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Metrology in health: a pilot study

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Abstract. The purpose of this paper is to identify and analyze some relevant issues which arise when the concept of metrological traceability is applied to health care facilities. Discussion is structured around the results that were obtained through a characterization and comparative description of the practices applied in 45 different Portuguese health entities. Following a qualitative exploratory approach, the information collected was the support for the initial research hypotheses and the development of the questionnaire survey. It was also applied a quantitative methodology that included a descriptive and inferential statistical analysis of the experimental data set.

1. Introduction

Measurement, as a field of scientific and technical activity, encompass a set of activities aimed at determining the quantities and registers a remarkable evolution throughout the centuries. The scientific context that serves these activities is called Metrology which includes a wide-range of activities with a key role in all sectors of society, being a fundamental basis for sustainable development [1], [2], [3] [4].

According to international recommendations, every system of measurement must use accurate and reliable results [5]. Metrological traceability [3] and uncertainty measurement [3] are the main elements that support this assurance. This means improving a chain of measurements from a single measurable result in a commonly accepted reference, as well as the uncertainty value associated to this measuring result [6]. Surely due to the inherent risk of life, these principles are strongly applied in health systems. Measurements and measuring instruments are present in day-to-day life and are fundamental processes in prevention, diagnosis and treatment of diseases. Measurement results are vital in the medical field, which requires they are accurate, real and comparable over time, i.e., they must exhibit repeatability and reproducibility [7]. Nevertheless, one must be aware that errors and uncertainties of measuring instruments could be the origin of unsuitable clinical procedures, such as a false diagnosis or inadequate treatments.

Clinical laboratories constitute a good example for the improvements achieved by metrology as regards traceability in medicine. The Joint Committee for Traceability in Laboratory Medicine (JCTLM) [8] [9], hosted by the International Bureau of Weights and Measures (BIPM), is the first international committee focused on clinical metrology and constitutes a platform envisaging the harmonization and dissemination of good practices within the framework of analytical chemistry [10].

Therefore, under the scope of the European Medical Devices Directives [11], new responsibilities and technical requirements for the measuring instruments were put in place, for preventing the existence of barriers as regards the free trade. For one hand, although a wide range of instruments is covered by the medical devices directive, this sphere of regulation allows each Member State considering additional measures to protect public health and citizens. On the other hand, after



placing them in the market and putting them into service, no further regulated control (according to EU policy) exists for those medical devices [12].

As the awareness of the benefits for having traceable measurement results increases, some researchers and technical experts (in metrology and medicine), have been increasing their efforts and interest for developing research within this scope. In recent years several pieces of research were published focusing some relevant measuring instruments used by health professionals. As regards specific diseases, some authors highlighted the key role of metrological traceability of sphygmomanometers as a tool for reducing health care costs and improving patient's care [13], [14], [15]. Likewise, other researchers pointed out the traceability of clinical temperature's measurement devices, such as thermometers [16], [17], [18]. In what concerns the evaluation of some ophthalmic diseases, the clinical metrology of tonometers' utilization has also been under metrological research [19], [20], [21]. Work has been developed regarding pulmonary and respiratory diseases, proving how important reproducibility is and its impact on diagnosis [22], [23].

Regardless the aforementioned work, much remains to be done. In fact, the various actors with jurisdiction in these subjects, and in particular in some areas of activity, didn't put in place enough actions -packed for assuring metrological traceability in health measurements. Furthermore, the growing concern with issues related to quality in health care made emerge new areas of activities in this important field of society. Moreover, it is also considered that the interoperability between these three disciplines is not contextualized within the current European regulatory framework. The lack of information regarding the perception of metrology by health professionals is a topic requiring evaluation.

2. Methodology

Taking into account the literature review, as well as the current framework of national health care facilities, the applied methodology aimed to identify the main indicators of health professionals' practices with their working instruments for measurement.

The Portuguese hospitals were the target of this work research, which was developed in 2011 and included private and public hospitals (national health system). A survey was applied to the hospitals included in the last database from Portuguese Directorate-General of Health (DGS) that was available at the time [24]. However, at the time, private hospitals were not available in the aforementioned national database. Hence, the universe of private hospitals was identified by regional random search.

