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## **METROLOGY RELIABILITY IN THE BRAZILIAN HEALTH SECTOR: A STUDY CASE IN THE PUBLIC HEALTH CARE AND METROLOGICAL CONTROL OF HOSPITAL MEDICAL EQUIPMENT**

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**Abstract** – The present paper is related to laboratory quality in the Brazilian health care sector in general and to public health services in particular. Its purpose is to contribute to the development of reliable measurement practices in the hospital care section within the scope of at least 4 basic aspects: (i) identification of the available metrology legislation in Brazil which, as a rule, is sparsely organized and is not easily accessible to the end-user/practitioner, whose bibliographical research reveals an explicit lack of specialized literature; (ii) analysis of the compiled measurement standards and recommendations for the sector; (iii) diagnosis of laboratory quality in Central Public Health Care Laboratories as a means by which to implement an alternative strategy for introducing a quality system in a public health care laboratory based on a new approach that focuses on the quality of the laboratories that comprise the National Network of Official Quality and Health Care Control Laboratories; (iv) diagnosis of instruments that are employed in hospital services in terms of their conformity to measurement standards based on case studies of scales for controlling the mass of neonates, and of biomedical instruments for measuring blood pressure.

**Keywords:** laboratory quality in the public health care sector, hospital care equipment, reliable measurement practices in the hospital care equipment.

### 1. INTRODUCTION

The growing technological development of methods to help the medical diagnosis, as well as the methods of therapy which uses equipments of measurement, demands specialized knowledge of the people involved in its use, especially by the technical sophistication inherent to this type of equipment.

The medical diagnosis is a process that is a result of the combination of the following aspects: patient claim, medical experience, physical exams and anamnesis, leading the doctor to formulate diagnosis hypothesis. Sometimes, to arrive in a complete and definitive diagnostic, complementary exams based on measurements performed by biomedical equipments are strict necessary.

It is very easy to conclude that the reliability in the results furnished by those equipments are extremely

important for the medical decisions, to evaluate the effectiveness or the efficacious of the therapeutic method utilized, or to evaluate extreme situations in which the same equipment can be responsible for the maintenance or for the improvement of the human life. It can be mentioned as an example the pulmonary mechanical ventilators, that have the purpose of maintaining the patient lungs ventilated when this is incapable to properly ventilate itself by natural process. The correct measurement of diagnostic parameters as inspired volume or the pressure in the lungs, are essential for the patient survival.

### 2. BRAZILIAN METROLOGY LEGISLATION

In Brazil, the quality certification of hospital care equipment, manufactured and commercialized, is turning into an usual practice since the last decade in the scenery of medical technologies, because of its importance to the industrial sector, and because of the management of assistance health establishments in the governmental sphere, which stimulates regulation of this process. [1]

However, calibration of medical instruments and metrological control of hospital equipment is a new area of concern, facing many challenges, mainly due to the lack of suitable public policies and regulations which foresee and impose minimum criteria of performance, since it is related to voluntary practices dependent on manufacturers and equipment owners willing.

In spite of the fact that biomedical equipment metrological control regulation is very incipient in Brazil, certainly experiment its embryony phase, many efforts are being performed to fulfill this necessity and to make available to the nation a suitable compulsory legislation. As an example, it can be mentioned the compulsory metrology legislation recently implemented in Brazil which controls sphygmomanometers and clinical thermometers, under the control of the nation's National Metrology Institute, which has the responsibility to develop and validate criteria and calibrations methods. Another example is the electrocardiograph and the electroencephalograph, now in final process of analysis to support the appropriate legislation.

Based upon specific legislation (INMETRO 234 regulation [2] and NIE-DIMEL-005 [3]) Clinical

thermometers have been safely used, benefiting from a periodic control and verifications conducted on a sampling basis. Another regulation (number 24 [4]) establishes the condition under which the sphygmomanometers have to operate while their metrological verification conforms with NIE-DIMEL-006 [5]. According to these legislations all sphygmomanometers have to be verified and a governmental controlled label must be fixed on the instrument in order to demonstrate that it is in metrological good conditions to be used.

In spite of the laudable effort developed in this area, the regulatory actions is still insufficient to meet national demands due to lack of global technical conditions; lack of standards to validate calibration procedures and lack of trained people to provide all necessary services.

