THE IMPORTANCE OF METROLOGICAL TRACEABILITY FOR CLINICAL DIAGNOSTIC

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Abstract: This article highlights the importance of metrological traceability in clinical diagnoses, highlighting its benefits and impacts on the accuracy of results. Fundamental concepts of metrological traceability will be addressed, as well as its practical application in the health area. Metrological traceability, which is part of the field of metrology, encompasses the ability to establish the link between the measurements performed by an instrument and a reference standard, providing confidence that the measurements are accurate and reliable. In Clinical Engineering, which focuses on healthcare, metrological traceability plays a key role in ensuring compliance of electromedical equipment. From a methodological perspective, this study adopts an exploratory approach, being built and developed based on bibliographic and documentary research. A detailed review of the literature was conducted, using databases such as Google Scholar, Scielo, books, monographs, scientific articles and specialized sites relevant to the topic in question. Data analysis was performed critically, following a qualitative approach.

1. Metrology in health

Metrology, the science of measurements, brings the concept of measuring, which is directly linked to comparison. However, it is only possible to compare something of the same species, in this case, in the same magnitude. [1]

The concern with quality in health has been one of the pillars for the technological evolution in the sector. With the constant search for the benefits provided by technological advancement, more and more the health area needs to have to make use of technologically advanced equipment, which demands high accuracy.

Over the past 50 years, there has been rapid technological advancement that has required adaptation, but health systems have not been able to keep up with this evolution at the same speed. [2]. The World Health Organization (WHO), as well as other organizations of international scope and prestige, recognize the fundamental importance of technology and medical instruments for quality in the health of communities. This evidences the fact that the metrological characteristics of the instruments and the reduction of measurement uncertainties are important elements in contributing to more accurate diagnoses and treatments, directly influencing the assertiveness of health professionals' decisions. [2]

In the international scenario, especially in the most developed countries, there is a concern with the metrological applicability and reliability of the measurements carried out in the health sector, since

they have long verified and recognized the serious consequences that eventual errors can represent for the health and safety of their users of health services. [3]

Therefore, it is essential to carry out the quality control of the equipment and verify that they are working correctly within their specifications, in order to ensure the reliability of the measurements and the results obtained.

2. Clinical Engineering

Clinical Engineering has become a reality in Brazil, standing out as a profession in full expansion. Currently, the market has a wide range of postgraduate courses aimed at training new professionals in this area. [4]. In this context, the Brazilian Association of Clinical Engineering (ABEClin), which was established with the objective of encouraging, consolidating, integrating and qualifying professionals working in the area of Clinical Engineering, has played a key role in promoting important initiatives to expand the recognition of the profession, even announcing that the process of recognition of Clinical Engineering in Brazil is underway and is heading for a conclusion soon. These advances are undoubtedly relevant, but there is still a path to be traveled so that the occupation is fully recognized and effectively valued in the country. [4]

The Resolution of the Collegiate Board of Directors (RDC) 2/2010, updated by RDC 20/2012, plays a fundamental role in establishing minimum criteria for the management of health technologies in health facilities. This regulation aims to ensure the traceability, quality, efficacy, effectiveness, safety and, when applicable, the performance of these technologies used in the provision of health services. [5]

Faced with this situation, the clinical engineer plays a crucial role, assuming several responsibilities throughout the life cycle of this equipment. Its attributions range from the receipt of equipment to installation, the performance of preventive and corrective maintenance, performance evaluation and proper disposal, among many other indispensable tasks.

3. Metrological Traceability

Metrological traceability can be defined as the ability to evidence the link between the measurements performed by an instrument and a reference standard, ensuring confidence that the measurements are accurate, accurate and reliable.