According to that information and based on the real context of observational analysis, a multimethod design [25] approach was applied: i) inductive and deductive reasoning methods [26], ii) qualitative and quantitative research methodology [27].

Survey characterization

The issues in survey formulation were designed and developed based on the analysis of the National and European metrological requirements in health care facilities. Therefore, the research hypotheses and the development of the measurement instrument (survey) were performed through an exploratory qualitative approach without a previous similar validated survey.

From May to September 2011, 122 questionnaires were sent by e-mail to Portuguese hospitals. From those, 99 were addressed to public hospitals, including islands, and 35 responses were received. The remaining 23 were sent to private hospitals, and 9 responses were received. All surveys were sent by e-mail with a follow-up procedure and received through the same way. Thus, considering a stratified sample, a response rate of 35,4 % was obtained for public hospitals and 39,1 % for private hospitals, leading to an overall response rate of 36%, that were collected and analyzed.

A 'tree' questionnaire was developed, in which the choice of certain issues is determined by the answers in previous questions. The ten questions included in the developed survey were distributed between open and closed questions, including dichotomous (yes/no) and ordinal scales (Likert type). Envisaging the assurance of survey's validation, a pretesting was conducted [28]. Apart from slight changes, the questions were maintained after the pretesting.

The questionnaire was designed to characterize information regarding the following issues:

- a) Relationship between qualification systems implemented by health care facilities and associated metrological practices;
- b) Metrological requirements that could influence the acquisition of medical instruments;
- c) Budget for medical equipment;
- d) Levels of literacy in health's metrology.

In a first stage a univariate analysis was adopted for characterizing the trend of responses in each scale item. Descriptive statistics were utilized for computing the mean, standard deviation, minimum, maximum and frequency response. The second stage focused the correlation between variables, including a bivariate statistical analysis from the dataset. Finally, in the third stage, it were utilized statistical inference, nonparametric tests, correspondence analysis and factor analysis.

3. Results

Data analysis was performed using the Statistical Package for Social Sciences (SPSS) version 19. A value for Cronbach alpha of 0,74 was achieved, thus making acceptable the internal consistency [29]. Once more, it is important to stress that the questionnaire constitutes a new survey model, entirely developed for this piece of research.

Quality systems of survey respondents

According to data analysis, 53,3 % of hospitals had a partial qualification, 25,0 % were accredited and 22,7 % of respondents referred that the hospitals were certified as a whole. In addition, the results' overview regarding the quality management system of hospitals shows that more than 50,0 % of public hospitals are qualified according to international standards. All responses from private hospitals revealed a certification by ISO 9001[30]. Both typologies of hospitals prefer national certifiers entities.

Procedure for acquiring equipment's vs metrology

The importance given to metrological requirements within the procedures for equipment's acquisition was assessed. Exploratory Factorial Analysis (EFA) was utilized with Varimax rotation. Table 1 shows the grouped variables by factor: i) the maintenance conditions and the historical of the equipment were named as *post-sales factor* (1st EFA factor); ii) the 2nd EFA factor was named as *legal requirements* and it includes the compliance of requirements by producers requisites as well as the hospitals' requirements for the notified bodies; iii) the price and supplier trust were grouped in the 3rd factor (*pre-sales factor*). The high value obtained for communalities shows that retained factors are appropriate for describing the latent correlation structure. The measure of sampling adequacy was validated by the result from KMO (Kaiser-Meyer-Olkin) and the Bartlett test [29].

Table n° 1: Factor Structure of Exploratory Factorial Analyses

	Factor			
Variable	1	2	3	Communality
Price	-0,211	0,004	0,828	0,730
Supplier trust	0,286	0,054	0,752	0,650
Requirements of ISO 13485	-0,074	0,892	0,136	0,819
Maintenance conditions	0,801	0,265	0,131	0,729
Historical of the equipment	0,770	-0,050	-0,048	0,597
Requirements of the Notified Body	0,440	0,708	-0,129	0,711
<i>Eigenvalues</i>	1,926	1,302	1,009	
Variance (%)	32,1	21,7	16,8	

Through the utilization of cross analyses, the maintenance requirement was considered the most relevant for private hospitals (Figure 1), whereas for the public hospitals (Figure 2), this issue is less important than the supplier's confidence (59,0 %). For these hospitals, price was the most important requirement (51,0 %) which constitutes a strong restriction for the enforcement of metrological traceability.