### 3. HEALTH MINISTRY EFFORTS

In the last few years, a tremendous attention has been devoted by the Ministry of Health, through its National Agency of Sanitary Vigilance (Agência Nacional de Vigilância Sanitária, ANVISA), to implement a national project aiming at the implementation of a program for Quality in the health sector, this became the techno vigilance (tecnovigilância) program, responsible for the development of specific actions towards the controlling of the market associated with health care equipment, based on a performance and security follow up process which takes into consideration the notification of any adverse happening or technical complains registered during the commercialization license period. The notification of adverse events can be issued spontaneously by anyone or by the sentinel hospitals (hospitais sentinelas) which has the responsibility for registering any technical complain emerging from any other hospital. Completing the process, there is a subsequent action of ANVISA for further analysis of any important failure source. There are nowadays in Brazil one hundred of these hospitals spread all over the Country, therefore spreading a culture towards metrology-quality control.[6]

Another important effort also recently implemented by ANVISA is the development of a Brazilian Laboratory Network for analytical measurements to support the increasing demand of laboratory services in the health sector, particularly to public health (Rede Brasileira de Laboratórios Analíticos em Saúde, REBLAS, www.anvisa.gov.br), aiming at encompassing all analytical health laboratories in operation in the country in a single coherent laboratory system, assuring conformance with ISO/IEC 17025 or other Good Laboratory Practices. In order not to conflict with other national accreditation concepts applied to calibration and testing laboratories which has a different national accreditation authority, the agency has implemented what was called a “REBLAS habilitation methodology” providing a specific scheme supporting laboratories to demonstrate their technical competence.. With this effort, the Country can count nowadays with a network of laboratories that meet the principals requirements of analytical quality managing and laboratories good practice.

## 4. CASE STUDIES

### 4.1. Analysis performed by the INMETRO

The state of calibration of sphygmomanometers in use in Brazilian public and private hospitals is now been verified in Brazil. Preliminary results from a survey conducted by the Brazilian National Metrology Institute (INMETRO) became available for four hospitals located in three important cities (Juiz de Fora, MG; São Paulo, SP and Rio de Janeiro, RJ). All measurement verifications were conducted by specialized technicians, based upon specific regulation which assures traceability to national standards.

TABLE I. sphygmomanometers state of calibration

CITY	Total number of Sphygmom. tested	Approved	Rejected	Largest Deviation Found
J. Fora	77	42%	58%	10 mm Hg
Rio de Janeiro	76	60%	40%	18 mm Hg
São Paulo	130	24%	76%	33 mm Hg
Total	283	39%	61%	33 mm Hg

The results of the survey shows that the majority of the sphygmomanometers tested display a deviation band which exceeds the allowed limit, which is 4 mm Hg. The extremely high rejection level (61%) was far beyond expectation level, raising attention of Brazilian authorities.

### 4.2. Consequences induced by improper metrology

The use of a sphygmomanometer not calibrated can cause several problems leading to a false diagnostic. Among other critical health complications, the patient can be erroneously diagnosed as hypertension under normtension situations; that can result on a psychological iatrogeny or even develop a stigma of an inexistence disease, in most cases influenced for having a hypertension case in his family.

When the hypertension is diagnosed in the doctor’s office, it is a routine to ask for complementary exams which can have a cost of about USD 50,00 or even more. Besides, the doctor will prescribe a diet to the patient followed by an regulator treatment. Even for the most favorable conditions that medicament has no significant impact on norm tension patients, there will be a financial damage impact due to unnecessary clinical exams performed or on medication purchase. The diagnostic of a false hypertension when verified in a urgency sector of a hospital may have serious consequences, inducing wrong medical actions such as inducing rapid lowering of high blood pressure which may be fatal. Miss medication is often due to false blood pressure measurement conducted by not calibrated sphygmomanometers. Such a procedure may cause an asthenia (tiredness), cardiac arrhythmia and if the patient has a nephro pathology or diabetes, it may worse his clinical health condition.

On the critical cases that the patient has hypertension and also a clinical silence on his symptomatology, he can be diagnosticate as normtension due to a non calibrated sphygmomanometer, therefore the accuracy of any medical

sphygmomanometer plays an important share on doctor's diagnosis decision which may induce consequences related to arteriosclerotic diseases, specially the coronary arterial disease, angina pectoris and also, under extreme situations, a myocardium infarct or peripheral arterial diseases such as the vascular cerebral accident (CVA) that can also occur.

It is pertinent to mention that the arterial hypertension reaches almost epidemic level in nowadays; arterial diseases kill more than any other disease. It is known that the costs of treatment on an hypertension patient, when his clinical situation is proper diagnosed at the beginning, is much cheaper than when it is identified on an advanced stage. Ten years ago an arterial pressure of 100/140 mm Hg would not be considered as a disease that should be treated. Nowadays, as a result of the impact and consequences of the hypertension risks, new references arise for considering hypertension: 80/140 mm Hg is now considered as a cardiovascular diseases risk factor. On this scenery it is very clear the importance of an accurate blood pressure measurement.

