 16/2014 introduces the concept and definition of an operating authorization (AFE, acronym in Portuguese). AFE is an act of competence provided by Anvisa, which includes an authorization for the operation of activities or establishments, institutions, and professional bodies, granted by the fulfillment of the technical and administrative requirements defined in the respective resolution. Companies must have an AFE to perform activities such as manipulation of goods and equipment, including its servicing. This conflicts with the previously mentioned RDC 16/2013 by the simple definition of AFE, and it became even more evident concerning RDC 16/2014, which clearly states that an AFE is not mandatory for professionals and companies that exclusively conduct the installation, maintenance, and technical assistance of health equipment.

Regarding the certification of MEE in Brazil, the National Institute of Metrology, Quality, and Technology (Inmetro) is responsible for the conformity assessment of this industrial sector. The regulation is defined in ordinance Inmetro 54/2016, presenting the requirements for the conformity assessment of MEE (INMETRO 2016). Conformity assessment is an activity that determines whether specified requirements relating to a product, process, system, person, or body are fulfilled (BIPM JCGM 2012). In ordinance Inmetro 54/2016, an extended definition of technical assistance is presented: It is the process in which a professional, with knowledge of specific technical content, provides information and clarifications, or performs actions to meet the identified needs. Furthermore, technical assistance allows the collection of information pertinent to an MEE that could be used to improve its project, industrial quality, effectiveness, and efficiency. Therefore, technical assistance contributes to the competitiveness of companies in the market as well as the strengthening of their quality management systems. Regarding the technician who will work on an MEE, the evaluation of his skills and abilities must be developed by training and professional capacitation, including the knowledge of "best practices" and relevant standards or regulatory documents. It would be of national interest if Anvisa implemented a PMS, including the establishment of a database in which all the records of post-production interventions on an MME could be reported.

Internationally, there is a growing concern for PMS. For instance, Pane et al. (2019) discussed the current European Regulation on Medical Devices (EU) 2017/745. According to this regulation, "post-market surveillance" means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service to identify any need to immediately apply any necessary corrective or preventive actions. Therefore, it states that the manufacturer of an MEE is in charge of maintaining the information regarding the post-production phase, along with other stakeholders, such as medical professionals and laboratories.

The approach proposed in this paper is similar to that in the USA. In the USA, the Food and Drug Administration operates a passive PMS called "MedWatch," which is quite similar to the present system of Anvisa. However, the proposed actions go further as it defines the minimum technical capabilities for the stakeholders responsible for the maintenance and assurance of the essential performance and basic safety of MEE.

The importance of an appropriate PMS is clarified by analyzing the system of adverse events and technical complaints of health products in the post-marketing of Anvisa (ANVISA 2020b). Until now (as of July 2020), more than 3280 communications have been inserted in the system. The amount of underreporting cannot be ensured. However, if a computer information system could be used to manage the post-market MEE in Brazil, for instance, allowing used or refurbished medical devices to be commercialized provided their maintenance records are updated, the underreporting could be minimized.

Conclusion

Despite their simplicity, the three proposed actions in this paper would improve the quality of life of numerous citizens with limited access to the technologies for the diagnosis and treatment of countless diseases.

The present Brazilian legislation is imperfect because numerous technical assistance providers simply perform repairs and maintenance on the MEE, in disagreement with RDC 16/2013 (ANVISA 2013), based on the interpretations of RDC 16/2014 (ANVISA 2014) and ordinance Inmetro 54/2016 (INMETRO 2016). The result is that there is no appropriate evaluation of those who provide technical assistance. Proposed action 1 would prevent this by defining the technical competencies for the "technical assistance for MEE."

Moreover, a mandatory procedure for recording the maintenance and repair of an MEE throughout its lifecycle would positively impact a public health agent. Along with proposed action 1, action 2 would establish a new level of following the conformity assessment of an MEE after it has been commissioned.

Finally, revising the legislation regarding the commercialization of used and refurbished MEE, considering actions 1 and 2, action 3 would allow renewing and the dispersion of technologies to those who currently do not have access to them. For instance, if an owner could sell his tomography machine to a clinic or a hospital in a neighborhood or a county with less financial resources, the technology would spread, and modern technology could be introduced in a new MEE.

Although changing a regulatory scheme appears to require significant work, the pandemic of COVID-19 has clarified that government agencies can rapidly respond to a defined demand. Both Anvisa and Inmetro changed their legislation in less than 2 months since the first case of the disease was confirmed in Brazil. The new conformity assessment and certification of lung ventilators are temporary and urgent (ANVISA 2020a, b; INMETRO 2020a, b); however, it is evident that legislation improvement is possible.

Ultimately, the last disclosed references highlight that rapid legislation improvement is feasible. If it is possible to achieve this in pandemic scenarios, it could be also done regularly to improve the PMS for MEE. The review of RDC 249/2020 was fast-tracked because of a pressing issue. However, the implementation of the proposals presented in this paper should follow internationally accepted good practices for regulation. The main players and stakeholders should be invited, including the government, customers, health facilities technical staff, managers, professional associations (such as biomedical and clinical engineers), and patient associations. If fully accepted, or even partially, the proposals in this document are offered to the health tech and health care Brazilian community as a starting point to improve the post-market technical quality of medical devices.

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Compliance with ethical standards

The authors declare that they have no conflict of interest. Ethical approval was not required as the data were collected from the public literature, legislation database, and technical standards. No humans or animals were studied in this research.

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