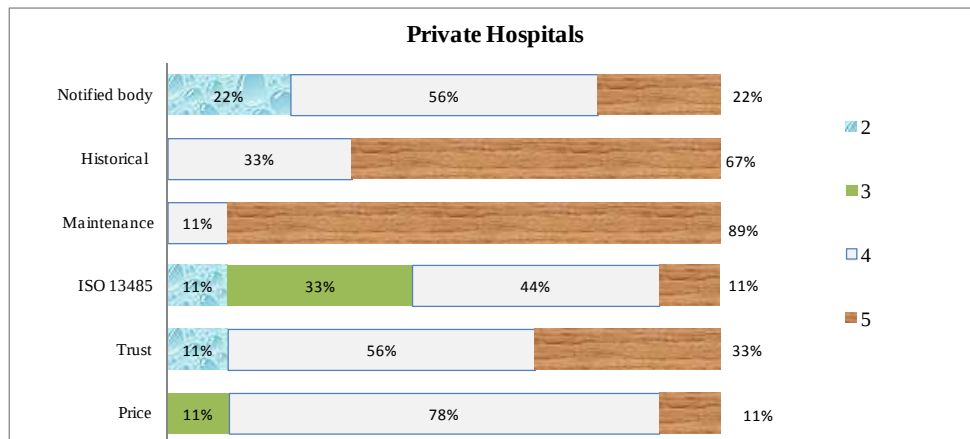


Figure n° 1: Indicators from private hospitals

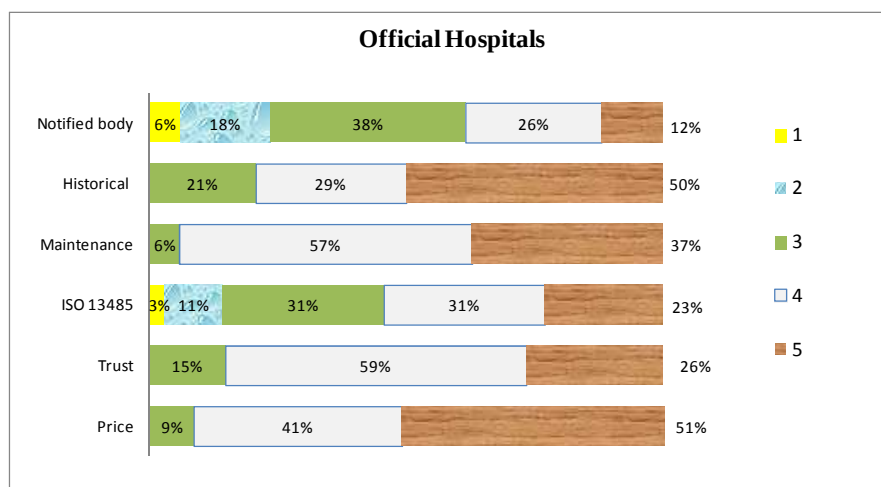


Figure n° 2: Indicators from official hospitals

Metrological documentation that is included in the terms of reference (contract document) was other aspect that was evaluated on the acquisition phase. Multiple Correspondence Analysis (MCA) was utilized [29], with eigenvalue ≥ 1 as a retention criteria for components. According to values shown in Table 2, orthogonal components explain 74,0 % of data variability. One component (first dimension) was represented by the verification certificate and the measures report. The calibration certificate and the conformity report have different scores, representing the 2nd and 3rd dimension.

The 1st dimension is influenced by respondents who have no preference for calibration certificates, which are replaced by verification certificates and test reports. Opposite reasoning is applied to the variables in the 2nd dimension. The analysis for the 3rd dimension indicates that respondents who receive evaluation reports are influenced by receiving test reports. The chi-square χ^2 ($\alpha = 0,05$) was

utilized for analyzing the relation between those variables and the hospital's typology (public vs private). Since the null hypothesis H_0 is rejected, one concludes that the acquisition of medical measuring instruments with conformity report is dependent of hospital typology (Table nº 2). This situation was also assessed using the *odds ratio* θ evaluation, whose values show that the choice of the conformity report depends on the type of hospital, and this probability is more pronounced in private hospitals ($\theta_1 = 0,650$; $\theta_2 = 8,000$).