Metrological traceability requires an established calibration hierarchy and the reference specification shall include the date on which it was used in establishing the calibration hierarchy, together with any other relevant metrological information about the reference, such as the date on which the first calibration of the calibration hierarchy was performed. [6]

The metrological reliability of biomedical equipment, when subjected to calibrations traced to international standards, ensures not only the essential safety of diagnoses and treatments, but also the desired international comparability in biomedical measurements. [7]

4. Metrological Traceability in the clinical area

In Brazil, to manufacture and market biomedical equipment, it is necessary to obtain registration with ANVISA. This process involves the assessment of conformity with technical standards by the Product Certification Bodies (OCP) accredited by INMETRO. This regulation aims to ensure the safety and quality of this equipment, ensuring that it meets the requirements established by the current technical standards.

However, it is important to emphasize that, after the commercialization of medical equipment, with the exception of the clinical mercury thermometer in glass and the non-invasive mechanical sphygmomanometer of aneroid measurement, which are regulated by INMETRO, there is currently no legislation or mandatory regulation that requires the control of other biomedical instruments to ensure metrological reliability throughout their useful life through tracked calibrations. [8]

In order to ensure the metrological reliability of Electromedical Equipment (EEM), it is extremely important to rely not only on the competence of clinical engineers, whose training is complemented with knowledge in metrology, but also on the quality of calibration and testing laboratories. This quality is proven through an accreditation process, which attests to the ability of these laboratories to perform calibrations and tests according to the established standards and requirements.

In this context, it is important to emphasize that the need for adequate calibration of electromedical equipment is intrinsically linked to the continuous search for quality and the guarantee of reliable results. However, it goes beyond simply conforming to pre-established parameters. In fact, proper calibration can make all the difference between ensuring or not the health, functionality and even the lives of health service users.

5. Impacts of metrological nonconformities on health

The area of medicine is based on consensus, guidelines and shared techniques for the treatment of diseases, which depend on the results obtained through clinical examinations performed by analysis equipment. This highlights the importance of the metrological reliability of these devices, since the diagnoses are directly linked to it. In other words, the accuracy and reliability of the equipment used in the performance of clinical examinations are essential to ensure reliable diagnoses and support an adequate treatment for patients.

INMETRO allows a static error of no more than ± 3 mmHg in non-invasive mechanical sphygmomanometers2 of the aneroid type, but a study done in Australia demonstrates that this maximum permissible error increases by 83% the number of patients with diastolic blood pressure greater than 95 mmHg. This means that, assuming the higher permissible error, for every 5 patients correctly diagnosed as hypertensive, another 4 are wrongly diagnosed with this disease. Already when one assumes the error 1 Emphasis ours. 2 Clinical equipment used for blood pressure measurement, commonly referred to as "pressure devices." 23 lower permissible, almost half of patients with diastolic pressure greater than 95 mmHg are not identified [7]

It is relevant to this study the special alert made by the WHO for developing or underdeveloped countries, where adverse situations and the precariousness – or even the lack – of legislation on the subject can further aggravate the situation. In this notice, the WHO estimates that 50% of the electromedical equipment available in these countries, among which Brazil is inserted, are operating outside the standards recommended by the manufacturers. [9]

6. Conclusion

In this article we explore the importance of metrological traceability for clinical diagnoses with greater accuracy. Our goal is to highlight the direct benefits of this concept for patient safety, clinical decision-making, and compliance with standards and regulations. The reflections presented reinforce the need to adopt rigorous metrological practices in order to ensure an adequate diagnosis through reliable measurements comparable to reference standards in a clinical setting.

When considering the main points discussed in this study, it is possible to clearly perceive that metrology plays a fundamental role for the

Engineering and for the health area, however, it is alarming to note that its true application is not yet widely adopted, which can lead to a series of negative consequences, such as inaccurate measurements, lack of reliability in the results, violation of norms and regulations, loss of credibility and the compromise of patient safety with inadequate diagnoses.

Given this scenario, it is essential that regulatory mechanisms are established that promote the guarantee of the metrological reliability of biomedical equipment, through the implementation of

tracked calibrations. These calibrations, performed periodically during the life of the equipment, ensure that the results obtained are accurate, reliable and consistent. However, the creation of standards alone is not enough: it is important that they are effectively applied.

We believe that this article can stimulate future academics in the area of Engineering to be interested in exploring this field, which has great potential and is deeply present in the daily life of most Brazilian Hospitals.

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