#### 4.3. Mass measurement scales in maternity hospitals

The Brazilian legislation suitable for metrological control of weighing instruments (body weight determination) to protect the consumer is under INMETRO responsibility, that has approved the N. 236 legislation issued on December, 1994 [7].

This legislation establishes the technical and metrological conditions, as well as the metrological control that must be applicable to the weighing instruments. On its attached number I item 1.2 on the application field, it is defined which weighing instruments must be under INMETRO metrological control, among them, it is defined on item 1.2.2 letter d, the weighing instruments to determine the mass on the medical practices that concerns the weighing of patients for vigilance reasons, diagnosis and medical treatment.

In order to verify how the legislation is being implemented, it was performed a survey on six hospitals functioning in the city of Rio de Janeiro belonging to the municipal network hospitals. Neonatal intensive care unit hospitals have been chosen to host the survey. Among other issues, it was analyzed the metrological conditions of 16 digital scales being used daily on maternity hospitals.

The diagnosis-survey consisted on the verification of the scales located in the neonatal intensive care units of these hospitals, following the number 236 INMETRO legislation, with the purpose to verify the metrological conditions of these scales.

After the results analysis, the following information can be reported:

TABLE II. Metrological conditions of 16 mass scales

ITEM	QUANTITY
Scales exhibiting an expired date label	14
Maximum error beneath 5 g	3
Maximum error at the level of 5 g	10
Maximum error at the level of 10 g	2
Maximum error at the level of 15 g	1

Accordingly to the survey, two out of 16 mass scales do not meet the INMETRO 236 legislation requirements for the maximum permissible error.

#### 4.4. Consequence

The fact that a doctor can not always rely on your instruments, which may provide false reading due to lack of scale calibration, inadequate medicaments administration and food prescription to the neonates may happen.

This can be considered a severe problem among pre-term child and low birth weight infants especially if they had less than 37 weeks of pregnancy, therefore characterizing a situation where small variations can have a big effect on the child health. It is known that a neonate needs about 125 Kcal per day, to complete his basic metabolism maintenance. To achieve this, he needs to ingest 150 ml of milk per kg each day. Based on this figures it can be seen that any difference on the weight figures will have a direct impact on the food prescription of the child.

The maximum error found on the research survey performed reveals that it would not have an important impact on the children health. However, the variation found is sufficient to confuse the doctor that would not be able to predict if the children is gaining or losing weight, being difficult to know if he has to increase or decrease the children diet. A useful practice to reduce error is to calculate the average weight over a longer period (daily or weekly).

## 5. CONCLUSIONS

Apart from other complex problems of political or economic nature that affect any health care system as a whole, the limitations associated with measurements in this broad medical and hospital environments are related to (i) the inherent difficulties associated with measurement in the health sector, not always linked to straight SI units; (ii) the lack of a suitable metrology culture within the sector because this intrinsic factor hampers the implementation of a laboratory quality system being the latter an essential requirement for providing objective evidence that a laboratory is technically competent (accredited), and (iii) the astonishing variety and number of models and types of instruments/equipment that are in use in this sector, which, as a rule, depend on sophisticated calibration procedures and require complex laboratory infrastructures and calibration methods and practices that are not available in the accredited laboratories within the laboratory networks that have been implemented in the country.

The considerations related to the metrological performance of sphygmomanometers as perceived in the survey conducted and characterized in this paper makes clear the importance of the actions that are being taken, particularly those related to the enforcement of a legislation which obliges manufacturers to conform with the requirement of a "model approval", considered to be an important element of the legal metrology inspection.

Besides, it is important to observe that the errors identified in some of the cases investigated, are above and beneath the reference values, possibly leading to wrong medical decision based on false premises.

The neonatal scales for infant weight determination also investigated revealed that this can also be a source of mistreatment, although this type of equipment proved to be much less susceptible to loose their calibration when compared with the sphygmomanometer. In spite of this functional advantage, this should be no excuse for not controlling the performance of neonatal scales, mainly when we considered that there exists a rigid official metrological control for scales used for commercial transactions which not necessarily affects health or life.

The proposed paper describes studies developed as part of the outcome of a Master Thesis [8] developed at the Post Graduate Metrology Program of Catholic University, Rio de Janeiro, Brazil. Despite the complexity and extent of the health care sector, the research that was carried out not only revealed that the technical literature available is insufficient and unsuitable, but also that measurement provided by laboratories and hospital care equipment may, under some situations, lack metrological control. The diagnosis that was performed in a typical health care laboratory also brought to light a number of major challenges for the introduction of a laboratory quality system. An alternate approach supported by ISO/IEC 17025 is recommended to support laboratories to declare their technical competence and major recommendations are proposed to substantially improve the implementation of a quality system in laboratories that operate in the health sector, public health environments, particularly those dealing with care and metrological control of hospital medical equipment.

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