Table 2: Survey MCA

Variables	Principal Components (dimensions)			χ^2	p-value
	1	2	3		
calibration certificate	0,006	0,706	0,088	0,754	0,385
verification certificate	0,523	0,023	0,075	0,937	0,333
test report	0,582	0,000	0,090	0,075	0,784
conformity report (product)	0,287	0,026	0,498	6,929	0,008
no certificate	0,003	0,461	0,362	0,024	0,877
<i>Eigenvalue</i>	1,402	1,216	1,113		
Variance (%)	28,0	24,3	22,3		
Relevance of the traceability of medical instruments	0,315	0,339			0,000
Metrological Legislation	0,644	0,007			0,542
External calibrations	0,237	0,306			0,000
Internal calibrations	0,032	0,497			0,049
Metrological knowledge for measuring instruments	0,477	0,642			
Interpretation of certificates vs tests reports	0,923	-0,057			
Relation adverse event vs error of instrument	0,924	-0,068			
Relation error of instrument vs indication results	0,226	-0,842			
<i>Eigenvalue</i>	1,198	1,129			
Variância (%)	49,6	28,3			
Preventive maintenance	0,544	0,973			
Curative maintenance	0,847	0,022			
Calibrations	0,928	-0,306			
Verifications	0,938	-,0282			
<i>Eigenvalue</i>	2,755	1,121			
α de Cronbach	0,849	0,144			

It was also analyzed the relation between hospitals that acquire equipments with calibration certificates and the related relevance as regards *i)* metrological knowledge and *ii)* technical competence for certificates' analyses. The opinion of relevant respondents pointed out that hospitals that purchase certified equipment (calibrated measuring instruments) consider relevant their certified interpretation (50,0 %). Furthermore, 46,0 % expressed their interest in metrological's knowledge applied on clinical practice.

Metrology vs risk management vs patient safety

Another issue that was evaluated focuses the key role of metrology in the risk management and patient safety. The MCA methodology (Table 2) was adopted as statistical approach. According to those values, it was possible to characterize the 1st dimension through the association between the needs to interpret the metrological certificates of equipment and the reflection of this interpretation on the errors provided by the measuring instruments. These errors can be widespread by the diagnostics and therapeutic procedures. Extrapolation of this interpretation for clinical practice, whose influence on adverse effects can be significant, is also present in this dimension.

Within this framework, the metrological knowledge that health professionals may acquire regarding their measuring instruments is very important and can influence the evaluation assigned to measurement's error as well as the outcomes. The high score value of 1st dimension for the interpretation of certificates vs tests reports and relation adverse event vs error of instrument show a significant concerns revolve around patient safety. Based upon these results, we sustain that the assessment of the risk associated to the utilization of medical equipment and patient safety might be considered exogenous latent variables, with special relevance in health metrology.

Budget for medical equipment's with measuring functions

It was also assessed the budget outcomes from hospitals that are applied to metrological operations and maintenance, notably preventive and curative maintenance, calibrations and verifications of measuring instruments. Having this in mind, the categorical variables were distributed by an interval range, from less than 10 % to more than 30 % of hospital's overall budget allocation. According with these results, curative maintenance is the operation selected by 13,6 % of hospitals with a budget more than 30,0 % whereas 75 % of hospitals allocated less than 10% of such overall budget.

It is worth mentioning that the number of medical equipments with measuring functions in the respondents' hospitals was above 1100 units. On the other hand, only 2,3 % of respondents reported more than fourty calibrated instruments by calibration period. Therefore, one can assume that the results obtained for the budget that is applied by hospitals represents a worrying indicator and a poor predictor for the metrology in the health services.

According the MCA analyses for such dataset (Table 2), the curative maintenance, the calibrations and verifications are included in the same principal component, being all of them close to saturation value. The preventive maintenance has the highest score for the second component. The value of Cronbach α shows a good internal consistence ($\alpha = 0,849$).

Metrological factors as a transversal tool in health care facilities

This issue is clearly cross-sectional, which led to its inclusion in several questions. For these purposes, the following variables were evaluated: *i)* Relevance of traceability for medical instruments, *ii)* Metrological Legislation, *iii)* External calibrations, *iiii)* Internal calibrations.

As the responses presented lack of harmonization, a binomial test was applied to the aforementioned variables. The null hypothesis was rejected as regards metrological legislation, which reveals that the proportion of hospitals that considers sufficient the present legislation in the field of traceability of medical devices, is statistically similar to the proportion of those who do not consider this factor as relevant. A MCA was applied for validating this conclusion (Table 2). Two dimensions were retained, whose values lead to designating dimension 1 as the component focused on the law (metrological traceability) and the second dimension as the traceability component. Among the

respondents that classify the traceability as relevant, 93.2% make use of external calibration. Among the hospitals that perform internal calibrations, 63,6 % apply this procedure to evaluate the conditions of metrological instruments, without support of external calibrations (no evidence of a traceability reliably). The two approaches (external and internal calibrations) are practiced by only 34,1 % of respondents. The Odds Ratio (θ) was assessed for studying the relationship between internal calibration and hospital's typology. It was concluded that the probability of private hospitals to practice internal calibrations is 1,5 higher than the public hospitals and that there is no dependency relationship between both variables.

4. Discussion

This study showed that a large majority of respondents were representing organizations with recognized qualifications, which constitutes a valuable piece of information for establishing their profile.

Regarding the metrological issues, notably for public hospitals, the price of the product is the prevailing requirement. However, it was also verified that there is a significant correlation between trust in the supplier and the price of product to be delivered. This suggests that the score of the variable price may be undervalued when remaining confidence in the entity provider.. Nevertheless, as the economic downturn has raised major concerns for all sectors of activity, this component can represent an even greater concern in acquisition procedures. Thereby, the criterion of price is in fact the most important requirement to acquire equipment, which deserves a proper reflection.

Usually, the metrological documentation accompanying the equipment during its acquisition phase does is not dependent neither of the type of hospitals nor of systems of quality management, which reflects the reduced concern regarding the compliance to requirements of metrological equipment. Hence, despite the statistical significance for matters regarding the maintenance and taking into account the analysis performed on the metrological documentation mentioned on the previous items, it is suggested that the protocol established by hospitals to acquire instruments measurement does not reflect metrological concerns.

For both types of hospitals, the relationship between the adverse event and the instrument was fairly valued, being an indicator of the perception of health professionals regarding the dimension of risk management vs metrology.

In addition, entities that acquire equipment with calibration certificates are those who consider that its interpretation is important, which requires an improved metrological knowledge. Hence, the obtained results suggest that healthcare professionals have the perception that the metrological performance of equipment is important and that can influence the outcome of the measurements in their clinical practice. However, in most institutions, the metrological traceability is still concealed in maintenance operations, thus contributing for the low level of best practices of metrology in medicine.

The research results also stressed that a greater confidence in supplier is proportional to a lower overall budget for maintenance operations. The interpretation could be made under the framework of health and metrological literacy, encompassing a weak frontier between maintenance and metrology operations.

Therefore, considering the ratio of total number of equipments to the number of equipments subjected to calibration's operations (previous issue), one can assume that Portuguese hospitals has a reduced number of instruments that are submitted to procedures able to assure the quality control of obtained results.

The hospitals tend to realize external calibrations, showing no tendency to perform internal calibrations. Those entities that perform it internally are predominantly private, and perform those operation for assuring the conditions of their metrological instruments. These entities have technicians that received specific training for this field of work.

The knowledge and opinions of respondents as regards metrological legislation proved to be incipient. It was also concluded that a trend for the application of metrological practices prevails in

those entities that revealed more knowledge and awareness for metrology issues, emphasizing the implementation of procedures that promote the metrological traceability of measuring instruments.

5. Conclusion

Taking into account the obtained results, one concludes that metrological traceability is a subject that is absent from day-to-day life of healthcare professionals, although it is known by them.

Some factors contributing for this perception were identified, which might enrich the scientific knowledge regarding the fields of health and metrology.

Considering the quality in health care facilities, this piece of research aims to contribute for introducing the metrology subject in hospitals' framework.

Further work, focusing on the impact of measurements on Gross National Product (GDP) of globalized economies, particularly regarding health systems, is clearly necessary. Hence, further informations allowing updates and improvement developments on this important subject are obviously wellcome.

At the European level, a continuous international collaboration of experts is needed for promoting comprehensive Metrology within the framework of quality in health care. This is a major challenge.

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